

Reconciling patient safety and liability: Lessons from a Just Culture.

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DECLARATION

I declare that the thesis, which I hereby submit for the degree Doctor Legum (LLD) at the University of Pretoria, is my own work and has not previously been submitted for a degree at another university.

Signed at Pretoria, November 2017.

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ABSTRACT

Patient safety is a serious global public health issue. Approximately 1 in 10 hospitalised patients are harmed by medical mistakes. Most of these adverse events are preventable. Medical error causes substantial morbidity and mortality. Unsafe care is not only responsible for immeasurable suffering, but also substantial added (and unnecessary) financial expenditure. Developing countries that can ill-afford these additional costs, likely face an even greater burden of harm.

As South Africa transitions toward Universal Health Coverage, access to safe care will become all the more important. Lamentably, the poor performance of the public health system has compromised the care many patients receive. Increased instances of substandard care have probably also contributed to the recent proliferation of malpractice claims.

The malpractice system has traditionally been the point at which the law and medical errors converge. This confluence and the recent regulatory and policy developments are examined to assess whether it is possible to reconcile patient safety and liability. By adopting a systems approach to error (as employed in other high-risk industries), inclusive of a safety/just culture, the healthcare and malpractice systems can be better aligned to foster prospective collective accountability. This approach, in turn, would not only create an environment conducive to safer care but could also allow for the application of processes rooted in restorative justice theory, that might assist in the healing of harm.

TABLE OF CONTENTS

INTRODUCTION.....	1
CHAPTER 1. A BRIEF HISTORY OF HARM	15
1. INTRODUCTION	15
2. HISTORY OF HARM.....	15
2.1. HEROIC MEDICINE, CLINICAL EMPIRICISM AND NATURAL HEALING	16
2.1. INHOSPITABLE HOSPITALS.....	19
3. CODMAN AND THE ‘END-RESULT IDEA’	25
3.1. SURGING SURGERY	25
3.2. A SIMPLE IDEA.....	26
3.3. THE END RESULT SYSTEM	28
3.4. THE ‘PRODUCT’ OF THE END RESULT HOSPITAL	29
3.5. A SELF-PUBLISHED REPORT	30
3.6. HOSPITAL STANDARDISATION PROGRAMME	32
3.7. THE JOINT COMMISSION ON ACCREDITATION OF HOSPITALS	34
4. IATROGENIC ILLNESS	35
4.1. NEW MEDICINES, NEW HAZARDS.....	35
4.2. THE PRICE OF PROGRESS.....	36
5. HAZARDS OF HOSPITALISATION.....	40
5.1. SCHIMMEL	40
5.2. OGILVIE AND RUEDY	42
5.3. MCLAMB AND HUNTLEY	43
5.4. SECKLER AND SPRITZER – THE TOLERABLE LIMITS.....	44
5.5. STEEL ET AL	45
6. MEDICAL NEMESIS	46
6.1. THREE LEVELS OF IATROGENESIS.....	47
7. CONCLUSION.....	48
CHAPTER 2. TO ERR IS HUMAN	51
1. INTRODUCTION	51
1.1. ‘THREE JUMBO-JET CRASHES EVERY TWO DAYS’.....	51
1.2. AN OVERLOOKED EPIDEMIC.....	52
1.3. THE SAFETY MOVEMENT	53
2. TO ERR IS HUMAN	54
3. A CATALYST FOR CHANGE	56
4. INTERNATIONAL AGENDA.....	59
4.1. RESOLUTION WHA55.18	60

4.2. WHO PATIENT SAFETY PROGRAMME.....	61
4.3. GLOBAL PATIENT SAFETY CHALLENGES.....	62
4.4. THE GLOBAL PRIORITIES FOR PATIENT SAFETY RESEARCH.....	63
4.5. PATIENTS FOR PATIENT SAFETY.....	64
4.6. INTERNATIONAL CLASSIFICATION FRAMEWORK.....	64
4.7. PATIENT SAFETY EDUCATION.....	65
5. AFRICA AFFLICTED.....	65
5.1. AFRICAN PARTNERSHIPS FOR PATIENT SAFETY.....	68
6. CONCLUSION.....	70
CHAPTER 3. THE BURDEN OF UNSAFE MEDICAL CARE.....	72
1. INTRODUCTION.....	72
1.1. HARVARD MEDICAL PRACTICE STUDY.....	72
1.2. AN ABUNDANCE OF ERROR, A PAUCITY OF INFORMATION.....	74
1.3. UTAH/COLORADO STUDY.....	75
2. THE GLOBAL SCALE OF HARM.....	75
3. SIGNIFICANT SOURCES OF HARM.....	78
3.1. ADVERSE EVENTS DUE TO DRUG TREATMENT.....	79
3.2. ADVERSE EVENTS AND INJURIES DUE TO MEDICAL DEVICES.....	80
3.3. INJURIES DUE TO SURGICAL AND ANAESTHESIA ERRORS.....	82
3.4. HEALTH CARE-ASSOCIATED INFECTIONS.....	86
3.5. UNSAFE INJECTION PRACTICES.....	89
3.6. UNSAFE BLOOD PRODUCTS.....	92
3.7. SAFETY OF PREGNANT WOMEN AND NEWBORNS.....	94
3.8. SAFETY OF THE ELDERLY.....	99
3.9. INJURIES DUE TO FALLS IN HOSPITALS.....	101
3.10. PRESSURE ULCERS.....	103
4. CONCLUSION.....	105
CHAPTER 4. THE KEY CONCEPTS OF MEDICAL ERROR AND PATIENT SAFETY.....	107
1. INTRODUCTION.....	107
1.1. ESTIMATES OF MEDICAL HARM.....	107
1.2. THE FINANCIAL COST OF HARM.....	109
1.3. THE KNOWN UNKNOWNNS.....	111
1.4. EXPANDING ACCESS (TO SAFE CARE).....	111
2. CONFRONTING THE PROBLEM OF MEDICAL HARM – THE KEY CONCEPTS OF MEDICAL ERROR AND PATIENT SAFETY.....	113
2.1. INTRODUCTION.....	113
2.2. SAFETY - ‘THE HEART OF HEALTHCARE QUALITY’.....	115

2.3. LEAPE – ERROR IN MEDICINE.....	117
3. EXPLAINING HUMAN ERROR	121
3.1. INTRODUCTION.....	121
3.2. CAUSAL CLASSIFICATION OF ERROR.....	121
3.3. PERSON- VS SYSTEM APPROACH.....	126
3.4. REASON’S SWISS CHEESE MODEL	127
3.5. AETIOLOGY OF AN ORGANISATIONAL ACCIDENT	128
3.6. ‘ROOT CAUSES’-FRAMEWORK.....	129
3.7. ANALYSING ERRORS USING THE SYSTEM APPROACH	130
4. CONCLUSION.....	135
CHAPTER 5. HIGH-RELIABILITY ORGANISATIONS AND SAFETY CULTURE.....	136
1. INTRODUCTION	136
2. MINDFUL ORGANISING – FIVE CHARACTERISTICS OF HIGH RELIABILITY ORGANISATIONS.....	137
2.1. PREOCCUPATION WITH FAILURE.....	137
2.2. RELUCTANCE TO SIMPLIFY.....	138
2.3. SENSITIVITY TO OPERATIONS.....	138
2.4. COMMITMENT TO RESILIENCE	139
2.5. DEFERENCE TO EXPERTISE.....	141
3. ORGANISATIONAL CULTURE.....	142
3.1. SAFETY CULTURE.....	142
3.2. TEAMWORK AND COMMUNICATION.....	145
3.3. DIMENSIONS OF A SAFETY CULTURE.....	148
3.4. SAFETY CULTURE IMPLEMENTATION STRATEGIES.....	149
4. CONCLUSION.....	159
CHAPTER 6. JUST CULTURE - BALANCING ‘NO BLAME’ AND ACCOUNTABILITY	161
1. INTRODUCTION	161
1.1. THE SYSTEM APPROACH.....	161
1.2. THE ‘NO BLAME’ MODEL.....	163
2. BALANCING ‘NO BLAME’ AND ACCOUNTABILITY.....	164
3. JUST CULTURE	168
3.1. MARX’S ALGORITHM.....	168
3.2. MEASURED AND REFINED	172
4. HIGH-RELIABILITY AND JUST CULTURE.....	173
4.1. ALGORITHMS AND INCIDENT DECISION TREES.....	174
4.2. UNIFORM APPLICATION OF ACCOUNTABILITY ALGORITHMS.....	180
5. CONCLUSION.....	182

CHAPTER 7. JUST CULTURE – WHO DRAWS THE LINE?	184
1. INTRODUCTION	184
2. ACCOUNTABLE TO WHOM?	184
3. POWER AND PERCEPTION	185
4. WHO DRAWS THE LINE?.....	188
4.1. <i>THE ORGANISATION</i>	188
4.2. <i>PROFESSIONAL BOARDS</i>	193
4.3. <i>HEALTHCARE REGULATOR OR OMBUD</i>	195
4.4. <i>JUDICIARY</i>	196
5. CONCLUSION.....	205
CHAPTER 8. JUST CULTURE - WHAT HAPPENS AFTER THE LINE HAS BEEN DRAWN?	206
1. INTRODUCTION	206
2. TWO FORMS OF ACCOUNTABILITY	206
3. ERROR WISDOM AND FORESIGHT.....	208
3.1. <i>REASON'S THREE BUCKET MODEL</i>	209
3.2. <i>EARLY WARNINGS AND COLLECTIVE FORESIGHT</i>	211
4. HEALING.....	215
4.1. <i>FROM RETRIBUTIVE TO RESTORATIVE JUSTICE</i>	217
4.2. <i>A BRIEF OVERVIEW OF RESTORATIVE JUSTICE THEORY</i>	219
4.3. <i>REPARATIVE ACCOUNTABILITY</i>	223
5. CONCLUSION.....	229
CHAPTER 9. JUST CULTURE – PRACTICAL APPLICATION: LESSONS FROM AVIATION.....	231
1. INTRODUCTION	231
2. EUROPEAN UNION	232
2.1. <i>REGULATION (EU) NO 996/2010 - INVESTIGATION AND PREVENTION OF ACCIDENTS AND INCIDENTS IN CIVIL AVIATION</i>	232
2.2. <i>REGULATION (EU) NO 376/2014 - REPORTING, ANALYSIS AND FOLLOW-UP OF OCCURRENCES IN CIVIL AVIATION</i>	233
3. THE INTERNATIONAL CIVIL AVIATION ORGANISATION (ICAO).....	237
3.1. ANNEX 19	238
4. SOUTH AFRICA - CIVIL AVIATION ACT	241
4.1. <i>CIVIL AVIATION REGULATIONS AND CIVIL AVIATION TECHNICAL STANDARDS</i>	241
5. CONCLUSION.....	248
CHAPTER 10. THE FUNCTIONING AND EFFICACY OF THE MEDICAL MALPRACTICE SYSTEM	250
1. INTRODUCTION	250

2. THE MALPRACTICE LITIGATION STUDIES – UNCOVERING THE UNDERLYING PATIENT SAFETY PROBLEM	252
2.1. THE MEDICAL INSURANCE FEASIBILITY STUDY (CALIFORNIA)	252
2.2. THE HARVARD MEDICAL PRACTICE STUDY (NEW YORK).....	253
2.3. UTAH/COLORADO STUDY.....	255
2.4. FROM NEGLIGENCE TO PREVENTABILITY.....	256
2.5. THE MALPRACTICE LITIGATION ‘LOTTERY’	257
3. FUNCTIONING AND EFFICACY OF THE MALPRACTICE SYSTEM.....	258
3.1. CAPACITY TO COMPENSATE INJURED PATIENTS	259
3.2. ABILITY TO IDENTIFY AND DETER SUBSTANDARD CARE	264
3.3. ADDITIONAL PROBLEMS WITH THE MALPRACTICE SYSTEM.....	281
4. CONCLUSION.....	292
i. Healthcare and Medical Malpractice Systems - Healing the divide.....	297
ii. The South African Healthcare System.....	299

CHAPTER 11. THE SOUTH AFRICAN HEALTHCARE SYSTEM – QUALITY AND SAFETY ON THE POLICY AGENDA.....300

1. INTRODUCTION	300
2. QUALITY AND SAFETY IN SOUTH AFRICA.....	301
THE CONSTITUTION	301
INTRODUCTION.....	303
2.1. CONFIDENTIAL ENQUIRY SYSTEM.....	305
2.2. THE 10-POINT PLAN.....	306
2.3. BATHO PELE PRINCIPLES	307
2.4. PATIENTS’ RIGHTS CHARTER.....	307
2.5. THE PRIMARY HEALTH CARE PACKAGE FOR SOUTH AFRICA – A SET OF NORMS AND STANDARDS.....	308
2.6. POLICY ON QUALITY IN HEALTH CARE FOR SOUTH AFRICA	309
2.7. THE NATIONAL HEALTH ACT.....	313
2.8. THE HEALTH PROFESSIONS AMENDMENT ACT 29 OF 2007	314
3. RENEWED FOCUS ON QUALITY.....	315
3.1. THE CORE STANDARDS	315
3.2. A HOSPITAL CLINICAL ADVERSE EVENT PREVENTION PROGRAMME IN THE FREE STATE	316
3.3. NATIONAL CORE STANDARDS FOR HEALTH ESTABLISHMENTS IN SOUTH AFRICA	317
3.4. NATIONAL PLANNING COMMISSION - DIAGNOSTIC REPORT.....	322
3.5. NATIONAL PLANNING COMMISSION - NATIONAL DEVELOPMENT PLAN 2030	323
4. CONCLUSION.....	325

CHAPTER 12. THE SOUTH AFRICAN HEALTHCARE SYSTEM - THE OFFICE OF HEALTH STANDARDS COMPLIANCE.....	327
1. INTRODUCTION	327
2. NATIONAL HEALTH INSURANCE.....	327
3. THE OFFICE OF HEALTH STANDARDS COMPLIANCE	329
3.1. <i>THE NATIONAL HEALTH AMENDMENT ACT 2013</i>	330
3.2. <i>REGULATIONS – THE OPERATIONAL FRAMEWORK</i>	339
4. CONCLUSION.....	348
CHAPTER 13. THE SOUTH AFRICAN HEALTHCARE SYSTEM – THE IDEAL CLINIC AND IMPROVEMENT STRATEGIES	349
1. INTRODUCTION	349
1.1. <i>OPERATION PHAKISA</i>	350
2. THE IDEAL CLINIC INITIATIVE.....	350
2.1. <i>THE COMPONENTS AND ELEMENTS OF AN IDEAL CLINIC</i>	351
2.2. <i>INTEGRATED CLINICAL SERVICES MANAGEMENT</i>	352
3. IDEAL CLINIC - DOCUMENTS, POLICIES, GUIDELINES AND STANDARD OPERATING PROCEDURES	353
3.1. <i>CLINICAL GUIDELINES AND PROTOCOLS</i>	353
4. CONCLUSION.....	372
CHAPTER 14. THE SOUTH AFRICAN MEDICAL MALPRACTICE SITUATION.....	376
1. INTRODUCTION	376
2. THE EXTENT OF THE CURRENT MEDICAL MALPRACTICE SITUATION	376
2.2. <i>CIVIL CLAIMS</i>	386
3. PATIENTS PAY THE PRICE	409
3.1. <i>A FAULTY SYSTEM</i>	410
4. CAUSES OF INCREASED MALPRACTICE LITIGATION	416
4.1. <i>THE HEALTHCARE SYSTEM</i>	416
4.2. <i>MEDICAL PROFESSION</i>	418
4.3. <i>THE LEGAL PROFESSION</i>	419
4.4. <i>INCREASED PATIENT AWARENESS</i>	421
5. CONCLUSION.....	428
CHAPTER 15. THE SOUTH AFRICAN MALPRACTICE SITUATION – RIPE FOR REFORM?	430
1. INTRODUCTION	430
1.1. <i>A WORLDWIDE CONCERN</i>	430
2. THE SOUTH AFRICAN CONTEXT.....	431
2.1. <i>THE CIVIL JUSTICE SYSTEM</i>	431

2.2. MEDICAL MALPRACTICE REFORMS	438
2.3. REIGNITED INTEREST IN REFORM	443
3. SOUTH AFRICAN LAW REFORM COMMISSION: ISSUE PAPER 33 (PROJECT 141) MEDICO- LEGAL CLAIMS.....	454
3.1. CHAPTER 1: EVENTS PRECEDING SALRC INVESTIGATION	455
3.2. CHAPTER 2: INVESTIGATION INTO MEDICO-LEGAL CLAIMS.....	456
3.3. CHAPTER 3: LEGAL PRINCIPLES UNDERLYING MEDICO-LEGAL CLAIMS.....	458
3.4. CHAPTER 4: PAYMENT OF COMPENSATION.....	461
3.5. CHAPTER 5: POSSIBLE LEGISLATIVE INTERVENTION.....	463
3.6. CHAPTER 6: QUESTIONS FOR CONSIDERATION.....	466
4. CONCLUSION.....	467
CHAPTER 16. THE UK EXPERIENCE – AN ILLUSTRATIVE CASE STUDY	470
1. INTRODUCTION	470
2. THE CIVIL JUSTICE SYSTEM AND MEDICAL MALPRACTICE	471
2.1. THE WOOLF REPORT.....	471
2.2. NHS LITIGATION AUTHORITY/RESOLUTION	481
2.3. LEARNING FROM BRISTOL.....	484
2.4. MAKING AMENDS.....	487
2.5. NHS REDRESS ACT 2006.....	490
2.6. LORD JUSTICE JACKSON'S REVIEW OF CIVIL LITIGATION COSTS.....	492
2.7. LEGAL AID, SENTENCING AND PUNISHMENT OF OFFENDERS ACT 2012.....	495
2.8. LATEST DEVELOPMENTS.....	497
3. THE HEALTH SYSTEM	498
3.1. INTRODUCTION.....	498
3.2. AN ORGANISATION WITH A MEMORY.....	498
3.3. CARE QUALITY COMMISSION	500
3.4. ROBERT FRANCIS QC'S REPORT OF THE MID STAFFORDSHIRE NHS FOUNDATION TRUST PUBLIC INQUIRY.....	502
3.5. A PROMISE TO LEARN - A COMMITMENT TO ACT: IMPROVING THE SAFETY OF PATIENTS IN ENGLAN.....	505
3.6. SIGN UP TO SAFETY	511
3.7. HARD TRUTHS.....	513
3.8. FREEDOM TO SPEAK UP	514
3.9. LEARNING NOT BLAMING.....	514
3.10. HEALTH SAFETY INVESTIGATION BRANCH	516
4. CONCLUSION.....	517
CONCLUSION	520

1. 'FIRST, DO NO HARM'	520
1.1. HISTORY OF HARM.....	520
1.2. TO ERR IS HUMAN AND THE BURDEN OF UNSAFE CARE	521
2. CONFRONTING THE PROBLEM OF MEDICAL HARM.....	524
2.1. INTRODUCTION.....	524
2.2. MINDFUL ORGANISATION.....	524
2.3. SHIFTING TO A SAFETY CULTURE.....	525
2.4. LEARNING FROM ERROR – THE SYSTEMS APPROACH	527
3. BALANCING 'NO BLAME' AND ACCOUNTABILITY	530
3.1. JUST CULTURE.....	530
3.2. ALGORITHMS AND DECISION TREES.....	531
3.3. DRAWING A LINE.....	532
3.4. WHO DRAWS THE LINE?.....	532
4. BLAME VS. ACCOUNTABILITY	537
4.1. PROSPECTIVE ACCOUNTABILITY.....	537
4.2. ERROR WISDOM AND COLLECTIVE FORESIGHT	539
5. HEALING.....	541
5.1. FROM RETRIBUTIVE TO RESTORATIVE JUSTICE.....	544
6. MEDICAL ERROR AND THE LIABILITY SYSTEM.....	547
6.1. COMPENSATION	548
6.2. DETERRENCE.....	549
6.3. ADDITIONAL PROBLEMS.....	550
7. SOUTH AFRICA - HEALTHCARE AND MALPRACTICE.....	551
7.1. REFORM ON THE HORIZON.....	553
7.2. CONVENTIONAL LIABILITY-LIMITING REFORMS.....	554
7.3. REFORMS THAT ADDRESS PATIENT SAFETY	557
7.4. EFFECTIVENESS OF INNOVATIVE REFORMS.....	559
8. RECOMMENDATIONS - ALIGNING SYSTEMS TO PROMOTE SAFETY	562
8.1. WHAT ARE THE WEAKNESSES?.....	562
8.2. WHAT STEPS ARE BEING TAKEN TO IMPROVE SAFETY?	564
8.3. WHAT FURTHER STEPS COULD BE TAKEN TO PROMOTE SAFETY?.....	565
9. SUMMATION	574
BIBLIOGRAPHY.....	575

INTRODUCTION

‘...the most difficult step has been taken when the staff of a hospital once agrees to admit and record the lack of perfection in the results of its treatment. Improvement is then sure to follow, for it often is the error of which we are ignorant that we persist in carrying with us.’¹

‘The single greatest impediment to error prevention in the medical industry is that we punish people for making mistakes.’²

‘What is needed is a just culture, an atmosphere of trust in which people are encouraged, even rewarded, for providing essential safety-related information – but in which they are also clear about where the line must be drawn between acceptable and unacceptable behaviour.’³

‘Rules, standards, regulations and enforcement have a place in the pursuit of quality, but they pale in potential compared to the power of pervasive and constant learning.’⁴

BACKGROUND AND CONTEXT

Patient safety is now recognised as a serious global public health issue.⁵ However, until relatively recently, medical error and harm had received very little attention.⁶ This began to change after the publication of the Institute of Medicine’s seminal report, ‘To Err is Human’.⁷ The report, released nearly two decades ago, estimated that up to 98 000

¹ Codman *A study in hospital efficiency: as demonstrated by the case report of the first five years of a private hospital* (1917) 9.

² Leape *Testimony, United States Congress, Subcommittee on health of the committee on veterans’ affairs, House of Representatives. One Hundred Fifth Congress* (1997) 105-23.

³ Reason “Managing the Risks of Organizational Accidents” (1997) 195.

⁴ Berwick “A promise to learn—a commitment to act: improving the safety of patients in England” (2013) 38.

⁵ Donaldson and Philip “Patient safety: a global priority” *Bulletin of the World Health Organization* (2004) 82 892; Donaldson “Patient safety: global momentum builds” *Quality and Safety in Health Care* (2004) 13 86.

⁶ Vincent “Research into medical accidents: a case of negligence” *BMJ* (1989) 299 1150.

⁷ Kohn et al. *To Err Is Human* (2000) 1.

American patients die in hospital each year due to medical mistakes. It raised awareness around a seldom acknowledged, rarely discussed and up until then scarcely studied problem.⁸ 'To Err is Human' is credited for having launched the patient safety movement.⁹ Several countries have since published similar reports and conducted their own investigations into the incidence of adverse events.¹⁰ We now have a much greater understanding of the immense burden of unsafe care.¹¹

Most of the evidence, however, comes from developed nations.¹² Studies conducted in these countries suggest that approximately 1 in 10 patients suffer harm while receiving hospital care.¹³ Half of these injuries are thought to be preventable.¹⁴ The limited evidence (itself a major problem) suggests that the frequency and preventability of harm in developing countries could be even more severe.¹⁵ One study of eight developing countries found that 83% of adverse events could have been prevented, while 30% contributed to the death of the patient.¹⁶ Nearly 2% of hospitalised patients in these countries sustained an adverse event that was associated with their death.¹⁷

Research sponsored by the World Health Organisation estimated that out of the 421 million hospitalisations that take place around the world annually, just seven types of

⁸ Stelfox et al. "The "To Err is Human" report and the patient safety literature." *Qual Saf Health Care* (2006) 15 174.

⁹ Foundation "Patient Safety" (2015) 1.

¹⁰ Organization "Patient safety: making health care safer" (2017) 1.

¹¹ Jha et al. "Patient safety research: an overview of the global evidence." *Qual Saf Health Care* (2010) 19 42.

¹² Shekelle et al. "Making health care safer II: an updated critical analysis of the evidence for patient safety practices." *Evid Rep Technol Assess* (2013) 1.

¹³ de Vries et al. "The incidence and nature of in-hospital adverse events: a systematic review." *Qual Saf Health Care* (2008) 17 216.

¹⁴ Adhikari "Patient safety without borders: measuring the global burden of adverse events." *BMJ Qual Saf* (2013) 22 798.

¹⁵ World "The launch of the World Alliance for Patient Safety" (2004).

¹⁶ Wilson et al. "Patient safety in developing countries: retrospective estimation of scale and nature of harm to patients in hospital" *BMJ* (2012) 344 e832.

¹⁷ *Ibid.*

adverse events are responsible for approximately 42.7 million injuries.¹⁸ Of concern is the fact that, two-thirds of all adverse events occurred in low-income and middle-income countries.¹⁹ Patient harm is estimated to be the 14th leading cause of the global disease burden.²⁰

Unsafe care is, thus tragically common. It is also a major source of death and disability. Patients and their families bear the unimaginable suffering of the initial injury, which may be exacerbated if the incident is subsequently handled improperly and unsympathetically.²¹ Patients and their loved ones, are of course, the most severely affected and may need support to deal with the aftermath of harm. However, the physician or nurse who made the harmful mistake could, as the ‘second victim’, also require support to deal with the anguish or guilt.²²

Harm comes with significant physical and psychological costs, but the financial costs can also be enormous.²³ Additional (and unnecessary) expenditure is incurred in the form of: the cost of lost productivity and future income, lengthened hospitalisation, added medical expenses, and litigation costs. Unsafe care diverts substantial amounts of money and resources away from other areas of the health system.

A recent report conservatively estimated that 15% of hospital expenditure and activity in OECD countries could be attributed to treating safety failure.²⁴ If lost capacity and productivity of patients are factored in, the aggregate costs amount to trillions of dollars each year.

¹⁸ Jha et al. “The global burden of unsafe medical care: analytic modelling of observational studies.” *BMJ Qual Saf* (2013) 22 809.

¹⁹ *Ibid.*

²⁰ *Ibid.*

²¹ Vincent and Coulter “Patient safety: what about the patient” *Qual Saf Health Care* (2002) 11 76; Vincent “Understanding and responding to adverse events.” *N Engl J Med* (2003) 348 1051.

²² Wu “Medical error: the second victim” *BMJ* (2000) 320 726.

²³ Slawomirski et al. “The economics of patient safety” (2017).

²⁴ *Ibid.*

There is, aside from the moral and ethical case, thus a strong economic case for safety.²⁵ The costs of improving safety are paltry, compared to the cost of failure. For instance, US Medicare hospitals are estimated to have saved \$28 billion between 2010 and 2015 by providing safer care.²⁶

A few common adverse events are responsible for the bulk of the economic burden associated with unsafe care: healthcare-associated infections, venous thromboembolism, pressure ulcers, medication error and wrong or delayed diagnosis.²⁷

These types of adverse events are likely even more common and devastating in developing countries. For instance, a systematic review and meta-analysis found that the prevalence of healthcare-associated infections was at least double the rate recorded in the developed world and infections acquired in intensive-care units were three times as prevalent.²⁸ The limited evidence available from South Africa, suggest that our infection rates are just as high, if not higher, leading to significant morbidity, mortality and healthcare costs.²⁹

²⁵ Waters et al. "The business case for quality: economic analysis of the Michigan Keystone Patient Safety Program in ICUs." *Am J Med Qual* (2011) 26 333; Padula et al. "Using Economic Evaluation to Illustrate Value of Care for Improving Patient Safety and Quality: Choosing the Right Method." *Journal of Patient Safety* (2017).

²⁶ "National Scorecard on Rates of Hospital-Acquired Conditions 2010 to 2015: Interim data from national efforts to make health care safer" Agency for Healthcare Research and Quality (2016-12-01) <http://www.ahrq.gov/professionals/quality-patient-safety/pfp/2015-interim.html>.

²⁷ Hauck et al. "Healthy Life-Years Lost and Excess Bed-Days Due to 6 Patient Safety Incidents: Empirical Evidence From English Hospitals" *Medical Care* (2017) 55 125.

²⁸ Allegranzi et al. "Burden of endemic health-care-associated infection in developing countries: systematic review and meta-analysis." *Lancet* (2011) 377 228; Rosenthal "Health-care-associated infections in developing countries" *The Lancet* (2011b) 377 186.

²⁹ McKay and Bamford "Community- versus healthcare-acquired bloodstream infections at Groote Schuur Hospital, Cape Town, South Africa" *SAMJ: South African Medical Journal* (2015) 105 363; Dramowski et al. "Burden, spectrum, and impact of healthcare-associated infection at a south African children's hospital" *Journal of Hospital Infection* (2016) 94 364; Dramowski et al. "Surveillance of healthcare-associated infection in hospitalised South African children: Which method performs best" *South African Medical Journal* (2016) 107 56. These findings have highlighted the need for more research, better training, strategic policies, as well as surveillance, reporting and prevention programmes. Dramowski et al. "A framework for preventing healthcare-associated infection in neonates and children in South Africa." *SAMJ: South African Medical Journal* (2017) 107 192. Although, resource and other constraints may hinder efforts to address these issues. Mahomed et al. "Challenges with Surveillance

This is not all that surprising—the South African healthcare system faces significant challenges and disparities.³⁰ Many of these challenges and disparities can be directly ascribed to our country’s devastating persisting legacy of colonial exploitation and racial segregation.³¹ The post-apartheid government certainly inherited a disaster.

Since 1994, the government has put forward commendable plans and have made progress in broadening access to care.³² Unfortunately, many of these plans have not been well-executed and other policies have been ill-conceived or detrimental to public health.³³ Furthermore, initial progress has been hindered by inadequate human resource capacity and planning, insufficient basic supplies and equipment, crumbling infrastructure, poor stewardship, incapable leadership, careless management, and weak governance structures and accountability. To make things worse, a quadruple burden of disease has overwhelmed an already deficient and struggling public health system.³⁴ The vast majority of the population rely on the public health sector for their care and these factors have all contributed to its poor performance.³⁵

The National Planning Commission described the system as ‘crumbling’ and ‘broken’ and have called for a ‘root-and-branch effort to improve the quality of care’.³⁶ The

of Healthcare-Associated Infections in Intensive Care Units in South Africa” *Critical Care Research and Practice* (2017) 1.

³⁰ Benatar “The challenges of health disparities in South Africa” *South African Medical Journal* (2013) 103 154.

³¹ Coovadia et al. “The health and health system of South Africa: historical roots of current public health challenges.” *Lancet* (2009) 374 817.

³² African A national health plan for South Africa. (1994).

³³ Benatar “Health care reform and the crisis of HIV and AIDS in South Africa” (2004) 81; Sanders and Chopra “Key challenges to achieving health for all in an inequitable society: The case of South Africa” *American Journal of Public Health* (2006) 96 73; Mayosi et al. “Health in South Africa: changes and challenges since 2009.” *Lancet* (2012) 380 2029. Also see Hassim et al. “Health and democracy: a guide to human rights, health law and policy in post-apartheid South Africa” (2014).

³⁴ Mayosi and Benatar “Health and health care in South Africa--20 years after Mandela.” *N Engl J Med* (2014) 371 1344.

³⁵ As more than 80% of the population receive their care in the public sector, most of the discussion will be focused on the public health system.

³⁶ Commission “National Development Plan, 2030” (2012) 51.

National Health Insurance policy documents have acknowledged that there are ‘quality problems in the areas of staff attitudes, waiting times, cleanliness, drug stock-outs, infection control, and safety and security of staff and patients’ that continue to persist in the public sector.³⁷ The National Health Care Facilities Baseline Audit revealed the appalling state of public hospitals and clinics.³⁸ The findings were so atrocious and politically sensitive that the National Department of Health unsuccessfully tried to suppress the final report.³⁹

The prevailing conditions at state facilities more than likely compromise the safety of care patients receive. A healthcare system conducive to substandard care and an increased awareness from patients regarding their rights have both probably contributed to the current proliferation of malpractice claims.

Neither the healthcare system nor the malpractice system is functioning optimally.⁴⁰ Unsafe care delivered in the healthcare system injures too many patients and those

³⁷ National Department of Health “National health insurance for South Africa: towards universal health coverage” (2017d) 12.

³⁸ Health “The National Health Care Facilities Baseline Audit” (2013) 1.

³⁹ Bateman “SA’s ailing public health sector responding to treatment” *SAMJ: South African Medical Journal* (2015) 105 11.

⁴⁰ Sidley “South African doctors demand action on “unethical” colleagues.” *BMJ* (1999) 319 594; Dhai and McQuoid-Mason... “The South African law and the health profession-Issues in litigation” *Obstetrics & Gynaecology Forum* (2003) 13 p. 22; Ncayiyana “Compensation for injury from medical treatment is a social justice obligation.” *S Afr Med J* (2004) 94 303; Matsaseng and Moodley “Adverse events in gynaecology at King Edward VIII Hospital, Durban, South Africa.” *J Obstet Gynaecol* (2005) 25 676; Von Holdt and Murphy “Public hospitals in South Africa: stressed institutions, disempowered management” *State of the nation: South Africa* (2007) 312; Carstens “Judicial recognition of substandard medical treatment in South African public hospitals: the slippery slope of policy considerations and implications for liability in the ...” *SA Publikereg= SA Public Law* (2008) 23 168; South “Every death counts: use of mortality audit data for decision making to save the lives of mothers, babies, and children in South Africa” *The Lancet* (2008) 371 1294; Chopra et al. “Saving the lives of South Africa’s mothers, babies, and children: can the health system deliver” *The Lancet* (2009) 374 835; Dhai “Medical law and litigation” *South African Journal of Bioethics and Law* (2009) 8 38; Pieterse and Hassim “Placing human rights at the centre of public health: a critique of Minister of Health, Western Cape v Goliath” *South African Law Journal* (2009); Van Niekerk “HPCSA: A mess in the Health Department’s pocket” *SAMJ: South African Medical Journal* (2009) 99 203; Africa “A roadmap for the reform of the South African health system” (2009) 1; Bateman “Gvt crafts its own hospital quality standards, sans world-class local body” *SAMJ: South African Medical Journal* (2010) 100 620;

injured by substandard care face significant difficulties in obtaining redress from the malpractice system. As alluded to, the costs involved can be immense – for all involved.

South Africa has been slow to address the problem of patient safety. However, the prevalence of poor quality care and the increasing number of malpractice claims, have both recently garnered considerable attention from stakeholders and policymakers.⁴¹

Coetzee “The spectre of litigation-a dark cloud on the obstetric horizon: guest editorial” *Obstetrics and Gynaecology Forum* (2010) 20 109; Harrison “An Overview of Health and Health Care in South Africa 1994-2010” (2010) 40; Bateman “Medical negligence pay-outs soar by 132%-subs follow” *SAMJ: South African Medical Journal* (2011) 101 216; Bateman “Coming soon: nowhere to hide for hospital managers” *SAMJ: South African Medical Journal* (2011b) 101 294; Bateman “Stillbirths: an invisible earthquake” *SAMJ: South African Medical Journal* (2011) 101 364; De Viliers “Protecting the Public, the HPCSA or the Profession” *South African Family Practice* (2011) 22; Health “National Core Standards for Health Establishments in South Africa” (2011) 12; Llewellyn et al. “Drug administration errors: time for national action” *SAMJ: South African Medical Journal* (2011) 101 319; Pepper and Slabbert “Is South Africa on the verge of a medical malpractice litigation storm” *South African Journal of Bioethics and Law* (2011) 6 60; Malherbe “Counting the cost: the consequences of increased medical malpractice litigation in South Africa.” *S Afr Med J* (2012) 103 83; Seggie “The ‘boom’ in medical malpractice claims – patients could be the losers” *S Afr Med J* (2013) 103 433; Wittenberg “Adverse individual outcomes of healthcare : editorial” *South African Journal of Child Health* (2013) 7 42; Coetzee et al. “A tale of two systems--nurses practice environment, well being, perceived quality of care and patient safety in private and public hospitals in South Africa: a questionnaire survey.” *Int J Nurs Stud* (2013) 50 162; Benatar (2013) *South African Medical Journal; Vol 103, No 3 (2013)*; Deaths *Saving Mothers 2011-2013: Sixth report on confidential enquiries into maternal deaths in South Africa, Short report* (2014); Pattinson and Rhoda *Saving babies 2012-2013: Ninth report on perinatal care in South Africa* (2014); Bateman “Saving our newborns by doing the basics right-and keeping it simple” *SAMJ: South African Medical Journal* (2015) 105 248; Carstens “A good complaints system : guest editorial” *SAMJ: South African Medical Journal* (2015) 105 425; Bateman “SAMA pitches in to help victims of medical negligence.” *SAMJ: South African Medical Journal* (2015) 105 337; Honda et al. “Improving the public health sector in South Africa: eliciting public preferences using a discrete choice experiment.” *Health Policy Plan* (2015) 30 600; Econex “Identifying the determinants of and solutions to the shortage of doctors in South Africa: Is there a role for the private sector in medical education?” (2015) 1; Bateman “Counting the public healthcare litigation bill” *SAMJ: South African Medical Journal* (2016) 106 1063; Bateman “Budget squeeze: Cutting clinicians hurts patients” *SAMJ: South African Medical Journal* (2016) 106 321; Maswime and Buchmann “Causes and avoidable factors in maternal death due to cesarean-related hemorrhage in South Africa” *International Journal of Gynecology & Obstetrics* (2016) 134 320; Project “Causes, implications and possible responses to the implementation of staffing moratoria in the public health system in South Africa during times of budget austerity” (2016) 1; Mathews et al. “Child deaths in South Africa: Lessons from the child death review pilot.” *SAMJ: South African Medical Journal* (2016) 106 851.

⁴¹ Motsoaledi “Doctors call for lawyers to get out of hospitals” *S Afr J BL* (2015) 8 4.

The National Development Plan, National Health Insurance and the dire results of the Facilities Baseline Audit, have provided new impetus to quality improvement efforts. The Office of Health Standards Compliance has been established to monitor and enforce norms and standards throughout the health system.⁴² The government has launched the Ideal Clinic initiative, as part of Operation Phakisa, to ensure that primary healthcare facilities in the public sector meet the prescribed norms and standards.⁴³ Several policies and guidelines have now been published as part of the initiative, some of which, finally and explicitly address patient safety.⁴⁴

Concerns about increases in the frequency and amount of malpractice claims have led to calls for reform.⁴⁵ Medical claims are currently the subject of an investigation by the South African Law Reform Commission.⁴⁶ The financial implications of claims have been the main driver behind these recent developments.

As many developing countries, including South Africa, strive to achieve universal health coverage, quality and safety of care will need to be addressed – ‘unsafe care is no care at all’ and will hinder efforts to expand of access.⁴⁷ Not only because unsafe care comes with exponential added costs these countries can ill afford, but also because unsafe care destroys trust in the healthcare system.⁴⁸

⁴² Act No. 12 of 2013: National Health Amendment Act, 2013 (GN529 in GG36702 of 24 July 2013).

⁴³ Fryatt and Hunter “The Ideal Clinic in South Africa: planning for implementation” *South African Health Review* (2014) 23.

⁴⁴ National Department of Health, *Ideal Clinic Definitions, Components and Checklists*, 2017; Ideal Clinic Realisation and Maintenance (ICRM) Lab; National Department of Health, Monitoring and Evaluation, South Africa *Operation Phakisa: Ideal Clinic Realisation and Maintenance - Final Lab Report* (2015).

⁴⁵ Dhai “Medico-legal litigation: Balancing spiralling Costs with fair compensation” *S Afr J BL* (2015) 8 2; Motsoaledi (2015) 8 *S Afr J BL* 4; Howarth and Hallinan “Challenging the cost of clinical negligence.” *S Afr Med J* (2016) 106 141.

⁴⁶ Commission “Issue Paper 33 (Project 141) Medico-Legal Claims” (2017) 1.

⁴⁷ Flott et al. “Health care must mean safe care: enshrining patient safety in global health.” *Lancet* (2017) 389 1279.

⁴⁸ A et al. “Patient Safety 2030” (2016) 7.

Evidence suggests that a few simple and relatively inexpensive interventions could obviate a significant share of adverse events in developing countries.⁴⁹ Proper training, increased stakeholder awareness, implementation and compliance with patient safety protocols, and other evidence-based measures can all improve safety. However, the literature has emphasised the fundamental importance of adopting a systems approach and fostering a culture of safety, as a precondition for the successful realisation of improvement.⁵⁰

PURPOSE AND PROBLEM STATEMENT

Healthcare, taking a cue from other safety-critical industries, has in recent years slowly transitioned from a traditional approach to medical error, whereby the most proximate individuals were blamed for their inevitable mistakes and lapses, towards an approach that strives to identify and address the systemic flaws that precipitate incidents. This ‘systems approach’ to medical error contends that flawed systems, rather than flawed individuals, are responsible for adverse events and patient harm. Some have raised concerns that absolving individuals of blame, may lead to a deterioration in accountability. This thesis contends that such a view incorrectly conflates blame and accountability.

Blame is the enemy of safety, whereas accountability is a crucial component thereof. The adoption of a systems approach, inclusive of a safety culture, allows us to change our understanding of the concept. Instead of being a retroactive retributive construct, and therefore detrimental to safety, accountability can take on a prospective collective form, thereby supporting resilience and advancing safety efforts.

Nevertheless, situations will arise where an inevitable line would have to be drawn to balance the ‘no blame’ system approach with individual accountability. The notion of a ‘just culture’ is advanced as a possible solution. It seeks to promote an environment in

⁴⁹ Wachter et al. “Strategies to improve patient safety: the evidence base matures.” *Ann Intern Med* (2013) 158 350; Pronovost et al. “Changing the narratives for patient safety” *Bulletin of the World ...* (2017); Slawomirski et al. (2017) 25.

⁵⁰ Berwick (2013); A et al. (2016) 1.

which errors can be reported, allowing healthcare organisations to learn from their mistakes, but clearly stipulates that certain conduct is unacceptable and will result in sanction. A just culture lies at the heart of a broader safety culture, which is fundamental to patient safety.

If our conception of accountability changes to align with the system approach, our responses to harmful errors can too. Instead of meeting harm with hurt, as is the case with our current retributive justice construct, we can attempt to heal. One way in which healing could be promoted would be through initiatives grounded in restorative justice theory. The principles and values of restorative justice theory could be well-suited to healthcare. Although there are substantial differences between the victim-offender and patient-doctor spheres, these differences may strengthen the case for its application, since the motives, conduct and relationships in the latter are founded on beneficence and non-maleficence. Thus, making it a much narrower gap to bridge.

Restorative processes also address many of the needs that parties may have after a harmful outcome, much more so than current retributive approaches. Unfortunately, compensation could generally only be obtained following protracted and adversarial medico-legal negotiations. However, alternative compensation options with restorative characteristics have emerged in recent years and should be considered.

The government plans to address harm by reforming the regulatory framework. The words of Berwick's review should be heeded: 'In the end, culture will trump rules, standards and control strategies every single time, and achieving a vastly safer NHS will depend far more on major cultural change than on a new regulatory regime.'

Therefore, reform of the healthcare system and the malpractice system should seek to support the establishment of a just culture, so as to enable the development of a safety culture. This thesis will argue that such an approach may also be key to reconciling patient safety and medical liability.

MOTIVATION AND VALUE CONTRIBUTION

Patient safety is a relatively new discipline. The field remained small and largely ignored until the 1990s. Most consider the publication of 'To Err is Human' in 1999, as the beginning of the modern patient safety movement. In less than two decades research has burgeoned. However, many gaps remain, particularly in developing countries.

Patient safety has only recently begun to receive attention from policymakers in South Africa. The National Core Standards were only established in 2008. The regulatory body tasked with monitoring and enforcing healthcare standards was only established in 2013 and is not yet operational. Policies and guidelines related to patient safety have only just now been published.

There have been very few studies of medical harm conducted in South Africa. Those that have been conducted have been small-scale and confined to a limited number of settings. There is thus, a considerable need to gather evidence on the prevalence and causes of unsafe care in our country. Aside from medical research, it is essential that patient safety is examined by other disciplines, to gain insight from various viewpoints.

This thesis attempts to fill some of that void, by examining patient safety and the newly established regulatory framework, which will aim to promote improved quality and safer care, from a South African legal perspective. The malpractice system has traditionally been the point where the law and medical errors converge, as such, the thesis also endeavours to investigate this confluence of the healthcare and civil justice systems. It does so by drawing on a diverse literature to propose a way in which to reconcile patient safety and liability. Furthermore, it seeks to align both systems in such a manner, so as to encourage the adoption of a just culture. Such an approach would create an environment conducive to prospective collective accountability and safer care. It would also allow for the application of restorative justice processes to aid healing in the aftermath of harm.

OVERVIEW OF CHAPTERS, RESEARCH METHODOLOGY AND LIMITATIONS.

Patient safety is a trans-disciplinary field encompassing health services research, clinical medicine, psychology, epidemiology, economics, engineering and the social sciences. As such, a diverse variety of sources were consulted for each chapter.⁵¹

Chapter 1 provides a historical account of medical harm and draws on authoritative textbooks and historical original literature where available.

Chapters 2 and 3 rely heavily on studies conducted in the healthcare domain and the various reports that have shaped the field. These studies and reports not only reveal the extent of the patient safety problem but also provide context for later discussions. Almost all our information comes from developed countries and establishes the broader framework of the discipline. An attempt was made to provide perspectives from developing countries, where available. However, there is as yet a limited evidence-base to draw from. The discussion of international instruments and global initiatives also draws attention to this fact.⁵²

The discussion in Chapter 4 then shifts to the underlying causes of human error and how they might be prevented. This necessitates the consideration of authoritative works in the fields of cognitive psychology, human factors and ergonomics, and organisational theory.

Throughout the patient safety literature, frequent reference is made and considerable importance is attached to the concept of a 'safety culture'. High-Reliability Organisations and their reliance on a 'safety culture' are discussed in Chapter 5.

A crucial component of a safety culture is the establishment of a 'just culture'. This concept has received significant attention in other safety-critical fields, such as aviation.

⁵¹ Including authoritative textbooks, studies and academic articles in the respective fields.

⁵² Low- and middle-income countries have been called on to prioritise safety. Addressing the paucity of data, especially from the African region is deemed to be essential for improvement efforts.

It is considered in Chapters 6 to 9. Writings of international authors are examined. The influence of law on a just culture is investigated. International legal instruments and legislation, as well as our recently enacted civil aviation statutory provisions that provide for the conservation of a just culture, are also discussed.

The malpractice system has traditionally been the point where the law and medical errors converge. Empirical evidence regarding the functioning and efficacy of the medical malpractice system is discussed in Chapter 10. The research in this area predominantly comes from the United States. Nevertheless, it allows us to consider the effectiveness of a fault-based tort system as it relates to patient safety and the needs of those involved after an incident.

The focus then turns to the South African context.⁵³ Chapters 11 to 13 consider the progression of the quality and patient safety framework in the healthcare system from a legal and policy perspective. Primary sources of our law that have given recognition to the provision of quality care and patient safety are discussed. Many of these developments have only recently occurred. In some instances, the legislation has been enacted, and the regulations have been published, but the provisions have not yet come into force. Due to their importance, these measures merit comprehensive discussion.

Chapter 14 provides a broad overview and evaluation of the current malpractice situation in South Africa, with specific reference to the extent, consequences, and possible causes of malpractice. The lack of accurate concrete information poses a significant challenge. Media reports, parliamentary replies, judicial pronouncements and departmental annual reports are examined to provide some insight on the prevailing circumstances and problems faced. Scant reliable evidence or statistics exist on the incidence of substandard care, claims and costs in South Africa.

⁵³ Primary sources of South African law were canvassed, including the Constitution, common law, case law, national legislation and regulations promulgated thereunder, as it pertains to healthcare and liability incurred in such settings. Authoritative textbooks and academic articles were also consulted as secondary sources of law.

Nonetheless, there have been several calls for reform. Pertinent developments are discussed and critically examined in Chapter 15. The discussion is centred around the Minister of Health's recent Medico-Legal Summit and the Law Reform Commission's Issue Paper on the subject.

Chapter 16 considers how the issues pertaining to safety and the needs of patients following an error, have been addressed in the United Kingdom. It does so by looking at some of the major events and changes that have shaped their health and civil justice system. As such, the chapter relies on governmental and independent reports and reviews, as well as the findings of public inquiries. British legislation and policy documents are also discussed, where applicable. The UK's experience with both their civil justice and healthcare system provides an illustrative example of the arduous journey ahead and may be particularly relevant to our context, providing lessons and guidance.

The final chapter attempts to consolidate the preceding chapters and proposes several recommendations that will align healthcare and the law to promote safer care and meet the needs of injured patients.

CHAPTER 1. A BRIEF HISTORY OF HARM

1. INTRODUCTION

This chapter provides a brief overview of the history of medically induced harm. It reflects on the origins of the concept and our changing understanding thereof. Notable historical developments are discussed, such as the changing therapeutics of the early 19th Century. The tensions and transitions which occurred between ‘heroic’ medicine, natural healing, empiricism and conservative medicine. The hazards of hospitalisation are examined. Codman and his ‘End Result System’, as a precursor to outcomes measurement and hospital standardisation is also considered. The focus then turns to the medical advances of the mid-20th century. Particularly, the new harms that were brought on by innovative pharmacological and surgical treatments. The proliferation of diagnostic and therapeutic procedures and the attention it received from the medical profession is also discussed. Finally, the chapter considers some of the earliest systematic studies of the hazards of hospitalisation.

2. HISTORY OF HARM

‘Medical harm’ – a seemingly paradoxical phrase if one considers the expectations we harbour and reliance we place in modern medicine’s ability to treat and mend. Injuries caused by medical treatment have, however, always been the dangerously sharp side of the double-edged sword of medical progress. The Greeks evidently recognised this paradox of medicine in that the word *pharmakos*, meant both remedy and poison; ‘kill’ and ‘cure’ were apparently also indiscernible from each other.¹ ‘Iatrogenic injury’ may have only been coined in the early twentieth century, but injury resulting from medical treatment has always been inherent to the practice of medicine. As early as the seventeenth century BC the code of Hammurapi described the penalties that physicians could incur for making harmful errors.² In Epidemics I, Hippocrates urged physicians to

¹ Porter *The Greatest Benefit to Mankind: A Medical History of Humanity* (1999) 4.

² Sharpe and Faden *Medical Harm: Historical, conceptual and ethical dimensions of iatrogenic illness* (1998) 45.

‘at least do no harm’.³ To this day *primum non nocere* still stands a foundational ethical tenet of medicine.⁴ Needless to say, the Hippocratic mandate plays a central role in the patient safety movement.⁵

2.1. HEROIC MEDICINE, CLINICAL EMPIRICISM AND NATURAL HEALING

2.1.1. HEROIC MEDICINE

The axiom ‘first do no harm’ is often mistakenly attributed to Hippocrates. The slight alteration in wording of his injunction originates from a treatise, *Physician and Patient*, written in 1849 by Worthington Booker, who in turn ascribed the phrase to A.F. Chomel.⁶ The renewed focus on non-maleficence at this point in western medical history was a reaction to the ascendancy of a more activist, interventionist therapeutic paradigm, referred to as ‘heroic medicine’.⁷ Sharpe and Faden describe the late eighteenth and early nineteenth century as a period of unprecedented iatrogenic violence. Proponents of ‘heroic medicine’ such as John Brown, Benjamin Rush and others caused considerable harm through their vigorous ‘life preserving’ remedies.⁸ Essentially, that is what ‘heroic medicine’ epitomised; the preservation of life above all else.⁹

The prevailing treatments of the early nineteenth century often required heroic bravery from patients! Rush, the ‘founding father’ of American medicine, was a sanguine proponent of blood-letting, calomel purges and mercury filled bilious pills.¹⁰ Patients would often have almost half of their total volume of blood withdrawn during one of Rush’s phlebotomies.¹¹ With the benefit of hindsight we can today see that these

³ Adams *The genuine works of Hippocrates* (1849) 306.

⁴ Smith “Origin and uses of *primum non nocere*--above all, do no harm” *J Clin Pharmacol* (2005) 45 371.

⁵ Leape et al. “Promoting patient safety by preventing medical error” *JAMA* (1998a) 280 1445.

⁶ Sharpe and Faden (1998) 42.

⁷ Warner *The therapeutic perspective: Medical practice, knowledge, and identity in America, 1820-1885* (2014) 91.

⁸ Sharpe and Faden (1998) 39.

⁹ Vincent *Patient safety* (2011) 4.

¹⁰ Porter (1999) 266.

¹¹ Ville *Medical malpractice in nineteenth-century America: origins and legacy* (1992) 67; Sharpe and Faden (1998) 39.

depletive therapies definitely did more harm than good, but not for one moment should we doubt that patient benefit was the foremost concern at the time.¹² Rush's commitment to his patients' well-being is evident in his decision to remain in Philadelphia during the yellow fever epidemic.¹³

How does one reconcile this noble commitment with the consequences of one's actions? Rush provides a glimpse into his justification therefore by stating that: '...it is impossible to calculate the mischief which Hippocrates has done by first marking nature with his name, and afterwards, letting her loose upon sick people. Millions have perished by her hands in all ages and countries.'¹⁴ Fighting disease was thus the first duty of a physician, losing a patient in doing so was regarded as a more acceptable outcome than passively allowing the sick to succumb. A doctor who acquiesces to such a death in the absence of adequate therapeutic vigour was deemed to be a murderer and a quack according to Rush.¹⁵

2.1.2. NATURAL HEALERS AND THE RISE OF EMPIRICISM

In response to these often harmful interventionist techniques, American medicine in the 1830s transitioned to a natural healing approach.¹⁶ Partly due to patients seeking out more moderate remedies and the rise of sceptical empiricism imported from France, natural healing replaced heroic medicine as the predominant therapeutic paradigm.¹⁷

The shift to empiricism is perfectly illustrated by Pierre Louis and his numerical method.¹⁸ By quantifying the outcomes of similar cases it was possible to evaluate the efficacy of interventions employed.¹⁹ This early pioneering approach, based on simple

¹² Rush *A Defence of Blood-letting, as a Remedy for Certain Diseases* (1805).

¹³ Sharpe and Faden (1998) 7.

¹⁴ Holmes *Currents and counter-currents in medical science: with other addresses and essays* (1861) 13.

¹⁵ Sharpe and Faden (1998) 41; Runes *The selected writings of Benjamin Rush* (2013).

¹⁶ Warner (2014) 97.

¹⁷ Ville (1992) 69.

¹⁸ Porter (1999) 312.

¹⁹ Ville (1992) 69.

arithmetic, laid the foundation for the clinical trial.²⁰ Through his research Louis found that many conventional therapies, such as phlebotomy, were at best futile.²¹ Recognising that medicine rarely cured and could often be harmful, empiricists advocated for less interventionist, benign practices.²²

In stark contrast to practitioners of 'heroic' medicine, natural healers strived to avoid harm and placed their faith in what they believed to be the curative powers of nature.²³

Natural healers would not intervene, but rather assist the patient in evading that which might inhibit nature's healing processes and would, consequently, only be held ethically accountable for harm suffered as a result of medical interference.²⁴ Nature was considered a benevolent force, some even believed that physical suffering caused by disease could be spiritually cleansing.²⁵

2.1.3. CONSERVATIVE MEDICINE

As alluded to earlier the phrase, *primum non nocere*, was conceived in a time when the efficacy of heroic remedies was called into question and a belief in the healing powers of nature was preferred above the dangers of orthodox medicines.²⁶ Those critical of the absolute reluctance to intervene, saw natural healing as a form of 'therapeutic nihilism' and sought a middle ground between the two extremes in the form of 'conservative medicine'.²⁷

²⁰ Best and Neuhauser "Pierre Charles Alexandre Louis: Master of the spirit of mathematical clinical science" *Quality and Safety in Health Care* (2005) 14 462.

²¹ Louis *Researches on the effects of bloodletting in some inflammatory diseases: and on the influence of tartarized antimony and vesication in pneumonitis* (1836).

²² Starr "The social transformation of American medicine: The rise of a sovereign profession and the making of a vast industry" *Basic books* (2008) 55.

²³ Sharpe and Faden (1998) 40.

²⁴ Warner (2014) 85.

²⁵ Ville (1992) 112.

²⁶ Sharpe and Faden (1998) 42.

²⁷ Starr (2008) *Basic books* 56.

The conservative practitioner was guided by statistics; the harm likely to be caused by interfering was assessed in relation to the dangers of allowing the natural progression of the ailment.²⁸ The weighing of risk and benefit, with patient outcome being the deciding factor.²⁹ A practice and norm we still subscribe to today.³⁰ The place of conservative medicine was cemented with the introduction of ether anaesthesia in 1846.³¹ The alleviation of pain, suffering and harm contributed greatly to patient benefit and the proportional calculation thereof.³² Proportional calculus also expanded the responsibilities of physicians, as they could now be held ethically accountable for harm caused by omission, in failing to avoid the natural sequence of an illness, or medical harm brought on by commission.³³

2.1. INHOSPITABLE HOSPITALS

The advent of anaesthesia made surgery bearable, but by no means less dangerous.³⁴ Pain had been conquered, infection had not. Sepsis was common and epidemical gangrene so fatal that those operated on in hospital were ‘exposed to more chances of death than was the English soldier on the field of Waterloo’.³⁵

2.2.1. PUERPERAL FEVER

The childbed fever tragedies of the eighteenth and nineteenth centuries brought the sepsis problem to the foreground.³⁶ Puerperal fever struck mothers after childbirth and was particularly deadly.³⁷ It soon became apparent that infection, and consequently death, was much more prevalent in hospital deliveries. Women giving birth at home

²⁸ Ville (1992) 153.

²⁹ Sharpe and Faden (1998) 43.

³⁰ Vincent (2011) 5.

³¹ Trent “Surgical Anesthesia, 1846–1946” *J Hist Med Allied Sci* (1946) 1 505; Robinson and Toledo “Historical development of modern anesthesia.” *J Invest Surg* (2012) 25 141.

³² Sharpe and Faden (1998) 43.

³³ *Ibid.*

³⁴ Porter (1999) 368.

³⁵ *Id.* 369. James Young Simpson, the first to use chloroform as anaesthetic, candidly made this remark about the risks of surgery.

³⁶ Nuland *The doctors’ plague: germs, childbed fever, and the strange story of Ignac Semmelweis* (2004).

³⁷ Loudon “The tragedy of childbed fever” (2000).

were estimated to be afflicted by 20 puerperal deaths per 1000 deliveries, whereas deliveries performed in hospitals proved fatal in as much as 150 per 1000 cases.³⁸

Alexander Gordon was one of the first to recognise the physicians' role in this discrepancy. In 'A Treatise on the Epidemic Puerperal Fever of Aberdeen' published in 1795, he ascribed the childbed fevers to doctors and midwives contaminating the uterus with 'putrid matter'.³⁹ Gordon suggested that those assisting with deliveries cleanse themselves as a preventative measure.

Oliver Wendell Holmes, whilst practising in Boston in 1843, drew a similar inference.⁴⁰ He too attributed the fevers to infection, presuming that 'germs' were introduced by practitioners attending to the birth.⁴¹ Holmes recommended that doctors wait at least a day between an autopsy and a delivery, he also suggested a change of suit before the procedure as well as a wash with chlorinated water.⁴²

However, many of his contemporaries were unconvinced. The suggestion that puerperal fever was contagious, let alone caused by doctors, was not only contrary to conventional wisdom at the time, but also the firmly held belief that physicians could not be guilty of patient harm.⁴³ Charles D. Meigs, a prominent obstetrician in Philadelphia, expressed this conviction in challenging Holmes.⁴⁴ Not willing to accept that he or any doctor could be responsible for the transmission of such an infection, Meigs asserted that 'a gentleman's hands are clean'.⁴⁵

³⁸ Nightingale *Introductory Notes on Lying-in Institutions: Together with a Proposal for Organising an Institution for Training Midwives and Midwifery Nurses* (1871).

³⁹ Porter (1999) 369.

⁴⁰ Holmes "ART. V.--The Contagiousness of Puerperal Fever." *New England Quarterly Journal of Medicine and Surgery (1842-1843)* (1843) 1 503.

⁴¹ Nuland (2004) 57.

⁴² Porter (1999) 369.

⁴³ Sharpe and Faden (1998) 154.

⁴⁴ Porter (1999) 369.

⁴⁵ Sharpe and Faden (1998) 154.

2.2.2. SEMMELWEIS

It was not until the pioneering work of Ignaz Semmelweis, at the Allgemeines Krankenhaus in Vienna during the mid-19th century, that the aetiology of puerperal fever became to be better understood.⁴⁶ The maternity ward, the biggest in the world at the time, was divided in two. Childbed fever was rampant in ward one, claiming the lives of 600-800 women, it had a devastating mortality rate of as high as 29%.⁴⁷ The mortality rate was much lower in ward two, where only around 3% of the women died. Semmelweis observed that the only difference between the wards were that ward one was attended by medical students and ward two by midwifery pupils. Investigating the disparity between the wards Semmelweis, as an experiment, made the medical students and midwifery pupils switch wards. This switch resulted in a corresponding turnaround in the mortality rate.⁴⁸

As part of their medical training, the students studied anatomy by dissecting cadavers and partaking in autopsies, they would then go straight from there to the parturient women in the maternity ward. Semmelweis believed that this practice transmitted the infection.⁴⁹ The death of Jakob Kolletschka, professor of forensic medicine, who contracted septicaemia after cutting his finger during an autopsy confirmed this hypothesis.⁵⁰ Semmelweis noted that his colleague suffered identical pathological changes to those seen in women stricken by childbed fever and concluded that he must have died from the same disease.⁵¹

Semmelweis' perspicacious clinical observations had led him to deduce that 'puerperal fever is caused by conveyance to the pregnant woman of putrid particles derived from living organisms, through the agency of the examining fingers'.⁵² In May 1847 he

⁴⁶ Semmelweis *The etiology, concept, and prophylaxis of childbed fever* (1983).

⁴⁷ Best "Ignaz Semmelweis and the birth of infection control" *Quality and Safety in Health Care* (2004) 13 233.

⁴⁸ Porter (1999) 369.

⁴⁹ Noakes et al. "Semmelweis and the aetiology of puerperal sepsis 160 years on: an historical review" *Epidemiology & Infection* (2008) 136 1.

⁵⁰ Nuland (2004) 99.

⁵¹ *Ibid.*

⁵² Porter (1999) 370.

instituted a hand-hygiene policy in order to curb infection.⁵³ Physicians were ordered to wash their hands with chlorinated lime before attending to deliveries. This change saw the mortality rate plunge to 1.2% in ward one.⁵⁴

Incredulous colleagues at the Vienna hospital failed to grasp the importance of the antiseptic measures imposed by Semmelweis and hand washing was gradually abandoned.⁵⁵ Frustrated by the opposition he faced, Semmelweis resigned and eventually became the head of the obstetrical department at St Rochus Hospital in Budapest.⁵⁶ His confidence in the benefits of disinfection resulted in a remarkably low puerperal fever mortality rate of less than one percent.⁵⁷

2.2.3. HOSPITALISM

During this period, post-operative mortality rates throughout Europe and North America remained devastatingly high as hospitals continued to be besieged by infection. Hospitals posed such a threat to the well-being of patients that James Young Simpson, who discovered chloroform anaesthesia, coined the term 'hospitalism'.⁵⁸ He believed that these virulent buildings should be burnt down every so often.⁵⁹

Florence Nightingale, likewise, recognised the detrimental effects of hospitals.⁶⁰ She writes in her Notes on Hospitals:

'It may seem a strange principle to enunciate as the very first requirement in a Hospital that it should do the sick no harm. It is quite necessary, nevertheless, to

⁵³ Pittet and Boyce "Hand hygiene and patient care: pursuing the Semmelweis legacy" *The Lancet Infectious Diseases* (2001) 1 9.

⁵⁴ Sharpe and Faden (1998) 153.

⁵⁵ Stewardson and Pittet "Ignác Semmelweis—celebrating a flawed pioneer of patient safety" *The Lancet* (2011) 378 22.

⁵⁶ Nuland (2004) 143.

⁵⁷ Porter (1999) 370.

⁵⁸ Neuhauser "Surgical experience, hospital size and severity adjusted mortality: James Y Simpson, 1869" *Quality and Safety in Health Care* (2005) 14 67.

⁵⁹ Porter (1999) 375.

⁶⁰ *Ibid.*

lay down such a principle, because the actual mortality in hospitals, especially in those of large crowded cities, is very much higher than any calculation founded on the mortality of the same class of diseases among patients treated out of hospital would lead us to expect.⁶¹

Nightingale set out to rectify what she believed to be a sanitation and hygiene problem; blaming institutional carelessness and ignorance for the deplorable state of hospitals.⁶² She gave no credence to germ-theory, instead she directed her efforts to nursing reform, advocating for ‘the proper use of fresh air, light, warmth, cleanliness, quiet, and the proper selection and administration of diet—all at the least expense of vital power to the patient’.⁶³

Nightingale made her mark during the Crimean war. Reports of injured soldiers being submitted to terrible hospital conditions galvanised her into volunteering her services. The filthy wards at the Scutari military base were cleaned up and in merely six months, Nightingale and her team of nurses had brought the mortality rate down from 40% to an astonishing 2%.⁶⁴ The war against disease was fought by employing hygiene and sanitation as weapons. Nightingale played a major role in the transformation of nursing care and hospital design.⁶⁵

2.2.4. LISTERIAN REVOLUTION

Sepsis, however, continued to plague surgery.⁶⁶ Despite antiseptics becoming more common, surgery only became safe once Joseph Lister started to routinely apply Pasteur’s ‘beautiful researches’ to surgical infections.⁶⁷ Lister considered it imperative to keep wounds clean and prevent further infection.⁶⁸ The first test was conducted in

⁶¹ Nightingale *Notes on hospitals* (1863).

⁶² Sharpe and Faden (1998) 157.

⁶³ Nightingale *Notes on nursing: What it is, and what it is not* (1992) 9.

⁶⁴ Porter (1999) 378.

⁶⁵ Cohen “Florence nightingale” *Scientific American* (1984) 250 128.

⁶⁶ Porter (1999) 371.

⁶⁷ Sharpe and Faden (1998) 155.

⁶⁸ Porter (1999) 371.

1865 on a patient with a tibia fracture, the wound was dressed with bandages soaked in carbolic acid and linseed oil. It worked, there was no sign of infection and the patient left the infirmary fully healed six weeks later.⁶⁹ Lister successfully applied this carbolic antiseptic technique in a subsequent case and noted that the condition had 'been entirely deprived of its most dangerous element'.⁷⁰

What had led to the Listerian revolution, was the fact that an effective antiseptic regime was being consistently followed.⁷¹ Coagulated blood was removed; wounds cleansed and dressed with carbolic-soaked bandages; measures were implemented to prevent evaporation; and all the while a carbolic acid solution was sprayed in the room covering all in attendance.⁷² Adherence to this strict routine achieved both antisepsis and asepsis.⁷³ His method and overwhelmingly positive findings were first published in the *Lancet* in March 1867.⁷⁴

Some prominent physicians such as Samuel Gross, however, remained unconvinced, stating that: 'Little if any faith is placed by any enlightened or experienced surgeon on this side of the Atlantic in the so-called carbolic acid treatment of Prof Lister apart from the care which is taken in applying the dressing'.⁷⁵ A reliance on Hippocratic views on infection's role in the healing process; differences in transatlantic hospital sizes and resultant mortality rates; and a resistance to germ-theory, all contributed to the slow uptake of Lister's methods in America.⁷⁶ Henry Bigelow, Harvard's leading surgeon, gave expression to the scepticism in germ theory by remarking that: 'It flatters neither the vanity nor the scientific sense to exorcise an invisible enemy with something very like a censor'.⁷⁷

⁶⁹ Ellis *A history of surgery* (2002) 92.

⁷⁰ Zimmerman and Veith *Great ideas in the history of surgery* (1961) 465.

⁷¹ Ellis (2002) 93.

⁷² Sharpe and Faden (1998) 155.

⁷³ Porter (1999) 371.

⁷⁴ Lister "On the antiseptic principle in the practice of surgery." *The Lancet* (1867) 90 353.

⁷⁵ Sharpe and Faden (1998) 155.

⁷⁶ *Ibid.*

⁷⁷ *Id.* 156.

Notwithstanding, the slow adoption in North America Lister's practices eventually spread and physicians slowly became accustomed to the idea that benign surgery was not only possible, but indeed a duty.⁷⁸

3. CODMAN AND THE 'END-RESULT IDEA'

3.1. SURGING SURGERY

Surgery, previously only undertaken as a desperate final recourse, had become much more common because of the refinements in anaesthesia, antiseptics and nursing.⁷⁹ These advances led to the proliferation of hospitals, both public and private, offering a range of new operations.⁸⁰ Rapid developments in diagnostic and surgical abilities appealed to wealthier patients, leading to an ever-increasing demand for innovative interventions. A growing number of specialist physicians and institutions were more than willing to meet the demand. Surgeons were especially adept at attracting patients and filling the constantly expanding number of hospital beds.⁸¹ Medicine had become a lucrative business, and business was booming.⁸² Hospitals profited from the increased admissions that surgeons were providing; surgeons benefitted from the status and opportunities a hospital appointment bestowed.⁸³

Doctors were predominantly absolved of scrutiny in that there was no real formal oversight. Allegiance to the profession and hospital guaranteed considerable unhindered clinical discretion and freedom. Physicians were mainly accountable to their own conscience and evaluated on character and good standing amongst colleagues alone.⁸⁴

⁷⁸ Porter (1999) 374.

⁷⁹ *Id.* 380.

⁸⁰ *Id.* 636.

⁸¹ Sharpe and Faden (1998) 21.

⁸² Porter (1999) 637.

⁸³ Sharpe and Faden (1998) 29.

⁸⁴ *Id.* 25.

There was clearly no patient benefit to be gained from such self-regulatory accountability. No meaningful conclusions could be reached about the efficacy and safety of interventions by subjecting it only to your own moral judgement.⁸⁵ The coinciding financial and reputational conflicts served as further disincentive to expose your results to critical appraisal and possible reproach.

3.2. A SIMPLE IDEA

Early in the 20th century Ernest Amory Codman had a very simple idea.⁸⁶ He himself described it as an idea ‘so simple as to seem childlike’.⁸⁷ An idea so obvious and important that patients and the public would ‘suppose that of course somebody is looking into it’.⁸⁸ Codman describes the epiphany in his own words as, ‘merely the common-sense notion that every hospital should follow every patient it treats, long enough to determine whether or not the treatment has been successful, and then to inquire “if not, why not?” with a view to preventing a similar failure in the future’.⁸⁹

After graduating from Harvard Medical School, Codman served his medical internship at Massachusetts General Hospital and was subsequently appointed as assistant surgeon at the same institution.⁹⁰ Facing resistance to his ‘end-result idea’ and being overlooked for promotion on the basis of a seniority system he was morally opposed to, Codman resigned.⁹¹ Leaving behind 15 years of service, he followed his convictions and dedicated himself to his own modest ‘end-result’ hospital.⁹² His resignation was not without controversy, Codman made sure to let the trustees of the hospital know of his

⁸⁵ *Ibid.*

⁸⁶ Codman (1917).

⁸⁷ *Id.* 8.

⁸⁸ *Id.* 6.

⁸⁹ Codman “The product of a hospital” *Surgery, Gynecology Obstetrics* (1914) 18 491.

⁹⁰ Donabedian “The end results of health care: Ernest Codman’s contribution to quality assessment and beyond.” *Milbank Q* (1989) 67 233.

⁹¹ Codman (1917) 110.

⁹² Donabedian (1989) 67 *Milbank Q* 235.

concerns.⁹³ The very same day that his resignation had been accepted, in dramatic protest over the superiority system of promotion, he asked to be appointed Surgeon-in-Chief. Codman substantiated his facetious request by pointing out to the trustees that the ‘results of [his] treatment of patients at their hospital during the last ten years, had been better than those of other surgeons’.⁹⁴

Codman alienated even more members of the surgical and educational community the following year by unveiling, ‘with a great flourish’, a scathing six-foot cartoon at a conference on hospital efficiency. The cartoon depicted residents at Harvard and Massachusetts General as an ostrich with its head in a mound of ‘humbuggery’, purposely ignorant of ‘clinical truth’, reaping financial gain in the form of ‘golden surgical goose eggs’. The board of trustees and the president of the medical school looked on, wondering whether disclosure of patient outcomes would put an end to their lucrative hospital revenues: ‘If we let her know the truth about our patients would she still be willing to lay?’.⁹⁵

Codman took issue with a profession that relied on nothing more than reputation and prestige to advance its own interests. He challenged the medical fraternity to open themselves up to evaluation. To reassess the prevailing form of personal accountability, imposed only by one’s own conscience. And to demonstrate how their practices contributed to patient benefit.⁹⁶

⁹³ Mallon “Ernest Amory Codman: the end result of a life in medicine” *WB Saunders Company* (2000).

⁹⁴ Codman *The shoulder; rupture of the supraspinatus tendon and other lesions in or about the subacromial bursa* (1934). Codman related these accounts in the preface of the publication, which he commenced as follows: “THE PREFACES in medical books, particularly in those that concern new fields, are often too brief and impersonal. If an author has conscientiously labored to present his material in clear English, properly punctuated and painstakingly illustrated for the benefit of the reader, surely he deserves to be allowed to indulge himself in his preface. Let him try his sense of humor, however heavy it may be, let him ride his hobbies, relate his favorite anecdotes, tell his life history or otherwise endeavor to please himself.”

⁹⁵ *Ibid.* The story and picture are recollected in the preface.

⁹⁶ Sharpe and Faden (1998) 29.

3.3. THE END RESULT SYSTEM

The 'End Result System' Codman advocated was a direct response to these perceived shortcomings of conventional early 20th century medical practice. He proposed that: 'Trustees of Hospitals should see to it that an effort is made to follow up each patient they treat, long enough to determine whether the treatment given has permanently relieved the condition or symptoms complained of'. Staff should be credited for successful treatment and be promoted on that basis. Where treatment has failed to remedy the patient's condition, it should be analysed in order to determine where responsibility for such failure lies. It needed to be established whether the failure should be imputed to the: physician or surgeon; organisation carrying out the treatment; patient's underlying disease or condition; or other personal or social factors preventing the cooperation of the patient. Such an assessment will provide 'a definite basis on which to make effort at improvement'.⁹⁷

To implement the system, a hospital would have introduced an 'End Result Card' for each patient and on it 'recorded in the briefest possible terms' the: symptoms or condition; diagnosis believed to be the cause of such symptoms; treatment plan; complications which arose in hospital; diagnosis at discharge; and 'result each year afterward'. An 'efficiency committee' would be formed to oversee and assess the results. The findings would then be made available by the 'efficiency committee', in the form of a detailed report or typewritten review. Codman was convinced that empirical evaluation of treatment, which had up until that point been disregarded by the medical community at large, had to be prioritised if there was to be any real clinical progress. As Codman, himself proclaimed on the significance of his 'end result idea': 'When this step is taken by our Great Hospitals, True Clinical Science will begin'.⁹⁸

As Donabedian points out, this is an early example of what we now refer to as 'outcomes' monitoring'.⁹⁹ Codman's methodology was ground-breaking, he not only

⁹⁷ Codman (1917) 6.

⁹⁸ *Ibid.*

⁹⁹ Donabedian (1989) 67 *Milbank Q* 239.

described the results achieved, but also provided his findings as to how such results could have been improved. Anticipating what we now call ‘process measures’ – diverse outcomes were to be examined. This concurrent assessment of interventions and of its consequences is the hallmark of Codman's system.

Codman even made a financial argument for his reforms, an argument we are very familiar with today – at times the only argument that gains any traction. By reducing the number of complications, you reduce the number of days a patient would stay in hospital, thereby increasing efficiency and ‘economizing hospital funds’.¹⁰⁰

‘To effect improvement, the first step is to admit and record the lack of perfection. The next step is to analyse the causes of failure and to determine whether these causes are controllable. We can then rationally set about effecting improvement by enforcing the control of those causes which we admit are controllable, and by directing study to methods of controlling those causes over which we now admit we have but little power.’¹⁰¹

In adhering to the first step of the system a physician is required to admit and keep a record of instances where treatment did not have the desired result. These instances resulting in a ‘lack of perfection’ were classified as follows: ‘Errors due to lack of technical knowledge or skill’; ‘errors due to lack of surgical judgement’; ‘errors due to lack of care or equipment’; ‘errors due to lack of diagnostic skill’; ‘the patient’s unconquerable disease’; ‘the patient’s refusal of treatment’; and ‘the calamities of surgery or those accidents or complications over which we have no known control’.¹⁰²

3.4. THE ‘PRODUCT’ OF THE END RESULT HOSPITAL

The ‘End Result Idea’ was no mere hypothetical recommendation. Codman went to great lengths to implement the system at the hospital he founded. Having resigned from his position at Massachusetts General, parting from a teaching post at Harvard and

¹⁰⁰ Codman (1917) 9.

¹⁰¹ *Ibid.*

¹⁰² *Id.* 11.

being ostracised by the medical community due to his, often abrasive sentiments, Codman experienced a significant dip in income.¹⁰³ He had only his small hospital to fall back on. As mentioned, the hospital was truly modest: 12 beds that were hardly ever filled, dust in the corners, wooden floors, the instrument boiler only cost \$0.87, the hot-water sterilisers were commercial kitchen utensils and both the X-ray machines were second-hand.¹⁰⁴ Despite these setbacks Codman remained committed to his 'End-Result System'. To demonstrate the feasibility of his idea, he self-published a study consisting of the case reports from the first five years at his hospital.¹⁰⁵

What might have drove Codman to such great personal and financial sacrifice? Perhaps his belief in what he considered to be the most important 'Product of a Hospital' – the end result.¹⁰⁶ He endeavoured to improve health through administered care. More specifically, 'the satisfied and relieved patient', was the product he strove to deliver.¹⁰⁷ Codman was far ahead of his time in identifying patient benefit, rather than monetary value alone, as a definitive measure of hospital efficiency. Adhering to the ancient and fundamental ethical principles of non-maleficence and beneficence, Codman challenged the therapeutic constructs of his time by attempting to advance his reforms.¹⁰⁸ Codman seemed almost convinced that the medical profession had a moral obligation to change, as evidenced by his proclamation that 'the adoption of the End Result System by the hospitals of this country will at the same time render our work more scientific and our practice more efficient and honourable'.¹⁰⁹

3.5. A SELF-PUBLISHED REPORT

In his self-published report, detailing the cases of 337 patients treated between 1911 and 1916 at his hospital, Codman painstakingly recorded 123 errors and categorised them accordingly. 'Calamities' were also recorded, as Codman believed these 'should

¹⁰³ Donabedian (1989) 67 *Milbank Q* 235.

¹⁰⁴ Codman (1917) 101.

¹⁰⁵ *Ibid.*

¹⁰⁶ Codman (1914) 18 *Surgery, Gynecology Obstetrics* 491.

¹⁰⁷ Donabedian (1989) 67 *Milbank Q* 242.

¹⁰⁸ Sharpe and Faden (1998) 30.

¹⁰⁹ Codman (1917) 64.

be acknowledged to ourselves and to the public, and study directed to their prevention'.¹¹⁰

Nowhere is the commitment to his system and patient benefit more evident, than in case number 77 of his study.¹¹¹ Codman offers to the reader, in the hope that some knowledge can be gleaned to prevent a similar incident, a description of that which all surgeons dread the most – the loss of a patient due to error. Severely critical of himself, Codman writes of the passing of a 59-year old female, whose death was directly attributable to a mistake he had made during her cholecystectomy, as follows:

‘I was so sure that I had done the operation correctly, that I never once suspected the true cause of the unusual condition—division and ligation of the hepatic duct. A post-mortem examination through the incision showed that the cut ends of the hepatic duct lay free in the wound. There was no sepsis and the tissues looked exactly as they had done when I closed the wound after operation, except that the tie had been pulled off the cystic duct and there was no tie on the proximal end of the hepatic duct—where I remembered having placed one at the time of the haemorrhage, and had supposed the duct was a vein.’¹¹²

One cannot help but imagine how dejected Codman must have felt in admitting his mistake to himself and everyone that would encounter Codman at his most vulnerable as they read his report, as he goes on to say:

‘In other words, I had made an error of skill of the most gross character, and even then, failed to recognize that I had made it. More than that, I would not have believed it, unless I had made the post- mortem examination myself and seen it with my own eyes.’¹¹³

¹¹⁰ *Id.* 11.

¹¹¹ *Id.* 21.

¹¹² *Id.* 22.

¹¹³ *Ibid.*

In keeping with his grand 'idea', Codman eventually saw past the immediate despair; realising that reporting and analysing the tragic result, presented an opportunity to gain greater insight into how such an outcome could be avoided:

'To such errors experience owes its value. Some of the knowledge thus gained cannot be transmitted, but it needs only this case to teach me that if a case of cholecystectomy shows excessive pain in the first 24 hours which abates on the second day at the time of slight jaundice and an excess of biliary discharge, probably the hepatic duct has been cut and ligated, even if the surgeon who operated is sure that it was not.'¹¹⁴

3.6. HOSPITAL STANDARDISATION PROGRAMME

Codman's proposals eventually gained some traction in 1916, when the American College of Surgeons decided to incorporate his Committee on Hospital Standardisation.¹¹⁵ Unfortunately, World War I halted any progress. After the war, when the surgical and hospital reforms were revisited, the hospital standardisation plan advanced by the College had become significantly tempered. Although adopted in the form of the 'Minimum Standard for Hospitals', two vital components had been omitted. The analysis of patient outcomes and the reporting of preventable error, undoubtedly the components most valued by Codman, were left out.¹¹⁶

This omission, ostensibly quite deliberate, may perhaps be explained by the unfavourable results of the College's first broad study of surgical practice. The criteria employed and the findings were never published nor preserved in the archives of the College.¹¹⁷ A glimpse into the findings can however, be found in a 1919 bulletin of the American College of Surgeons.¹¹⁸ In this bulletin the director of the College, J.G.

¹¹⁴ *Ibid.*

¹¹⁵ Roberts et al. "A history of the Joint Commission on Accreditation of Hospitals." *JAMA* (1987) 258 936.

¹¹⁶ Sharpe and Faden (1998) 33.

¹¹⁷ Lembcke "Evolution of the medical audit" *JAMA* (1967) 543.

¹¹⁸ Bowman "Hospital standardization series: General hospitals of 100 or more beds, Report for 1919" *Bulletin of the American College of Surgeons* (1920) 4 3.

Bowman, describes the profession's commitment to hospital standardisation and the incentives that might follow increased public interest as follows:

'The initiative in the work springs from the medical profession. Through definite and regular analyses of the care given to patients in hospitals the profession has brought about a swift reconstruction of its own responsibility, socially and scientifically, to the public; and the public has responded in turn with new interest in hospitals, with increased confidence in the physicians and surgeons engaged in the work, and with additional financial support toward all that these physicians and surgeons desire.'¹¹⁹

The public may have been less confident in the physicians and surgeons had they known that out of the 697 hospitals surveyed, only 89 (or less than 13%) met the minimum standard.¹²⁰ The study was conducted to determine 'if any unnecessary surgical operations were performed, if incompetent surgeons were practicing, and/or if lax, lazy or incomplete diagnoses were made'. And that seemed to be the case in a large majority of the hospitals. Apparently, the findings were so shocking that the survey committee demanded that the individual survey reports be destroyed.¹²¹

Nevertheless, the Minimum Standard was employed and served as a basis for evaluation by the American College of Surgeons in their hospital standardisation programme from 1918 to 1952. The programme endeavoured to improve care by requiring hospitals to: institute medical staff organisation; set prerequisite qualifications for member physicians; implement rules and policies to regulate hospital activities; maintain medical records and; provide diagnostic and therapeutic facilities.¹²² A Point Rating System employed between 1948 and 1952, allowed for the quantitative measuring of standards.¹²³ Sharpe and Faden submit that the priority given to structural

¹¹⁹ *Ibid.*

¹²⁰ *Id.* 5.

¹²¹ Lembcke (1967) *JAMA* 545.

¹²² *Ibid.*

¹²³ *Id.* 546.

guidelines and the process of standardisation, superseded the more controversial issue of unnecessary operations and surgical failures.¹²⁴

3.7. THE JOINT COMMISSION ON ACCREDITATION OF HOSPITALS

The Hospital Standardisation programme increased in size and scope, to such an extent that the College could no longer support the undertaking on their own.¹²⁵ Other factors, such as the ever evolving complexity of health care, increasing number of sophisticated modern hospitals and various new medical specialities, necessitated the adoption of an updated, broadened and frequently revised minimum standard.¹²⁶ The College did not have the capacity or resources to administer a scheme of this magnitude. Fully aware that the backing of the entire field of medicine would be required to establish an independent entity that could oversee the accreditation effort, they turned to the other national professional organisations for support. After extensive consideration the American College of Physicians, American Hospital Association, American Medical Association, and the Canadian Medical Association joined the American College of Surgeons in establishing the Joint Commission on Accreditation of Hospitals. And in 1952 the American College of Surgeons transferred its hospital standardisation programme to the Joint Commission on Accreditation of Hospitals.¹²⁷ The Joint Commission has become the largest accrediting body in the United States and the organisation has made it its mission to ‘continuously improve health care for the public, in collaboration with other stakeholders, by evaluating health care organizations and inspiring them to excel in providing safe and effective care of the highest quality and value’.¹²⁸

¹²⁴ Sharpe and Faden (1998) 33.

¹²⁵ Roberts et al. (1987) 258 *JAMA* 936.

¹²⁶ *Id.* 938.

¹²⁷ *Ibid.*

¹²⁸ “About the Joint Commission” The Joint Commission

https://www.jointcommission.org/about_us/about_the_joint_commission_main.aspx.

4. IATROGENIC ILLNESS

The term ‘iatrogenic’¹²⁹, from the Greek for physician ‘iatros’ and ‘genesis’ meaning origin, was first recorded in Bleuler’s Textbook of Psychiatry published in 1924. Its use in Bleuler’s book was confined to the detrimental psychological effects a physician’s diagnosis might produce.¹³⁰ So for instance, if a doctor were to inform the patient that he or she suffers from a heart condition, the subsequent anxiety and distress caused would be imputed to the diagnosis. The recognition that disclosure could be against the patient’s best interest, well-meaning paternalism as it were, is still very much relevant today and has even gained statutory recognition in our National Health Act.¹³¹

4.1. NEW MEDICINES, NEW HAZARDS

The term evolved after the advent of new pharmacological and surgical treatments in the 20th century. Iatrogenic injuries were no longer restricted to doctor-patient communication, as new interventions brought with them new harms.

Rapid advances in clinical practice after World War II, prompted a surge in demand for diagnostic and therapeutic measures. For instance, when penicillin became widely available in 1945, one in four US citizens that same year, procured a prescription.¹³² This was only the start of what has become an insatiable need for healthcare. Thousands of new medications were introduced, consumer expenditure on prescription drugs soared, a great number of additional hospitals were constructed and medical insurance membership shot up.¹³³

Progress, however, always seems to come at a price.¹³⁴ The hazards associated with this newfound and thoroughly embraced therapeutic abundance started to attract the

¹²⁹ ‘Induced unintentionally by a physician through his diagnosis, manner, or treatment; of or pertaining to the induction of (mental or bodily) disorders, symptoms, etc., in this way.’

¹³⁰ Sharpe and Faden (1998) 61.

¹³¹ Section 6(1)(a) of the National Health Act 61 of 2003.

¹³² Sharpe and Faden (1998) 49.

¹³³ Porter (1999) 639.

¹³⁴ *Id.* 711.

attention of doctors during the 1950's, most notably in the publications of David Barr and Robert Moser. Therein, they describe how medical progress was unfortunately accompanied by rising iatrogenic illness.

4.2. THE PRICE OF PROGRESS

4.2.1. BARR

Barr reflects upon the increasingly complex nature of medicine and the proliferation of diagnostic and therapeutic procedures.¹³⁵ He posits the spectacular number of available medicines in 1953, 140 000 medicaments and 14 000 more were added during that year, as an example of the deluge physicians had to navigate. Barr saw the undeniable virtue of medical progression; however, he also recognised the inherent dangers.

‘Although incalculable benefits have come to mankind with the introduction of these newer diagnostic and therapeutic procedures, hazards of medical management have at the same time enormously increased.’¹³⁶

Barr believed that this enormous increase was justified. That it was an inevitable sacrifice that had to be made for the good of therapeutic advancement. He describes it in his own words, as follows:

‘These accidents, risks, and dangers may be regarded as the price that we, as responsible physicians, must pay for the inestimable benefits of modern diagnosis and therapy. They are the hazards to which, with best intent and most correct practice, we must occasionally subject our patients.’¹³⁷

¹³⁵ Barr “Hazards of modern diagnosis and therapy: the price we pay.” *Journal of the American Medical Association* (1955) 159 1452.

¹³⁶ *Id.* 1453.

¹³⁷ *Ibid.*

In his article Barr calls attention to some of the main categories of iatrogenic injuries that patients may experience, all of which we still grapple with today. He describes the risks involved with accidental drug overdoses, the modification of physiological processes, infections, allergic reactions and the dangers imposed by the multiplication of procedures. Despite acknowledging the life-threatening nature of some of the injuries and recounting the dire results of a survey conducted in a great hospital (out of the 1000 admitted patients more than 50 encountered major toxic reactions and consequences) it is clear that Barr held a utilitarian view, considering iatrogenic illness the unavoidable cost of progress.¹³⁸

4.2.2. MOSER

Moser in his article, published the same year, similarly contemplated the repercussions of 'potent new therapeutic agents, improved surgical procedure and more efficient equipment'.¹³⁹ In his brief review, Moser describes a number of physician induced illnesses, referring to them as 'diseases of medical progress'.¹⁴⁰ Moser defines these complications as 'diseases that would not have occurred if sound therapeutic procedure had not been employed', thus providing insight into the 1950's conceptualisation of iatrogenic disease, as illness which results from well founded and accepted clinical practice.¹⁴¹ This notion is also found in Barr's description of physician induced illness, as the 'unfortunate sequelae and accidents attributable to sanctioned and well-intentioned diagnosis and therapy'.¹⁴²

As Sharpe and Faden point out, publications on medical harm from that era were rooted firmly in the conventions of their time.¹⁴³ They were not meant to confront or challenge prevailing convictions regarding the societal responsibilities of medicine or the quality of medical care provided, they merely called attention to the inherent risks of new

¹³⁸ *Id.* 1456.

¹³⁹ Moser "Diseases of medical progress." *New England Journal of Medicine* (1956) 255 606.

¹⁴⁰ *Ibid.*

¹⁴¹ *Ibid.*

¹⁴² Barr (1955) 159 *Journal of the American Medical Association* 1456.

¹⁴³ Sharpe and Faden (1998) 64.

procedures and treatments.¹⁴⁴ These risks were acknowledged and the complications documented, however, confidence in the medical interventions and physicians that intervened remained undaunted.

Authors during this period endorsed a cautious 'rational therapeutics', comparable to nineteenth century conservative medicine, in that the balance of risk versus benefit would be the paramount consideration. Those most affected by the determined balance, patients, did not have much of a say considering that in the '1950s and 1960s, the determination of medical benefit, risk, and harm was still the exclusive prerogative of physicians'.¹⁴⁵ Informed consent had not yet infiltrated the consulting room.

4.2.3. ANAESTHETIC DEATHS - BEECHER AND TODD

Henry Beecher and Donald Todd were medical harm contrarians, challenging the more utilitarian interpretation espoused by their peers.¹⁴⁶ In their investigation into the death rate attributable to anaesthesia, conducted over five years at ten university hospitals, they emphasised medical evaluation and quality care. Like the work of Codman, this emphasis was ahead of its time and not readily accepted. Their appreciation for the fact that facilitation of therapy and patient safety could not be separated and had to be considered in conjunction, stood in stark contrast to the work of Barr and Moser that prioritised the previous over the latter and regarded the risks as the price of progress.¹⁴⁷

The purpose for the study was to determine, as accurately as possible, the mortality rate of surgeries in which anaesthesia had been administered.¹⁴⁸ And the desirability thereof was based on: 'the belief that anaesthesia has an unnecessarily high death rate'; 'our inadequate knowledge of where the dangers lie in making choices in the field of anaesthesia'; and 'the belief that the study itself, by directing attention to these

¹⁴⁴ *Ibid.*

¹⁴⁵ *Ibid.*

¹⁴⁶ Beecher and Todd "A study of the deaths associated with anesthesia and surgery: based on a study of 599,548 anesthetics in ten institutions 1948-1952, inclusive" *Annals of surgery* (1954) 140 2.

¹⁴⁷ *Ibid.*

¹⁴⁸ *Id.* 4.

matters, would lead to sharper criticism of existing practises with improvement in them'.¹⁴⁹

The overall death rate was found to be considerably higher than previous estimates. Of the 599 548 cases studied, death associated with anaesthesia occurred at a rate of 1:1560.¹⁵⁰ Some very concerning findings regarding muscle relaxants were also discovered, with the death rate increasing six-fold when these 'curare' are used.¹⁵¹ Based on these findings the authors strongly cautioned against the use of muscle relaxants, unless clear advantages in exceptional cases are to be gained by their utilisation.¹⁵²

Beecher and Todd framed the magnitude of anaesthetic deaths as a public health issue, insisting that: 'Any agent or agency which regularly and systematically injures a considerable number of citizens each year is a public health problem'.¹⁵³ By their estimation, the death rate uncovered by their study definitely merited national assistance and support. The authors provide the following comparison to bolster their argument: 'Anaesthesia might be likened to a disease which afflicts 8 000 000 persons in the United States each year. More than twice as many citizens out of the total population of the country die from anaesthesia as die from poliomyelitis'.¹⁵⁴ It was evident that this was a public health concern, one which received very little attention and 'next-to-nothing' in funding.

Although their work did lead to anaesthetic practice reform, it hardly had any significant impact on the study of medical harm. Sharpe and Faden point to a few reasons why the Beecher and Todd study didn't become the standard for the examination of iatrogenic disease.¹⁵⁵ There was the simple fact that their study did not explicitly link itself to what

¹⁴⁹ *Id.* 5.

¹⁵⁰ *Id.* 27.

¹⁵¹ *Id.* 30.

¹⁵² *Id.* 31.

¹⁵³ *Id.* 27.

¹⁵⁴ *Id.* 28.

¹⁵⁵ Sharpe and Faden (1998) 64.

would later become classified as ‘iatrogenic illness’. When this newly classified disease did gain traction amongst the medical community, the study thereof was primarily concerned with complications which arose from new treatments. Beecher and Todd instead turned their attention to an established area of medicine: ‘It might have been supposed that any field of medicine which has existed for over a hundred years would have attained a considerable degree of stability in its practice’.¹⁵⁶ They found that it was anything but stable, many problems were identified by their study and the authors hoped that this revelation would encourage future improvement efforts. The authors described it as follows: ‘if we could establish how things are, progress could then be made in the direction of how they should be’.¹⁵⁷ This brings us to the final reason, focusing on ‘how things are’ and the fallibility of medicine and medical practitioners did not gain them much support among their peers, as it also went against the ‘price of therapeutic progress’ narrative of the time.¹⁵⁸

5. HAZARDS OF HOSPITALISATION

5.1. SCHIMMEL

The first systematic prospective investigation into the type and frequency of hospital complications was conducted by Elihu Schimmel from 1960 to 1961 at the Yale University Medical Service of the Grace-New Haven Community Hospital.¹⁵⁹ Schimmel set out to determine the complete incidence of harmful reactions in order to assess the cumulative risk that procedures and medication posed to patients in a healthcare facility.¹⁶⁰ Great foresight was shown by explicitly defining harmful ‘episodes’ broadly in the study. It was required that the participating house officers document ‘every noxious response to medical care occurring among their patients’.¹⁶¹ These ‘untoward events,

¹⁵⁶ Beecher and Todd (1954) 140 *Annals of surgery* 26.

¹⁵⁷ *Id.* 4.

¹⁵⁸ Sharpe and Faden (1998) 65.

¹⁵⁹ Schimmel “The Hazards of Hospitalization” *Annals of internal medicine* (1964) 60 100.

¹⁶⁰ *Ibid.*

¹⁶¹ *Ibid.*

complications and mishaps' were to be included if they 'resulted from acceptable diagnostic or therapeutic measures deliberately instituted in the hospital'.¹⁶² The study was conventional in the sense that it only analysed 'episodes' that occurred as a result of accepted practice. It was however, the first to consider all noxious responses, as opposed to past publications that only recorded the most severe complications. If one considers the period in which the study took place, it is quite understandable that the author sensibly chose to exclude reactions that 'arose from inadvertent errors by physicians or nurses' or complications that came about postoperatively. Adverse effects of previous treatment, were also omitted from the study. Despite the omission of errors and complications related to previous treatment, 198 out of a total of 1014 admitted patients suffered an 'episode'. Schimmel thus found that '20% of the persons at risk suffered one or more episodes of medical complications and that of the 240 episodes recorded, 48 (5%) were classified as being very severe, 16 of which ended fatally'.¹⁶³ The incidence of severe episodes corresponds to the rate of 'major toxic reactions and accidents' reported by Barr.¹⁶⁴ Although, economic loss and emotional disturbance suffered fell outside the scope of the study, Schimmel noted that the impact thereof could not be said to be an insignificant complication of medical harm. The economic consequences have certainly received the lion's share of attention in recent years. Prolonged hospitalisation, with the associated drain on scarce health resources and increased expenditure has become a serious concern, in the Schimmel study tentative mention was already made of the correlation between lengthened hospital stays and patients who suffered adverse events. It was found that those patients were hospitalised for an average of 4 weeks, whereas patients who did not have an adverse episode only spent an average of 1.5 weeks in hospital.¹⁶⁵ Today, we still have much work to do if we are to adequately address the emotional trauma surrounding medical harm.¹⁶⁶

¹⁶² *Id.* 101.

¹⁶³ *Id.* 102.

¹⁶⁴ Barr (1955) 159 *Journal of the American Medical Association* 1456.

¹⁶⁵ Schimmel (1964) 60 *Annals of internal medicine* 100.

¹⁶⁶ *Ibid.* Unfortunately, the focus has often been on the financial repercussions even though the psychological aspects of the problem are just as, if not more important and deserving of study.

Schimmel's study brought to light the stark reality of modern medical management, it confirmed the unspoken suspicion that almost all treatments and procedures were thoroughly beset with hazards, and emphasised the importance of striking the correct balance between 'probable benefit' and 'possible risk'. Schimmel pragmatically noted that absolute safety was unachievable in the absence of more developed safer clinical methods and that an uncompromising adherence to absolute safety would only lead to diagnostic and therapeutic nihilism, needlessly denying patients of the good that medicine at the time had to offer. In most cases, more good than harm could certainly be achieved with medical intervention. The principal consideration would be the justification for the intervention having considered all the risks; he thus also espoused the conservative view that care should be administered according to the best interest of the patient.

5.2. OGILVIE AND RUEDY

Schimmel's findings, especially regarding the frequency and severity of adverse reactions galvanised Ogilvie and Ruedy to conduct a similar study at the Montreal General Hospital, a teaching centre at the McGill University, between 1965 and 1966.¹⁶⁷ For comparative purposes, the methods used in their study were very much the same as those employed by Schimmel. The only major difference being the surveillance approach followed, both nurses and interns submitted reports. This was a deliberate deviation, which allowed the authors to test different reporting methods.

The results of their study were almost identical to those published by Schimmel and confirmed many of the findings in the earlier study. During the 12-month period, 177 patients out of the 731 (24%) admitted, suffered one or more adverse reactions. The finding by Ogilvie and Ruedy, that 24% of patients experienced at least one adverse reaction, is congruous with the 20% reported in Schimmel's preceding study. The authors noted that the untoward reactions were not markedly unusual and that these events are more than likely observed by all physicians when treating patients. Sadly, because they are frequently encountered, when it comes to decisions regarding

¹⁶⁷ Ogilvie and Ruedy "Adverse reactions during hospitalization." *Can Med Assoc J* (1967) 97 1445.

diagnosis and treatment the risks are occasionally disregarded. The severity of these risks is consequently, not sufficiently acknowledged. Considering that 72% of the reactions were found to be of major or moderate severity, it would be very irresponsible to take these risks lightly.

Other significant findings of the study include, the prevalence of drug related adverse reactions and the duration of stay in hospital. Adverse drug reactions were by far the reason for most untoward events and the cause of all 17 fatal reactions in the study. The length of hospitalisation of those patients who suffered an adverse reaction differed substantially from those who did not, these patients stayed in hospital almost twice as long as non-reactors.

5.3. MCLAMB AND HUNTLEY

McLamb and Huntley published the results of their investigation into iatrogenic harm that same year.¹⁶⁸ Their study was conducted at the North Carolina Memorial Hospital, with the goal of developing quantitative estimates of the magnitude of hazardous episodes experienced by patients. They endeavoured to do so by determining the frequency, severity and type of untoward reactions suffered by the hospitalised population during a 30-day period between July and August in 1965. These reactions were recorded as 'episodes' and were categorised according to severity, as either mild, moderate or major. Major episodes encompassed events that were life-threatening, resulted in permanent disability or proved to be fatal.

Although, the study only lasted one month and just 240 admitted patients formed part thereof, the results were very much in line with Schimmel's earlier findings. They too found that 20% of patients suffered some kind of adverse reaction while in hospital. Of the 63 episodes reported, 22 were classified as moderate and 4 episodes were of major severity, one of which led to the loss of the patient. Adverse drug reactions again accounted for the most episodes (45%). The authors highlighted the potential danger posed by properly administered drugs, emphasising that 'no drug is completely

¹⁶⁸ McLamb and Huntley "The hazards of hospitalization." *South Med J* (1967) 60 469.

harmless' and that new drugs may bring with them side-effects that are not widely known, requiring physicians to be particularly attentive when prescribing such medication. As in the preceding studies, a possible correlation between patients that experienced an episode and their subsequent prolonged hospitalisation was again mentioned.

In the conclusion to their study McLamb and Huntley noted the pervasiveness of iatrogenic disease and the hazards brought on by hospitalisation, their findings attested to previous observations on the subject. The authors encouraged persistent vigilance on the part of all medical and hospital staff in order to see that 'the price we pay' is 'kept within tolerable limits'.

5.4. SECKLER AND SPRITZER – THE TOLERABLE LIMITS

What are the tolerable limits? Seckler and Spritzer, perhaps the first authors to openly caution against the toll imposed by medical progress, are of the opinion that 'very few people would care to challenge the fact that our present day knowledge and capabilities in medicine have been productive of more good for mankind than harm', however, they question if 'doing more harm' to patients can be justified 'simply because we can now do more good?'.¹⁶⁹ The authors liken the figurative explosive advances in our understanding and abilities in medicine to a more literal explosion whereby the individuals exposed are liable to be harmed, and in citing Schimmel's findings they continue the analogy by asserting that those 'closest to the centre of the explosion are most vulnerable to be more frequently and seriously injured'.

Seckler and Spritzer submit that iatrogenic disease cannot be adequately confronted if only the etiological elements thereof are to be addressed, what needs to be realised is that, similar to the Anopheles, the mosquito responsible for the transmission of the malarial parasite to humans, physicians are the vector for iatrogenic disease, and as such their role in transferring harm to patients must surely warrant attention. In their

¹⁶⁹ Seckler and Spritzer "Disseminated disease of medical progress" *Arch Intern Med* (1966) 117 447.

conclusion, the authors reflect on the part doctors play in deciding what the ‘tolerable limits’ of medical progress and iatrogenic disorders are, emphasising that ‘the physician is responsible for the existence of these disorders and must, therefore, be involved in their control’.

5.5. STEEL *ET AL.*

Fifteen years after the publication of Schimmel’s findings, Steel et al, in 1981, undertook a study to re-evaluate the risks of care in a tertiary hospital setting.¹⁷⁰ The authors noted that, in the decade and a lustrum following Schimmel’s study, the patient population had aged, diagnostic techniques had certainly become more complex and a copious number of new drugs have now become more readily utilised. Steel and his colleagues wanted to determine what effect the passing of time and these mentioned factors have had on the frequency and types of iatrogenic events. What they found was, that of the 815 patients involved in the study, 219 suffered one or more iatrogenic illnesses. An alarming 36% of patients were harmed while in hospital, 9% of which experienced major complications. Drugs (208 complications), cardiac catheterizations (45), and falls (35) were the most common sources of nosocomial disease.¹⁷¹ Patients’ age, heightened exposure to drugs, and the length of their stay were respectively positively associated with complications.

The authors observed that ‘the risk incurred during hospitalisation is not trivial’, almost an understatement when one considers that a third of all patients sustained some form of iatrogenic injury. They noted the numerous changes that occurred in clinical practice since Schimmel conducted his study. Patients are now continually monitored and this closer observation may have led to more frequent or earlier intervention. Although this may greatly benefit the patient, the increased use of therapeutic procedures and drugs, come with ineluctable risks.

¹⁷⁰ Steel et al. “Iatrogenic illness on a general medical service at a university hospital.” *N Engl J Med* (1981) 304 638.

¹⁷¹ Diseases originating in hospitals.

Steel *et al.* in their conclusion submitted that the risk of hospitalisation definitely had not diminished since the earlier study and that disconcertingly, 'the risk of a serious problem may well have increased'. In light of their findings, the authors called for improved methods of monitoring untoward events and the development of systems that allow for the continuous assessment of institutional hazards. They hoped that technological, educational and administrative measures could subsequently be harnessed to reduce the number and severity of adverse events.

Although, the authors explicitly avoided the question of culpability on the part of physicians that participated in the study, their conclusion does suggest that they believed that many of the injuries could be avoided or prevented if the necessary attention and resources were directed at the problem.

6. MEDICAL NEMESIS

'The medical establishment has become a major threat to health.' These are the opening words in the introduction of Ivan Illich's rebuke of the modern medical profession, acerbically titled, 'Medical Nemesis: The Expropriation of Health', published in 1975.¹⁷² According to Illich, doctors are not merely the vector of iatrogenic illness, the entire healthcare system has become a disease and the public are irreversibly infected. Illich, argues against conventional wisdom, which would have us believe that the majority of medical interventions have been effective and to society's great benefit, he instead posits that despite such impression being fabricated by 'awe-inspiring medical technology' in combination with 'egalitarian rhetoric', only a few procedures have proven to be useful, most are at best futile and many are downright harmful.¹⁷³

Comparing the 'pain, dysfunction, disability, and anguish' caused by modern medical practice to the morbidity of traffic accidents, the author submits that medicine has

¹⁷² Illich *Medical nemesis* (1976).

¹⁷³ *Id.* 14.

become 'one of the most rapidly spreading epidemics of our time'.¹⁷⁴ These side-effects of clinical conditions for which 'remedies, physicians, or hospitals are the pathogens, or "sickening" agents' are defined by the author as 'clinical iatrogenesis'.¹⁷⁵ The author believes that clinical iatrogenesis has become widespread, so pervasive in fact, that it has become ingrained as accepted and ordinary practice, those in the medical profession have acquiesced to the harm done.

6.1. THREE LEVELS OF IATROGENESIS

Illich further identifies what he deems to be 'social iatrogenesis', or the medicalisation of society, as a second category of iatrogenesis.¹⁷⁶ The author contends that medical practice has succeeded in promoting illness by 'reinforcing a morbid society that encourages people to become consumers of curative, preventive, industrial, and environmental medicine'. Iatrogenesis on this level has resulted in what the author refers to as 'the expropriation of health'.

Social iatrogenesis in turn has metastasised into the 'ultimate evil of medical "progress"', a third level of iatrogenesis – 'cultural iatrogenesis'.¹⁷⁷ A phenomenon, described by Illich as the acceptance of an engineered healthcare model, whereby 'better health' becomes a commodity. And in this relentless pursuit of 'better health' we, as a society are deprived of our ability to cope with human frailty and vulnerability in a self-affirmative and autonomous manner. Cultural iatrogenesis, in the author's own words, consists of 'the paralysis of healthy responses to suffering, impairment, and death'.¹⁷⁸

Furthermore, Illich argues that the three levels of iatrogenesis have become medically irreversible, inherent to the practice of medicine. What is more, the side-effects induced by diagnostic and therapeutic advancement, whether, physiological, psychological or

¹⁷⁴ *Id.* 15.

¹⁷⁵ *Id.* 16.

¹⁷⁶ *Id.* 20.

¹⁷⁷ *Id.* 18.

¹⁷⁸ *Ibid.*

social, 'have become resistant to medical remedies'. And even the supposed cures have evolved into diseases, in what the author terms a 'self-reinforcing iatrogenic loop'. Illich equates the retribution for our 'better health' hubris, to those condemned to endless self-defeat by the ancient Greek mythological figure, Nemesis.¹⁷⁹

'Medical nemesis is resistant to medical remedies. It can be reversed only through a recovery of the will to self-care among the laity, and through the legal, political, and institutional recognition of the right to care, which imposes limits upon the professional monopoly of physicians.'¹⁸⁰

Clearly, Illich perceives autonomy and freedom from bureaucratic healthcare as fundamental elements of personal well-being.¹⁸¹ A notion, quite distinct from the dominant paternal sentiments one gleans from language used in publications on medical harm originating from his time.

7. CONCLUSION

Primum non nocere is a time-honoured tenet of medicine. Physicians have for centuries committed themselves to the Hippocratic injunction to 'first, do no harm'. This expression has become even more significant considering what we have now come to recognise regarding the extent and prevalence of iatrogenic injuries. Although we have only relatively recently begun to study safety in healthcare, the potentially damaging effects of medical intervention have long been known.

This chapter provided a brief overview of this history of medically induced harm. It reflected on the origins of the concept and our changing understanding thereof and several notable historical developments were discussed.

¹⁷⁹ *Ibid.*

¹⁸⁰ *Id.* 19.

¹⁸¹ Illich "Clinical damage, medical monopoly, the expropriation of health: three dimensions of iatrogenic tort." *J Med Ethics* (1975) 1 78; Illich "Death undefeated." *BMJ* (1995) 311 1652.

Significant changes in therapeutics occurred during the early 19th Century, including the tensions and transitions between 'heroic' medicine, natural healing, empiricism and conservative medicine.

Hospitals brought new hazards. Doctors and midwives unknowingly contributed to countless puerperal fever tragedies. Sepsis, caused by poor hygiene, continued to plague surgery and kept post-operative mortality rates devastatingly high.

Lister's antiseptic methods, meant that infections could finally be prevented, making surgery safer, more common and very lucrative. This led to the proliferation of hospitals, offering a range of new operations. Medical intervention increased substantially with no real oversight and no incentive to disclose how effective these interventions were.

Codman, the father of outcomes measurement, took issue with a profession that relied on nothing more than reputation and prestige to advance its own interests. He wanted to follow up patients in order to determine whether the treatment they received had been successful or not. Codman's efforts and his 'End Result System' laid the foundations for the hospital standardisation movement and the Joint Commission on Accreditation of Hospitals.

By the mid-20th century, medical science had advanced to a stage where interventions were thoroughly embraced by society. This increase in drug use and treatments had the potential to be extremely harmful. Doctors started to reflect on the potential hazards associated with the proliferation of diagnostic and therapeutic procedures. Systematic studies of the hazards of hospitalisation followed, which started to uncover the scale of iatrogenic harm.

The negative impact of modern medicine had become so pervasive that Illich perceived healthcare as a threat to health. His views regarding iatrogenesis and comparisons to morbidity caused by traffic accidents may have seemed quite incendiary and hyperbolic at the time. However, as the true extent of iatrogenic harm became more widely

recognised, we began to see similar comparisons in official governmental reports and academic literature. As the following pages will show, Illich was not far off the mark.

CHAPTER 2. TO ERR IS HUMAN

1. INTRODUCTION

Fifteen years have now passed since the release of the Institute of Medicine's seminal 1999 report 'To Err is Human'.¹ Most would agree that the patient safety movement really only gained momentum after its publication.² The report was a major catalyst which brought attention to the immense scale of iatrogenic illness and reframed harm suffered from medical care as a public health issue.³ As Lucian Leape, widely regarded as the father of patient safety, noted: 'Few publications in recent memory have received as much notice or stimulated as swift a response among policymakers as the Institute of Medicine (IOM) report on medical errors'.⁴ The report was a call to action, its objective to encourage a concerted effort amongst stakeholders to acknowledge errors and build a safer healthcare system.⁵

1.1. 'THREE JUMBO-JET CRASHES EVERY TWO DAYS'

What initially grabbed the headlines and public attention, was the estimate that between 44 000 and 98 000 Americans die in hospitals each year as a result of medical errors.⁶ In his 1994 article 'Error in Medicine', Leape equated the number of fatalities associated with iatrogenic injury, 180 000 according to his approximation, to 'three jumbo-jet crashes every two days'.⁷ A variation of Leape's jumbo-jet analogy acquired notoriety, after having been picked up by various newspapers, magazines and network television

¹ Kohn et al. (2000); Donaldson "An overview of to err is human: re-emphasizing the message of patient safety" (2008). The Institute of Medicine has been renamed the National Academy of Medicine (NAM). The NAM is an American non-profit, non-governmental organisation that works to address critical issues in health, medicine, and related policy.

² Stelfox et al. (2006) 15 *Qual Saf Health Care* 174.

³ Elwyn and Corrigan "The patient safety story." *BMJ* (2005) 331 302.

⁴ Leape "Institute of Medicine medical error figures are not exaggerated." *JAMA* (2000) 284 95.

⁵ Bootman "To Err Is Human" *Arch Intern Med* (2000) 160 3189.

⁶ Kohn et al. (2000) 31.

⁷ Leape "Error in medicine." *JAMA* (1994) 272 1851.

shows.⁸ The publicity generated by the Institute of Medicine's findings, although, often lacking nuance and at times obfuscating, finally helped bring about the political will to confront the patient safety problem.⁹

1.2. AN OVERLOOKED EPIDEMIC

It is quite astonishing to think that the myriads of harmed patients and consequent inordinate amount of avertable expenditure could be overlooked, or perhaps disregarded, for so long.¹⁰ With the benefit of hindsight, one is struck by how lackadaisical the response to an issue of such grave importance had been. It is ultimately, a matter which affects us all, as everyone will at some stage of their life be a patient and safety would almost certainly be a foremost concern.

Practical measures and initiatives have been elusive, but an appreciation for this fact has persisted. The principal tenet of medicine, 'First, do no harm', followed by the ancient Greeks and still adhered to today, gives credence to the idea.¹¹ So too did Codman, leading him to question the prevailing practices of his time and culminated in his prescient outcomes management approach.¹² Beecher and Todd were guided by the principle as well, whilst investigating the hazards of anaesthesia during surgery, following concern about high mortality rates.¹³ Several studies into anaesthesia mortality followed, resulting in standardisation, closer monitoring and vastly improved

⁸ Editorial, 'Preventing Fatal Medical Errors', *The New York Times*, 1999, ; Miller "Two feet of mistakes." *Newsweek* (1995) 125 60.

⁹ Dentzer "Media mistakes in coverage of the Institute of Medicine's error report." *Eff Clin Pract* (2000) 3 305.

¹⁰ Vincent (1989) 299 *BMJ* 1150.

¹¹ Smith (2005) 45 *J Clin Pharmacol* 371.

¹² Codman (1914) 18 *Surgery, Gynecology Obstetrics* 491.

¹³ Beecher and Todd (1954) 140 *Annals of surgery* 2.

outcomes.¹⁴ The systematic approach to reduce harm adopted in the field of anaesthesia served as a prelude to the patient safety efforts the ensuing decade.¹⁵

1.3. THE SAFETY MOVEMENT

The widespread attention medical errors and patient harm have received the past decade and a half, from the medical profession, policy makers and public has been a turning point for the safety movement.¹⁶ Not too long ago medical error was hardly ever acknowledged by doctors or disclosed to patients, rarely appeared in medical journals and certainly did not attract governmental endeavour as it does today.¹⁷ Research in the sphere of clinical safety was considered at best a fringe interest and even seen as disreputable by some, which may explain the paucity thereof.¹⁸ Vincent, upon reviewing the literature available at the time, found the research to be so scant that he believed the absence of scrutiny and studies into medical accidents and negligence, in itself amounted to negligence.¹⁹ When the British Medical Journal (BMJ) in 1990 called for a study into the incidence of adverse events, which would emulate the studies conducted in the United States and Australia the previous decade, the publication was lambasted by the president of a medical royal college for drawing media attention to

¹⁴ Cooper et al. "Preventable anesthesia mishaps: a study of human factors." *Anesthesiology* (1978) 49 399; Cooper et al. "An analysis of major errors and equipment failures in anesthesia management: considerations for prevention and detection." *Anesthesiology* (1984) 60 34; Derrington and Smith "A review of studies of anaesthetic risk, morbidity and mortality." *Br J Anaesth* (1987) 59 815; Gaba et al. "Anesthetic mishaps: breaking the chain of accident evolution." *Anesthesiology* (1987) 66 670; Cheney "The American Society of Anesthesiologists Closed Claims Project: what have we learned, how has it affected practice, and how will it affect practice in the future" *Anesthesiology* (1999) 91 552.

¹⁵ Gaba "Anaesthesiology as a model for patient safety in health care." *BMJ* (2000) 320 785; Leape et al. "What practices will most improve safety?: evidence-based medicine meets patient safety" *JAMA* (2002) 288 501; Pierce "Looking back on the anesthesia critical incident studies and their role in catalysing patient safety." *Qual Saf Health Care* (2002) 11 282.

¹⁶ Vincent (2011) 14; Pronovost et al. "Fifteen years after To Err is Human: a success story to learn from." *BMJ Qual Saf* (2016) 25 396.

¹⁷ Wachter *Understanding Patient Safety* (2007) xiii.

¹⁸ Vincent (2011) 14.

¹⁹ Vincent (1989) 299 *BMJ* 1150.

medical error.²⁰ If you were to search Index Medicus²¹, a comprehensive bibliographic index of scientific journal articles focused on medical science fields, that same year, you would not find a section on medical error and accidents, the topic seemingly, didn't even merit classification.²² Since the mid-1990s however, the number of articles has increased exponentially and hundreds more are added each year under the medical error heading.

In 2000, Lucian Leape and Donald Berwick served as guest editors of the *BMJ* for a special theme issue devoted almost entirely to medical error.²³ The title of their editorial posed a rhetorical question: are medical practitioners prepared for safe health care? The authors provided the only possible answer in the subtitle, they have no choice, they had to be. They concluded with this urgent appeal to physicians:

'It may seem to some that the race for patient safety has just begun, but the patience of the public we serve is already wearing thin. They are asking us to promise something reasonable, but more than we have ever promised before: that they will not be harmed by the care that is supposed to help them. We owe them nothing less, and that debt is now due.'²⁴

2. TO ERR IS HUMAN

'To Err is Human' changed the conversation around medical injuries and accidents, it focussed the attention of journalists, healthcare leaders and the public on patient safety, a topic that had been little understood and even less discussed up to that point.²⁵ The authors of the report wanted to break the circle of inaction, advocating for a

²⁰ Smith "Facing up to medical error" *BMJ* (2000) 320.

²¹ Now computerised and incorporated into MEDLINE, one of the most important medical research databases.

²² Vincent (1989) 299 *BMJ* 1150.

²³ 18 March 2000 (vol. 320, issue 7237).

²⁴ Leape and Berwick "Safe health care: are we up to it" *BMJ* (2000) 320 725.

²⁵ Kohn et al. (2000); Leape and Berwick "Five years after To Err Is Human: what have we learned" *JAMA* (2005) 293 2384.

comprehensive approach to the problem of unsafe care and putting forth recommendations that would compel health care organisations and providers to respond and improve patient safety.²⁶

They noted that a major force for improving patient safety would be the intrinsic motivation of health care professionals, shaped by professional ethics, norms and expectations.²⁷ However, factors in the external environment and inside the healthcare organisation itself would also play a pivotal role.²⁸ External factors such as the availability of knowledge and tools to improve safety, determined and visible professional leadership, legislative and regulatory initiatives and a demand for improvement from healthcare purchasers and consumers would create an enabling foundation.²⁹ Factors that promote patient safety inside healthcare organisations for instance, managerial leadership, an institutional safety culture that encourages the recognition and learning from errors and an established patient safety program would interact with external factors, building upon an effective foundation.³⁰

The recommendations of the report, divided into a four-tiered approach, were summarised as follows:³¹

1. Establishing a national focus to create leadership, research, tools and protocols to enhance the knowledge base about safety;
2. Identifying and learning from errors through immediate and strong mandatory reporting efforts, as well as the encouragement of voluntary efforts, both with the aim of making sure the system continues to be made safer for patients;
3. Raising standards and expectations for improvements in safety through the actions of oversight organizations, group purchasers, and professional groups; and

²⁶ Kohn et al. (2000) 3.

²⁷ *Id.* 5.

²⁸ Institute “Crossing the Quality Chasm: A New Health System for the 21st Century” (2001).

²⁹ Kohn et al. (2000) 6.

³⁰ *Id.* 7.

³¹ *Id.* 6.

4. Creating safety systems inside health care organizations through the implementation of safe practices at the delivery level. This level is the ultimate target of all the recommendations.

The significance of the IOM report did not cease at the exposure it attracted to the scale and extent of iatrogenic injury. The enduring impact thereof is evident, especially in the changing views surrounding error prevention; engagement elicited from stakeholders; and safer practices adopted.³²

3. A CATALYST FOR CHANGE

Perspectives regarding error prevention have certainly changed in the aftermath of the IOMs findings.³³ Hardly acknowledged preceding the report, confronting preventable medical injuries has now become a primary concern. The widely disseminated notion that bad systems, instead of bad people, are responsible for the majority of errors and injuries has become somewhat of a mantra in healthcare. This concept, which emphasises systemic rather than individual failure, has been a critical scientific foundation for safety improvement in high reliability industries, such as aviation and nuclear power operations. The report highlighted the role that technologies can play in achieving safer care. Consequently, the potential benefits that computer-assisted physician order-entry systems and electronic medical records may yield have received considerable attention.

The report managed to galvanise extensive stakeholder support for safety initiatives in the United States.³⁴ The federal government in 2001, earmarked an annual amount of \$50 million for patient safety research.³⁵ The financial assistance drew hundreds of new researchers into the field, creating an academic foundation and establishing error

³² Pronovost et al. (2016) 25 *BMJ Qual Saf* 396.

³³ Shojania et al. "Making health care safer: a critical analysis of patient safety practices." *Evid Rep Technol Assess (Summ)* (2001) i.

³⁴ Zipperer "Patient Safety" (2014) 9.

³⁵ Clancy "Ten years after To Err is Human." *Am J Med Qual* (2009) 24 525.

prevention and patient safety research as a serious scholarly discipline.³⁶ The cause has also been helped along by key players such as the Agency for Healthcare Research and Quality (AHRQ). Established by an act of Congress in 1999, the AHRQ conducts scientific research and produces evidence to make healthcare safer, enhance quality and increase effectiveness as well as accessibility through the promotion of improvements in clinical and health system practices.³⁷ The AHRQ and its Centre for Quality Improvement and Safety have played a leading role in safety efforts by prioritising education and training, developing safety measures and standards, evaluating evidence-based best practices and promoting better reporting of adverse events.³⁸ Patient safety initiatives also found support in the Veteran's Health Administration (VHA), which implemented system-wide safe practices and training programs.³⁹ Other important role-players have emerged and taken steps to improve safety, a varied group that includes the: Joint Commission on Accreditation of Healthcare Organizations (JCAHO); National Quality Forum (NQF); Centres for Medicare and Medicaid Services; Centres for Disease Control and Prevention; American College of Physicians and other medical societies; National Patient Safety Foundation; Accreditation Council on Graduate Medical Education; American Board of Medical Specialties; Institute for Healthcare Improvement; purchasers and payers.

Leape and Berwick, however, submit that the most important stakeholders that have been mobilised are the numerous devoted healthcare professionals, who are in the trenches, now armed with a new appreciation for the hazards of medicine, and

³⁶ Walshe and Boaden *Patient Safety* (2005) 2.

³⁷ Meyer et al. "The US Agency for Healthcare Research and Quality's activities in patient safety research." *Int J Qual Health Care* (2003) 15 Suppl 1 i25.

³⁸ Shojania et al. (2001) *Evid Rep Technol Assess (Summ)* i.

³⁹ Bagian et al. "The Veterans Affairs root cause analysis system in action" *Jt Comm J Qual Patient Saf* (2002) 28 531; DeRosier et al. "Using health care Failure Mode and Effect Analysis: the VA National Center for Patient Safety's prospective risk analysis system." *Jt Comm J Qual Improv* (2002) 28 248; Dunn et al. "Medical team training: applying crew resource management in the Veterans Health Administration." *Jt Comm J Qual Patient Saf* (2007) 33 317.

consequently, fighting to improve the quality of care and outcomes their patients can expect.⁴⁰

The IOM report managed to expedite the adoption of safer practices.⁴¹ The changes hospitals and other healthcare institutions implemented were entirely voluntary at first, even so, the response was encouraging. A number of hospitals responded to recommendations from professional organisations and implemented medication safety systems.⁴² Other organisations enrolled teams in training programs at the Institute for Healthcare Improvement, which taught them how to incorporate rapid cycle improvement and human factors principles in their institutions.⁴³ Healthcare providers, responding to purchaser and payer groups, also began to alter their practices in a consolidated attempt to prevent iatrogenic harm.⁴⁴

In 2002, the NQF with support from the AHRQ, published a list of 30 evidenced-based safe practices that were ready for universal application.⁴⁵ The following year, the JCAHO required hospitals to implement a number of these practices in accordance with its newly established National Patient Safety Goals program.⁴⁶ Another significant change in practice occurred in 2003, with the implementation of residency training work

⁴⁰ Leape and Berwick (2000) 320 *BMJ* 725; Leape and Berwick (2005) 293 *JAMA* 2384.

⁴¹ Byers and White *Patient Safety: Principles and Practice* (2004) 47.

⁴² Samore et al. "Surveillance of medical device-related hazards and adverse events in hospitalized patients." *JAMA* (2004) 291 325.

⁴³ Series and Kilo "A Framework for Collaborative Improvement: Lessons from the Institute for Healthcare Improvement's Breakthrough Series" *Quality management in health care* (1998) 6 1; Nolan et al. *Improving the reliability of health care* (2004); Womack et al. "Going lean in health care" *Cambridge, MA: Institute for Healthcare Improvement* (2005); Classen et al. "Development and evaluation of the institute for healthcare improvement global trigger tool" *Journal of Patient Safety* (2008) 4 169.

⁴⁴ Leape and Berwick (2005) 293 *JAMA* 2384.

⁴⁵ National "Safe practices for better healthcare: a consensus report" (2003); Kizer and Blum, 'Safe Practices for Better Health Care' in Henriksen et al. (eds.), *Advances in Patient Safety: From Research to Implementation (Volume 4: Programs, Tools, and Products)*, Agency for Healthcare Research and Quality (US), Rockville (MD), 2005.

⁴⁶ Excellence "The Joint Commission announces 2014 national patient safety goal" *Joint Commission Perspectives* (2013).

hour limitations in teaching hospitals.⁴⁷ Although, scientific evidence indicating a correlation between fatigue and errors at work had been available for quite some time, the Accreditation Council on Graduate Medical Education finally acknowledged the problem and took steps to rectify the situation by implementing the restrictions.⁴⁸ Unfortunately, the limitations did not go as far as to address the issue of sleep deprivation due to extended shifts, a controversial issue that has recently come under discussion in our country as well.⁴⁹

4. INTERNATIONAL AGENDA

Several governments and professional associations have released reports and policy papers in the wake of 'To Err is Human'.⁵⁰ In 2000 for instance, the Department of Health in the United Kingdom under leadership of then Chief Medical Officer, Professor Liam Donaldson, released an equivalent report 'An Organisation with a Memory'.⁵¹ This report, much the same as the one released by the IOM, set out to determine the scale and nature of adverse events, but unlike its US counterpart, placed a much larger emphasis on the lessons that could be learnt from these failures and the safety knowledge that could be extracted from other high-risk industries in order to improve the British National Health Service (NHS). An Organisation with a Memory found that harm caused by adverse events occur in around 10% of all admissions, or at a rate in excess of 850 000 per year. The financial impact, just in terms of additional hospitalisation, is astounding, costing the NHS an estimated £2 billion.⁵²

⁴⁷ Philibert et al. "New requirements for resident duty hours" *Jama* (2002) 288 1112.

⁴⁸ Accreditation "Report of the ACGME work group on resident duty hours" *Chicago, IL: Accreditation Council for Graduate Medical Education* (2002).

⁴⁹ McQuoid-Mason "Harm to patients and others caused by impaired junior doctors compelled to work 30-hour shifts or longer: Can the minister of health, provincial MECs for health and public health officials be held liable" *S Afr J BL* (2016) 9 52.

⁵⁰ Organization *Quality of care: patient safety* (2002).

⁵¹ Health *An Organisation with a Memory: Report of an Expert Group on Learning from Adverse Events in the NHS Chaired by the Chief Medical Officer* (2000).

⁵² *Ibid.*

4.1. RESOLUTION WHA55.18

Mounting global concern about the incidence of adverse events, the significant avoidable human suffering caused thereby, and the financial burden these preventable injuries place on countries' health systems, led to the adoption of Resolution WHA55.18 by the World Health Assembly in May 2002.⁵³ The Assembly expressly recognised the need to promote patient safety as a fundamental principle in all health systems and urged member states to 'pay the closest possible attention to the problem of patient safety' and 'establish and strengthen science-based systems, necessary for improving patients' safety and the quality of health care'. The resolution also requested the Director-General of the World Health Organisation (WHO) to carry-out a series of initiatives to advance patient safety, including: the development of global norms, standards and guidelines; the promotion of evidenced-based policies; supporting efforts of Member States to establish a culture of safety; and encouraging research into risk factors, effective interventions, and the associated costs involved.⁵⁴

The pursuit of safer care had, with the adoption of the resolution, finally become a global endeavour.⁵⁵ A working group on patient safety was established that same year to coordinate the activities of the WHO, so as to enable the most efficacious response to the concerns raised in the resolution.⁵⁶ The response included the formation of work programmes aimed at addressing systemic factors, such as the preparation of a taxonomy of health-care errors and system failures, the development of methods and tools for estimating hazards and the implementation of reporting and learning systems. A subgroup on product safety was established, it focussed on issues specifically related to vaccines, other biologicals, medicines and equipment. At the same time, the WHO set out to improve the safety of services in the following areas: laboratory practice; diagnostic and treatment procedures and clinical practice; medical decision-making;

⁵³ Resolution "55.18. Quality of care: patient safety" *55th World Health Assembly, Geneva (2002)* 1.

⁵⁴ Organization (2002); Organization *Quality of care: patient safety* (2003).

⁵⁵ Donaldson (2004) 13 *Quality and Safety in Health Care* 86; Donaldson "When will health care pass the orange-wire test" *Lancet* (2004) 364 1567.

⁵⁶ Organization (2003).

medication errors; safe use of equipment; immunization and injection safety; hospital infections; patient management; and staff technical performance and competence.

4.2. WHO PATIENT SAFETY PROGRAMME

In November 2003, the WHO in collaboration with the United Kingdom, convened a meeting of senior policy-makers, clinical leaders and international experts to discuss future international cooperation on patient safety and the practical realisation of Resolution WHA55.18.⁵⁷ At this summit held in London, Professor Liam Donaldson proposed that a world alliance be established. The proposal received overwhelming support and a decision was taken to create an International Alliance for Patient Safety, with a view to accelerate improvements in patient safety.⁵⁸ The Alliance's core functions would include: supporting the development of patient safety policy and practice; enabling countries to assess their progress towards patient safety; global reporting; solution development; and research and development. The International Alliance was to play a fundamental role in the expansion of patient safety policy and practice in all member states. The World Alliance for Patient Safety was launched by the Director-General in October 2004.⁵⁹ This inauguration further emphasised the importance of patient safety as a global health issue.

In 2009 the Alliance was renamed and is now known as the WHO Patient Safety (WHOPS) Programme. Since its establishment in 2004, and through the involvement of several countries, interested bodies and international experts, the programme has had a major impact on the attainment of safer care throughout the world. WHOPS and the initiatives launched by it, have been influential in changing practices to enhance safety.⁶⁰

⁵⁷ Donaldson and Philip (2004) 82 *Bulletin of the World Health Organization* 892.

⁵⁸ Donaldson (2004) 13 *Quality and Safety in Health Care* 86.

⁵⁹ World (2004) *Forward programme*. Geneva: WHO Library.

⁶⁰ Organization "Secretariat report prepared for the Fifty-ninth World Health Assembly, held in May 2006" (2006) 1.

4.3. GLOBAL PATIENT SAFETY CHALLENGES

In 2005, it launched the first of the Global Patient Safety Challenges, 'Clean Care is Safer Care', encouraging health providers to adopt guidelines and tools that would help improve hand-hygiene, the ultimate aim being the achievement of reduced healthcare-associated infection rates.⁶¹ Many governments have since taken up the challenge and thousands of hospitals have now implemented the WHO recommendations relating to hand-hygiene.⁶²

In 2008, WHOPS launched the second of the Global Patient Safety Challenges, 'Safe Surgery Saves Lives'.⁶³ This initiative was aimed at improving the safety of surgical care by defining a key set of safety standards that could be universally applied in health systems of member states.⁶⁴ It led to the creation of the WHO Guidelines for Safe Surgery, a document that includes a review of the evidence for interventions that can

⁶¹ Organization "Global patient safety challenge: 2005-2006" (2005).

⁶² Pittet and Donaldson "Clean Care is Safer Care: a worldwide priority." *Lancet* (2005) 366 1246; Pittet et al. "Clean care is safer care": the global patient safety challenge 2005–2006" *International Journal of Infectious Diseases* (2006) 10 419; Allegranzi et al. "The first global patient safety challenge "clean care is safer care": from launch to current progress and achievements" *Journal of Hospital Infection* (2007) 65 115; Sax et al. "My five moments for hand hygiene": a user-centred design approach to understand, train, monitor and report hand hygiene" *Journal of Hospital Infection* (2007) 67 9; Allegranzi et al. "Religion and culture: potential undercurrents influencing hand hygiene promotion in health care" *American journal of infection control* (2009) 37 28; Pittet et al. "The World Health Organization guidelines on hand hygiene in health care and their consensus recommendations" *Infection Control & Hospital Epidemiology* (2009) 30 611; Mathai et al. "Promoting hand hygiene in healthcare through national/subnational campaigns" *Journal of Hospital Infection* (2011) 77 294.

⁶³ "Safe Surgery Saves Lives: The Second Global Patient Safety Challenge Safe Surgery Saves Lives Launch Event" *International Journal of Risk and Safety in Medicine* (2008) 20 181; Organization "The Second Global Patient Safety Challenge" *World Health Organization* (2008).

⁶⁴ Dziekan "Checklists save lives" *Bulletin of the World Health Organization* (2008) 86; Weiser et al. "An estimation of the global volume of surgery: a modelling strategy based on available data" *The Lancet* (2008) 372 139; Bickler and Spiegel "Improving surgical care in low-and middle-income countries: a pivotal role for the World Health Organization" *World journal of surgery* (2010) 34 386; Vats et al. "Practical challenges of introducing WHO surgical checklist: UK pilot experience" *BMJ: British Medical Journal* (2010) 340 ; Weiser et al. "Effect of a 19-item surgical safety checklist during urgent operations in a global patient population" *Annals of surgery* (2010) 251 976; Weiser et al. "Perspectives in quality: designing the WHO Surgical Safety Checklist" *International journal for quality in health care* (2010) 22 365; Haynes et al. "Safe Surgery Saves Lives Study Group: Changes in safety attitude and relationship to decreased postoperative morbidity and mortality following implementation of a checklist-based surgical safety intervention" *BMJ Qual Saf* (2011) 20 102.

improve surgical safety, as well as the WHO Surgical Safety Checklist.⁶⁵ The Checklist is based on the evidence contained in Guidelines and is used by surgical teams as a straightforward, practical tool to ensure that the preoperative, intraoperative and postoperative steps that have been shown to benefit patients are effectively followed.⁶⁶

4.4. THE GLOBAL PRIORITIES FOR PATIENT SAFETY RESEARCH

Great strides have been made in strengthening the scientific base of the discipline.⁶⁷ Recognising the importance of research for the development of government policy, healthcare funding, implementation of improved clinical practices and ultimately, better patient care, the WHO Patient Safety with the assistance of experts from all over the world identified a set of high priority research areas.⁶⁸ The Global Priorities for Patient Safety Research was published in May 2009, and provided a focussed global collaborative agenda as well as a strategic starting point for patient safety research.⁶⁹ The WHO has since generated global estimates for the burden and costs of unsafe care.⁷⁰ And studies emanating from the initiative, conducted in 13 member states have also brought much needed attention to the, often unique, patient safety challenges faced by developing countries.⁷¹

⁶⁵ Organization “Surgical Safety Checklist” (2008) 1; Organization *WHO Guidelines for Safe Surgery 2009* (2009c)

⁶⁶ Organization *WHO surgical safety checklist and implementation manual* (2009d); Organization (2009c)

⁶⁷ Organization “Secretariat report to the 132th session of the Executive Board” (2012) 1.

⁶⁸ Organization “Summary of the evidence on patient safety: implications for research” (2008a); Bates et al. “Global priorities for patient safety research” *BMJ: British Medical Journal* (2009) 338; Shekelle et al. “Advancing the science of patient safety” *Annals of internal medicine* (2011) 154 693; Cresswell et al. “Global research priorities to better understand the burden of iatrogenic harm in primary care: an international Delphi exercise” *PLoS medicine* (2013) 10 e1001554.

⁶⁹ Organization *Global priorities for patient safety research* (2009a); Bates et al. “Global priorities for patient safety research.” *BMJ* (2009) 338 b1775.

⁷⁰ Jha et al. (2010) 19 *Qual Saf Health Care* 42; Jha et al. (2013) 22 *BMJ Qual Saf* 809.

⁷¹ Carpenter et al. “Measures of patient safety in developing and emerging countries: a review of the literature.” *Qual Saf Health Care* (2010) 19 48.

4.5. PATIENTS FOR PATIENT SAFETY

It does seem quite obvious that patients would have a role to play in matters related to their own safety.⁷² The paternalism that often accompanied interactions with medical providers has slowly evolved into something more akin to a partnership in the pursuit of better health.⁷³ It is in this light that the Patients for Patient Safety network was created.⁷⁴ Its aim, to foster engagement with patients. The WHO recognises that patient involvement is vital, their experiences and insights, obtained at the centre of the healthcare system, represent an important source of information – a source that could provide learning opportunities and help improve health outcomes.⁷⁵

4.6. INTERNATIONAL CLASSIFICATION FRAMEWORK

The WHO Patient Safety has shown prodigious leadership in other areas affecting safer care. A Conceptual Framework for the International Classification for Patient Safety was drafted in 2009, in order to define, harmonise and group patient safety concepts into an internationally agreed classification.⁷⁶ With this framework it hoped to improve the analysis of safety problems and facilitate learning.⁷⁷

⁷² Koutantji et al. "The patient's role in patient safety: engaging patients, their representatives, and health professionals" *Clinical risk* (2005) 11 99; Organization *Patients for Patient Safety* (2006).

⁷³ Conway et al. "Partnering with patients and families to design a patient-and family-centered health care system: a roadmap for the future: a work in progress" (2006); Longtin et al. "Patient participation: current knowledge and applicability to patient safety" *Mayo Clinic Proceedings* (2010) 85 53.

⁷⁴ World "Patients for patient safety" *Geneva: World Health Organization* (2007).

⁷⁵ Laurance et al. "Patient engagement: four case studies that highlight the potential for improved health outcomes and reduced costs" *Health Affairs* (2014) 33 1627; Stang and Wong "Patients teaching patient safety: the challenge of turning negative patient experiences into positive learning opportunities" (2015); Ocloo and Matthews "From tokenism to empowerment: progressing patient and public involvement in healthcare improvement" *BMJ Qual Saf* (2016) bmjqs; Lawton et al. "Can patient involvement improve patient safety? A cluster randomised control trial of the Patient Reporting and Action for a Safe Environment (PRASE) intervention" *BMJ Qual Saf* (2017) bmjqs.

⁷⁶ Organization *Conceptual framework for the international classification for patient safety* (2009).

⁷⁷ World et al. "Towards an International Classification for Patient Safety: the conceptual framework." *Int J Qual Health Care* (2009) 21 2.

4.7. PATIENT SAFETY EDUCATION

The WHO has also been instrumental in promoting patient safety education. In October 2011, the WHO released the Multi-Professional Patient Safety Curriculum Guide.⁷⁸ The comprehensive guide assists universities and schools in various health-related fields to teach patient safety. It also supports the training of all health-care professionals on priority patient safety concepts and practices.⁷⁹ In 2012, workshops based on the topics of the Patient Safety Curriculum Guide were launched for this purpose. That same year it was reported that more than 300 universities have endorsed the curriculum and 30 universities were using it for teaching.⁸⁰

5. AFRICA AFFLICTED

In September 2008, at the 58th session of the WHO Regional Committee for Africa held in Yaoundé, Cameroon, the Regional Director, Dr Luis Sambo, delivered a report on patient safety and called on African countries to prioritise safer care in their respective health systems.⁸¹ The region has been slow to respond to the problems associated with patient safety, the paucity of data, perhaps, being the main impediment. Earlier prevalence studies on healthcare-related infection did, however, indicate that infection rates are disproportionately higher than those found in developed nations.⁸² These studies perhaps conjectured or forewarned that the burden of unsafe care could be comparatively severe in many developing states.⁸³ Especially, when one considers that

⁷⁸ Organization, *Patient Safety Curriculum Guide*, 2011.

⁷⁹ Leotsakos et al. "Educating future leaders in patient safety" *Journal of multidisciplinary healthcare* (2014) 7 381.

⁸⁰ Organization (2012) 1.

⁸¹ Region *Patient Safety in African Health Services: Issues and Solutions, Report of the Regional Director to the 58th WHO AFRO Regional Committee* (2008); Region "Fifty-Eighth Session of the WHO Regional Committee for Africa AFR/RC58/20" (2008).

⁸² Organization (2008a).

⁸³ Gosling et al. "Prevalence of hospital-acquired infections in a tertiary referral hospital in northern Tanzania." *Ann Trop Med Parasitol* (2003) 97 69; Hutin et al. "Use of injections in healthcare settings worldwide, 2000: literature review and regional estimates." *BMJ* (2003) 327 1075; Allegranzi and Pittet "Healthcare-associated infection in developing countries: simple solutions to meet complex challenges." *Infect Control Hosp Epidemiol* (2007) 28 1323; Pittet et al. "Infection control as a major World Health Organization priority for developing countries." *J Hosp Infect* (2008) 68 285.

the threat of adverse events would indubitably be exacerbated by poor healthcare delivery systems, substandard infrastructure, weak management capacity and under-resourced health facilities. Circumstances that, unfortunately, are all too prevalent in the region.⁸⁴

The Regional Director described some of the challenges, particularly related to patient safety strategies, faced: the absence of national policies for safe healthcare; inadequate funding for safety interventions; and a general lack of guidelines, standards and tools in most countries throughout the region. This gap in governmental investment and regulatory oversight would need to be addressed, whilst concurrently attending to the issues, as mentioned above, symptomatic of dysfunctional healthcare systems. Not an easy task, but the consequences of not doing so are dire, as Dr Luis Sambo noted in the report: 'Health-care systems that are not fully functional will inevitably result in error and patient harm'.⁸⁵

Other major concerns were highlighted in the report: the harm involved with invasive procedures and the need for the implementation of blood safety processes; the overuse, underuse or misuse of medicines that results in wastage of scarce resources and widespread health hazards; counterfeit and substandard drugs as well as access to quality medicines; unsafe surgical care; poor health-care waste management that exposes people to infections, toxic effects and injuries; human resource shortages; insufficient staff training and lack of continuing medical education; the cost of health care errors, financial and otherwise; and the unavailability of data due to weak health information systems, which restricts the development of evidence-based strategies and effective solutions.⁸⁶

⁸⁴ Kruk and Freedman "Assessing health system performance in developing countries: a review of the literature." *Health Policy* (2008) 85 263.

⁸⁵ Region (2008).

⁸⁶ *Id.* 22.

There are a multitude of challenges, many very serious, that need to be confronted.⁸⁷ Patient safety is a global problem, however, patients in developing countries may be predisposed to medical harm due to the systemic weaknesses, often pervasive in the African region.⁸⁸ The achievement of safer care requires well-designed healthcare systems so as to minimise risks to patients. Although changes at the systems level are vital, the healthcare workers who deliver care need to be competent, dedicated and safety-conscious. And perhaps most importantly, those on the frontlines must be supported by an organisational culture of safety, if real improvements are to be seen.

The Regional Director proposed a number of actions to improve patient safety, these included: the development and implementation of national policies for patient safety, together with the establishment of agencies to promote and monitor patient safety and quality of care; improving knowledge and learning capacity in regard to patient safety, by investigating and analysing medical errors in order to understand the underlying causes and prevent future occurrences; continuous education and the incorporation of patient safety into the curricula of medical training institutions; raising awareness about patient rights and launching campaigns aimed at engaging civil society; the reorientation of health systems to make patient safety an integral part of quality care improvement activities, while simultaneously upgrading health infrastructure and the provision of essential equipment and supplies; minimising healthcare-associated infections through the implementation of simple measures such as hand-hygiene, blood-safety and injection guidelines; ensuring that effective waste-management takes place; implementing safe surgery protocols; enforcing medication policies to ensure appropriate use, quality and safety; the provision of adequate funding; and strengthening surveillance and research capacity.⁸⁹

⁸⁷ Aveling et al. "Why is patient safety so hard in low-income countries? A qualitative study of healthcare workers' views in two African hospitals" *Globalization and health* (2015) 11 6.

⁸⁸ Region "Patient Safety in African Health Services: Issues and Solutions, Report of the Regional Director to the 58th WHO AFRO Regional Committee" *Brazzaville: WHO Regional Office for Africa* (2008); Nejad et al. "Health-care-associated infection in Africa: a systematic review" *Bulletin of the World Health Organization* (2011) 89 757; Rosenthal "Health-care-associated infections in developing countries" *The Lancet* (2011a) 377 186.

⁸⁹ Region (2008).

After considering the report, Members of the Programme Subcommittee recommended that a body be created within ministries of health to promote and oversee patient safety, and to coordinate the updating of norms, standards and codes of ethics on patient safety. It was agreed that patient safety should be included in the curriculum of health-related training institutions and that healthcare workers should be sensitised to the issues surrounding patient safety. The need to prioritise certain areas, such as blood-safety and waste management, was also acknowledged during the meeting. In addition, Members stressed the importance of Resolution WHA55.18 on patient safety and quality of care.⁹⁰

This quote from the Final Report of the 58th Session of the WHO Regional Committee, gives one an idea of the seriousness in which the Members viewed the issue and the adoption of document AFR/RC58/8:

‘The Regional Committee congratulated the Secretariat for preparing a document on an issue so important for the African Region. The members of the Regional Committee stressed that although the issue was important there was a general lack of information on the situation of patient safety in the Region. There was therefore a need to undertake research to ascertain the magnitude of the problem in countries. Strong health systems were also necessary in order to address patient safety issues and the safety of health care workers.’⁹¹

5.1. AFRICAN PARTNERSHIPS FOR PATIENT SAFETY

In response to this call for action by the Regional Committee for Africa at its 58th session, the African Partnerships for Patient Safety (APPS) programme was set up in 2009.⁹² Creating a network of hospital-to-hospital partnerships, involving 14 African and three

⁹⁰ *Ibid.*

⁹¹ *Id.* 48.

⁹² Syed et al. “African partnerships for patient safety: a vehicle for enhancing patient safety across two continents.[corrected].” *World hospitals and health services: the official journal of the International Hospital Federation* (2008) 45 24; *Organization African Partnerships for Patient Safety* (2009); Syed et al. “African partnerships for patient safety: a vehicle for enhancing patient safety across two continents. [corrected].” *World Hosp Health Serv* (2009) 45 24.

European countries, that facilitates ‘bi-directional’ patient safety learning.⁹³ According to the Secretariat, partnership experiences have prompted national patient safety change in six countries in the African Region.⁹⁴

In 2014, Dr Syed, the Programme Manager for APPS, in an article on the AHRQ website, reflected on the important lessons learned during his tenure.⁹⁵ His summary of key events and insights guide the rest of the discussion on APPS.

At its inception, it was agreed that APPS should embrace three objectives.⁹⁶ Firstly, strong patient safety partnerships needed to be fostered. A definition for effective partnership was subsequently developed and is defined as follows: ‘A collaborative relationship between two or more parties based on trust, equality, and mutual understanding for the achievement of a specified goal. Partnerships involve risks as well as benefits, making shared accountability critical’.⁹⁷ Secondly, concrete safety improvements needed to be attained in partnership hospitals. A patient safety situational analysis tool was developed in order to localise improvement efforts.⁹⁸ Different projects were undertaken to address local challenges, however, all of the groups focussed on the implementation of hand hygiene interventions.⁹⁹ Lastly, partnership efforts and experiences were disseminated nationally and locally to effect wider change.¹⁰⁰

⁹³ Siddiqi et al. “Patient Safety Friendly Hospital Initiative: from evidence to action in seven developing country hospitals.” *International Journal for Quality in Health Care* (2012) 24; Syed et al. “Developed-developing country partnerships: benefits to developed countries” *Globalization and Health* (2012) 8 17.

⁹⁴ Syed et al. “Strengthening the evidence-policy interface for patient safety: enhancing global health through hospital partnerships” *Globalization and health* (2013) 9 47.

⁹⁵ Syed, *African Partnerships for Patient Safety: Lessons Learned*, 2014.

⁹⁶ Syed et al. (2009) 45 *World Hosp Health Serv* 24.

⁹⁷ Rutter et al. “Development of an evaluation framework for African-European hospital patient safety partnerships.” *BMJ Qual Saf* (2014) 23 332.

⁹⁸ Safety “Patient Safety Situational Analysis (Long Form)” *World Health Organization* (2012) 1.

⁹⁹ Organization “Save Lives Clean Your Hands” *World Health Organization* (2009) 1.

¹⁰⁰ Syed et al. “Strengthening the evidence-policy interface for patient safety: enhancing global health through hospital partnerships.” *Global Health* (2013) 9 47; Gooden et al. “Building a community engagement approach for patient safety improvement” *Community Development Journal* (2014) 49 631.

Partnerships were expanded and a refined APPS Improvement Framework was applied.¹⁰¹ Although, approaches from health systems in high-income countries needed to be adapted for African partner hospitals, lessons learned through these partnerships were relevant and could be used to improve safety in both developing and developed countries.¹⁰² Hospitals in Africa were also able to learn from each other, sharing innovations and creating opportunities for implementation-informed policymaking across the continent.¹⁰³

After receiving numerous requests from Member States, from both the African Region and across the world, the APPS partnership model was opened to all African countries. A Web-based registration mechanism was launched during the World Health Assembly in May 2013.¹⁰⁴ The partnership-based approach is gaining traction as a patient safety improvement model, with a growing global network of participating hospitals.¹⁰⁵ The APPS has made promising progress in developing patient safety capacity in parts of the world where it is most needed.

6. CONCLUSION

'To Err is Human' launched the patient safety movement. It brought attention to iatrogenic harm in a way and with an impact not seen before. It reframed medical error as a public health issue and managed to galvanise widespread stakeholder engagement. The report also played a large part in ensuring that patient safety was placed firmly on the international agenda, leading to the adoption of WHO Resolution WHA55.18 and various global improvement efforts.

¹⁰¹ Safety "Improving Patient Safety - Partnership Preparation Package" *World Health Organization* (2012) 1.

¹⁰² Syed et al. "Developed-developing country partnerships: benefits to developed countries" *Global Health* (2012) 8 17.

¹⁰³ Safety "National Patient Safety Policy and Strategic Planning Workshop" *World Health Organization* (2013) 1.

¹⁰⁴ Organization, *WHO APPS registration*, <<http://www.who.int/patientsafety/implementation/apps/registration/en/>>.

¹⁰⁵ World "African partnership for patient safety: building momentum for safer health care" (2012).

Most of the research and improvement efforts have thus far focussed on developed countries. However, it has become apparent that developing countries are confronted with even bleaker safety problems. The African continent is likely severely afflicted by iatrogenic illness. Healthcare systems in many African countries face multifarious unique challenges, making them especially susceptible to unsafe care. Although countries in the region have been slow to respond to the problem, they have recently come to acknowledge that safety-issues need to be addressed. This will take considerable commitment and will require that health systems be strengthened. A further aspect that has been severely lacking in developing countries, is research into the extent and sources of harm. As we shall see from the following chapter, most of our information regarding the burden of unsafe medical care comes from high-income countries. This lack of information and the subsequent absence of a contrasting baseline complicates the evaluation of interventions.

CHAPTER 3. THE BURDEN OF UNSAFE MEDICAL CARE

1. INTRODUCTION

The IOM report, which first brought attention to the scale of medical error and injuries, based its findings and its estimate of the number of patients harmed on the work of a few committed patient safety pioneers a decade earlier.¹ The report's most startling finding, that between 44 000 and 98 000 Americans die in hospital each year due to preventable medical errors, was actually obtained by extrapolating data from the landmark Harvard Medical Practice Study (HMPS).²

1.1. HARVARD MEDICAL PRACTICE STUDY

The Harvard Medical Practice Study is widely regarded as having established the standard for identifying and estimating the incidence of adverse events.³ The study employed a similar, but refined methodology to the one used in the only other large-scale investigation into the frequency of iatrogenic injury and substandard care at the time, the 1977 California Medical Insurance Feasibility Study.⁴ Both of these studies were initially designed to evaluate the effectiveness of the tort system as a mechanism with which to compensate harmed patients and assess the economic impact of these adverse occurrences on health insurers.⁵ Concern about escalating professional liability costs provided the primary impetus for the investigations. However, in order to

¹ Kohn et al. (2000).

² Brennan et al. "Incidence of adverse events and negligence in hospitalized patients. Results of the Harvard Medical Practice Study I." *N Engl J Med* (1991) 324 370.

³ Vincent "Risk, safety, and the dark side of quality." *BMJ: British Medical Journal* (1997) 314 1775; Neale and Woloshynowych "Retrospective case record review: a blunt instrument that needs sharpening" (2003); Thomas and Petersen "Measuring errors and adverse events in health care" *Journal of general internal medicine* (2003) 18 61.

⁴ Association *Report of the medical insurance feasibility study* (1977); Mills "Medical insurance feasibility study: a technical summary" *Western Journal of Medicine* (1978) 128 360.

⁵ Sharpe and Faden (1998) 118.

determine the feasibility of alternative compensation systems, empirical evidence would be required on the type, frequency and severity of compensable injuries. For this reason, reliable estimates of the incidence of adverse events and negligence in hospitalised patients was developed. The findings regarding the prevalence of adverse events were, however, so disconcerting that it eclipsed the attention the assessment of the tort system and its associated costs received.⁶

The HMPS researchers reviewed a random sample of 30 121 medical records from New York State in 1984 and analysed them for the presence of adverse events and substandard care. Adverse events were defined as an injury that was caused by medical management (rather than the underlying disease) and that prolonged the hospitalisation, produced a disability at discharge, or both. For purposes of the study negligence was defined as care that fell below the standard expected from physicians in the particular community.⁷

The authors estimated the state-wide incidence rate of adverse events to have been 3.7% and found that approximately 1% of the adverse events could be attributed to negligence. Overall, 27.6% of adverse events were negligently caused. By using the weighting procedure, it was calculated that patients admitted in New York State during 1984 suffered 98 609 adverse events and that 27 179 of those adverse events were as a result of negligent care. The authors were able to give specific population figures by extrapolating from the results, revealing shocking numbers which demanded attention to an extent a stark rate could not quite convey. According to their estimates, 2550 patients suffered permanent total disability and 13 451 died, at least in part as a consequence of an adverse event. Undoubtedly, as the authors noted: 'the burden of iatrogenic injury was thus large'. Describing the number of adverse events caused by negligence as 'disturbing', they expressed concern about the 6895 deaths and 877 cases of permanent and total disability which resulted from substandard care. These

⁶ Baker "HARVARD MEDICAL PRACTICE STUDY" *Quality and Safety in Health Care* (2004) 13 151; Baker "Reconsidering the Harvard Medical Practice Study Conclusions about the Validity of Medical Malpractice Claims" *J Law Med Ethics* (2005) 33 501.

⁷ Brennan et al. (1991) 324 *N Engl J Med* 370.

findings, more or less matched the results of the California Medical Insurance Feasibility Study, conducted a decade earlier. In that study investigators reviewed a convenience sample of 20 864 patient charts, all with discharge dates in 1974. It was estimated that 4.6% of patients suffered an adverse event. The negligence rate in the California study was found to be just under one percent, 0.8 to be exact.⁸

1.2. AN ABUNDANCE OF ERROR, A PAUCITY OF INFORMATION

When the HMPS data were analysed it was found that 69% of the iatrogenic injuries were due to errors.⁹ Errors account for most iatrogenic injuries and many adverse events are thus potentially preventable. Leape brought the issue to the fore in a seminal paper, bringing new perspectives to the unacceptably high error rate in medicine.¹⁰ Leape noted the scant information available on medical error, and expressed concern about the 'distressingly' high error rates reported in the handful of studies where errors were specifically investigated. He highlighted the following examples: Bedell *et al.*, in a study on the contribution of iatrogenic illness to cardiac arrest among hospitalised patients, found that 64% of iatrogenic arrests were potentially preventable and could have been averted by improved attention or response to laboratory and clinical data available to clinicians prior to the time of arrest.¹¹ Autopsy studies have determined high rates (35-40%) of erroneous diagnoses resulting in death.¹² Another study on the causes of human errors in a Respiratory Intensive Care Unit, conducted over four months, revealed that an estimated average of 1.7 errors occurred per patient every 24 hours, of which 11% could have proved fatal and 18% could have caused severe damage.¹³ Leape, in his prescient and influential paper, introduced safety concepts

⁸ Association (1977) 1.

⁹ Leape et al. "Preventing medical injury." *QRB. Quality review bulletin* (1993) 19 144.

¹⁰ Leape (1994) 272 *JAMA* 1851.

¹¹ Bedell "Incidence and Characteristics of Preventable Iatrogenic Cardiac Arrests" *JAMA* (1991) 265 2815.

¹² Cameron and McGoogan "A prospective study of 1152 hospital autopsies: I. Inaccuracies in death certification." *J Pathol* (1981) 133 273; Goldman et al. "The value of the autopsy in three medical eras." *N Engl J Med* (1983) 308 1000; Anderson et al. "The sensitivity and specificity of clinical diagnostics during five decades. Toward an understanding of necessary fallibility." *JAMA* (1989) 261 1610.

¹³ Gopher et al. "The Nature and Causes of Human Errors in a Medical Intensive Care Unit" *Proceedings of the Human Factors Society Annual Meeting* (1989) 33 956.

from engineering and the social sciences to the medical literature for the first time, essentially, launching the patient safety field. His salient contribution, definitely merits attention and will be further discussed at a later stage.¹⁴

1.3. UTAH/COLORADO STUDY

In addition to the New York study, the IOM report also relied on findings from a second large scale investigation into iatrogenic illness. Based on the methods used in the HMPS, researchers set out to determine the generalisability of the previously obtained results by reviewing 15 000 randomly selected records of 1992 discharges, from a representative sample of hospitals located in Utah and Colorado.¹⁵ The Utah/Colorado study found that adverse events occurred in 2.9% of hospitalisations in each state. More or less consistent with the incidence rate observed in New York. In Utah, 32.6% of adverse events were due to negligence, whereas in Colorado, the rate was slightly less, at 27.4%. Death occurred in 6.6% of adverse events. While this was less than the 13.6% of adverse events found in New York, the burden of mortality and morbidity was still 'striking', as even with the lower rate it meant that 64 809 patients died as a result of iatrogenic injury, 24 979 of the deaths due to negligent care. In addition to the smaller group of negligent events, the researchers in the Utah/Colorado study also measured the number of preventable adverse events.¹⁶ It was estimated that 54% of adverse events were preventable in Utah, and 55.5% of adverse events were preventable in Colorado.

2. THE GLOBAL SCALE OF HARM

The findings of the HMPS were to a large extent corroborated by the Utah/Colorado study and both received much publicity after the release of 'To Err is Human'. The landmark IOM report provided an estimate of the burden of iatrogenic illness in the United States and prompted efforts to obtain data on medically induced harm in the rest

¹⁴ Chapter 4, Paragraph 2.4.

¹⁵ Thomas et al. "Incidence and Types of Adverse Events and Negligent Care in Utah and Colorado" *Medical Care* (2000) 38 261.

¹⁶ Thomas et al. "Costs of medical injuries in Utah and Colorado." *Inquiry* (1999) 36 255.

of the world.¹⁷ Significant progress has since been made in assessing the nature and scale of harm in many other countries. Similar studies have now been conducted in: Australia¹⁸; the United Kingdom¹⁹; Denmark²⁰; New Zealand²¹; Canada²²; France²³; Spain²⁴; Scotland²⁵; the Netherlands²⁶; Sweden²⁷; Brazil²⁸; Tunisia²⁹; Argentina, Colombia, Costa Rica, Mexico and Peru³⁰; Egypt, Jordan, Kenya, Morocco, Tunisia, South Africa, Sudan, and Yemen³¹; Italy³²; Portugal³³; and Ireland³⁴.

¹⁷ Kohn et al. (2000).

¹⁸ Wilson et al. "The Quality in Australian Health Care Study." *Med J Aust* (1995) 163 458.

¹⁹ Vincent et al. "Adverse events in British hospitals: preliminary retrospective record review." *BMJ* (2001) 322 517.

²⁰ Schiøler et al. "[Incidence of adverse events in hospitals. A retrospective study of medical records]." *Ugeskr Laeger* (2001) 163 5370.

²¹ Davis et al. "Adverse events in New Zealand public hospitals I: occurrence and impact." *N Z Med J* (2002) 115 U271.

²² Baker et al. "The Canadian Adverse Events Study: the incidence of adverse events among hospital patients in Canada." *CMAJ* (2004) 170 1678.

²³ Michel et al. "French national survey of inpatient adverse events prospectively assessed with ward staff." *Qual Saf Health Care* (2007) 16 369.

²⁴ Aranaz-Andrés et al. "Incidence of adverse events related to health care in Spain: results of the Spanish National Study of Adverse Events." *J Epidemiol Community Health* (2008) 62 1022.

²⁵ Williams et al. "Detection of adverse events in a Scottish hospital using a consensus-based methodology." *Scott Med J* (2008) 53 26.

²⁶ Zegers et al. "Adverse events and potentially preventable deaths in Dutch hospitals: results of a retrospective patient record review study." *Qual Saf Health Care* (2009) 18 297.

²⁷ Soop et al. "The incidence of adverse events in Swedish hospitals: a retrospective medical record review study." *Int J Qual Health Care* (2009) 21 285.

²⁸ Mendes et al. "The assessment of adverse events in hospitals in Brazil." *Int J Qual Health Care* (2009) 21 279.

²⁹ Letaief et al. "Adverse events in a Tunisian hospital: results of a retrospective cohort study." *Int J Qual Health Care* (2010) 22 380.

³⁰ Aranaz-Andres et al. "Prevalence of adverse events in the hospitals of five Latin American countries: results of the 'Iberoamerican study of adverse events' (IBEAS)" *BMJ Qual Saf* (2011) 1043.

³¹ Wilson et al. (2012) 344 *BMJ* e832.

³² Tartaglia et al. "[Adverse events and preventable consequences: retrospective study in five large Italian hospitals]." *Epidemiol Prev* (2012) 36 151.

³³ Sousa et al. "Estimating the incidence of adverse events in Portuguese hospitals: a contribution to improving quality and patient safety." *BMC Health Serv Res* (2014) 14 311.

³⁴ Rafter et al. "The Irish National Adverse Events Study (INAES): the frequency and nature of adverse events in Irish hospitals-a retrospective record review study." *BMJ Qual Saf* (2017) 26 111.

Various methods are utilised to study errors and adverse events, each with their own set of advantages and limitations, depending on the context in which they are applied, how they define certain terms, and what they attempt to measure.³⁵ The Institute for Healthcare Improvement's (IHI) Global Trigger Tool approach, which guides reviewers by identifying specific incidents that are indicative of adverse events or errors, has proved to be an efficient variation on the retrospective record review method, most notably employed by the researchers in the HMPS.³⁶ The trigger tool approach is currently the most reliable and consistent method with which to detect harm.³⁷

Previous retrospective record review studies have shown that 2.9% to 16.6% of in-hospital patients experience one or more adverse event, with between 4.5% and 20.8% of those adverse events resulting in death. Some of the large discrepancies observed could perhaps be explained by methodological factors, differences in record-keeping, outcome objectives and quality standards between countries.³⁸

As no general overview of the data existed, De Vries *et al.* identified the need to systematically compile the available evidence, so as to enable a more detailed understanding of the problem. They conducted a systematic review of in-hospital adverse event studies, in order to gain an insight into the overall incidence, preventability and outcome of such events. The median overall incidence of adverse events was shown to be 9.2%, and the authors concluded that almost half of these events were regarded as preventable. Permanent disability occurred in 7% of patients

³⁵ Woloshynowych et al. "Case record review of adverse events: a new approach" *Quality and Safety in Health Care* (2003) 12 411; Thomas and Petersen "Measuring errors and adverse events in health care." *J Gen Intern Med* (2003) 18 61.

³⁶ Classen et al. "Global trigger tool' shows that adverse events in hospitals may be ten times greater than previously measured." *Health Aff (Millwood)* (2011) 30 581; Sharek "The Emergence of the Trigger Tool as the Premier Measurement Strategy for Patient Safety." *AHRQ WebM&M* (2012).

³⁷ Levinson *Adverse events in hospitals: Methods for identifying events* (2010); James "A new, evidence-based estimate of patient harms associated with hospital care." *J Patient Saf* (2013) 9 122.

³⁸ Runciman et al. "A comparison of iatrogenic injury studies in Australia and the USA. II: Reviewer behaviour and quality of care." *International Journal for Quality in Health Care* (2000) 12 379; Thomas et al. "A comparison of iatrogenic injury studies in Australia and the USA. I: Context, methods, casemix, population, patient and hospital characteristics." *Int J Qual Health Care* (2000) 12 371.

who suffered an adverse event, while 7.4% of adverse events caused the death of the patient.³⁹

3. SIGNIFICANT SOURCES OF HARM

In order to determine the scope of the global challenge that unsafe care poses, the WHO World Alliance for Patient Safety commissioned an overview of the existing patient safety literature and research.⁴⁰ The group identified 23 major patient safety topics that warranted detailed examination, the topics that were selected have a significant impact on safety and were highlighted as a means to focus policy and research priorities among stakeholders. They observed that the available data suggests that harm from medical care poses a substantial burden in terms of morbidity and mortality on people around the world. The authors also noted that almost all of the evidence on structural and process factors that contribute to unsafe care emanate from a small number of developed countries, the underlying causes, frequency and harm of unsafe care in developing countries needs to be investigated if apt solutions are to be recommended.

Donabedian's quality-of-care framework, was used to organise the issues that contribute to unsafe care.⁴¹ The topics in the report were grouped in accordance with the three dimensions of the framework: outcome, structure and process.

As these specific topics have been determined, by internationally recognised experts, to be the most important to global patient safety efforts, it would be prudent to base the rest of this discussion of unsafe medical care around these 10 identified issues. These 10 topics, which fall under the outcome dimension, have been selected due to the fact that each represents a significant source of harm from medical care around the world.

³⁹ de Vries et al. (2008) 17 *Qual Saf Health Care* 216.

⁴⁰ Organization (2008a); Jha et al. (2010) 19 *Qual Saf Health Care* 42.

⁴¹ Donabedian "Evaluating the quality of medical care." *Milbank Mem Fund Q* (1966) 44 Suppl:166.

3.1. ADVERSE EVENTS DUE TO DRUG TREATMENT

Adverse events due to drug treatment are made up of errors of commission and errors of omission. These errors can creep in at the health system level (e.g. substandard drugs, stock-outs, conditions susceptible to error), the provider level (e.g. incorrect prescription, failure to prescribe or administer treatment, improper monitoring) and the patient level (e.g. intentional or unintentional lack of adherence).⁴² It is important to differentiate between studies of medication error, where the focus is on whether the drug was prescribed and administered correctly and investigations into adverse drug events, where the detection of harm, whether caused by error or not, is the primary concern.⁴³

Adverse drug events are one the most common causes of morbidity.⁴⁴ It is estimated that, in developed countries, between 7.5% and 10.4% of patients in hospital experience a drug related injury.⁴⁵ Mortality is also high, in the US it is suggested that adverse drug events contribute to 140 000 deaths annually.⁴⁶ The financial implications are immense. Adverse drug events cost the Australian health care system over US\$500 million each year, or 1% of the country's total health budget.⁴⁷ A study in the US estimated that adverse drug events, over a four-year period, contributed to an excess hospital expenditure of \$4.2 million, extrapolated nationally it would mean that 770 000 patients experience an adverse drug event, at a cost of \$1.56 billion per year.⁴⁸ The authors were quick to note that the figure could be as high as \$4.2 billion if a rate observed in an earlier study was assumed, and that the estimates only reflected the

⁴² Leape et al. "Systems analysis of adverse drug events" *JAMA* (1995) 274 35.

⁴³ Vincent (2011) 64.

⁴⁴ de Vries et al. (2008) 17 *Qual Saf Health Care* 291.

⁴⁵ Bates et al. "Incidence of adverse drug events and potential adverse drug events. Implications for prevention. ADE Prevention Study Group." *JAMA* (1995) 274 29; Miller et al. "Adverse drug events in general practice patients in Australia." *Med J Aust* (2006) 184 321.

⁴⁶ Classen et al. "Adverse drug events in hospitalized patients. Excess length of stay, extra costs, and attributable mortality." *JAMA* (1997) 277 301.

⁴⁷ Bates et al. "The costs of adverse drug events in hospitalized patients" *JAMA* (1997) 277 307; Runciman et al. "Adverse drug events and medication errors in Australia." *Int J Qual Health Care* (2003) 15 Suppl 1 i49.

⁴⁸ Classen et al. (1997) 277 *JAMA* 301.

direct hospital costs, if the cost of outpatient treatment or disability are added the amounts would increase exponentially.⁴⁹ A meta-analysis of studies showed that approximately half of all adverse drug events are preventable.⁵⁰

Adverse drug events have received some attention from South African researchers.⁵¹

3.2. ADVERSE EVENTS AND INJURIES DUE TO MEDICAL DEVICES

⁴⁹ *Id.* 304.

⁵⁰ Hakkarainen et al. "Percentage of patients with preventable adverse drug reactions and preventability of adverse drug reactions--a meta-analysis." *PLoS One* (2012) 7 e33236.

⁵¹ Harrison "Anaesthetic contributory death-its incidence and causes: Part I. Incidence" *South African Medical Journal* (1968a); Harrison "Anaesthetic contributory death-its incidence and causes: Part II. Causes" *South African Medical Journal* (1968b); Harrison "Anaesthetic-associated mortality" *South African Medical Journal* (1974); Gordon "Wrong drug administration errors amongst anaesthetists in a South African teaching hospital" *Southern African Journal of Anaesthesia and Analgesia* (2004) 10 7; Gordon et al. "Drug administration errors by South African anaesthetists-a survey" *South African Medical Journal* (2006) 96 630; Tipping et al. "The burden and risk factors for adverse drug events in older patients--a prospective cross-sectional study." *S Afr Med J* (2006) 96 1255; Llewellyn et al. "Drug administration errors: a prospective survey from three South African teaching hospitals" *Anaesthesia and intensive care* (2009) 37 93; Labuschagne et al. "Errors in drug administration by anaesthetists in public hospitals in the Free State" *S Afr Med J* (2011) 101 324; Llewellyn et al. (2011) 101 *SAMJ: South African Medical Journal* 319; Rout and Farina "Anaesthesia-related maternal deaths in South Africa" *Southern African Journal of Anaesthesia and Analgesia* (2012) 18 ; Shean et al. "Drug-associated adverse events and their relationship with outcomes in patients receiving treatment for extensively drug-resistant tuberculosis in South Africa." *PLoS One* (2013) 8 e63057; Gordon "Wrong drug administration errors amongst anaesthetists in a South African teaching hospital" *Southern African Journal of Anaesthesia and Analgesia* (2014) 10 7; Larsen and Stockwell "Taking Aim at Harm—Adverse Event Detection in a South African PICU*" *Pediatric Critical Care Medicine* (2014) 15 N2; Mehta et al. "Strengthening pharmacovigilance in South Africa." *S Afr Med J* (2014) 104 104; Vermeulen et al. "Patient safety in South Africa: PICU adverse event registration*." *Pediatr Crit Care Med* (2014) 15 464; Cronjé "A review of paediatric anaesthetic-related mortality, serious adverse events and critical incidents" *Southern African Journal of Anaesthesia and Analgesia* (2015) 21 147; Masenyetse et al. "An assessment of adverse drug reactions among HIV positive patients receiving antiretroviral treatment in South Africa." *AIDS Res Ther* (2015) 12 6; Mouton et al. "Mortality from adverse drug reactions in adult medical inpatients at four hospitals in South Africa: a cross-sectional survey." *Br J Clin Pharmacol* (2015) 80 818; Gokhul et al. "Iatrogenic medication errors in a paediatric intensive care unit in Durban, South Africa" *S Afr Med J* (2016) 106 1222; Reed and Gordon "SANS 444: 2014: A new standard for small-ampoule labelling and a chance to reduce drug administration errors in South Africa" *SAMJ: South African Medical Journal* (2016) 106 227; Blignaut et al. "Medication administration errors and related deviations from safe practice: an observational study." *J Clin Nurs* (2017) 26 3610.

Medical devices, whether rudimentary or incomprehensibly complex, are ubiquitous in almost all health care environments, operated by various users, ranging from the highly trained and skilled to the patient him/herself, and present in many different settings and contexts.⁵² These devices assist in diagnoses, treatment and health management. Perhaps owing to their ubiquity, medical devices pose a significant risk and are a substantial source of harm. Adverse medical device events have been defined as ‘any patient harm caused by device-related medical or surgical management rather than the patient's illness’.⁵³

Errors involving medical devices are often categorised into three groups: manufacturer-related errors, user errors and design errors.⁵⁴ The hazards involved with specific medical devices have been studied with regard to certain specialities, such as: cardiology, orthopaedics and anaesthesiology.⁵⁵ However, an overview of the broader burden is lacking.

Some estimates indicate that over a million adverse medical device events occur annually in US hospitals, at a rate of 6.3 events per 1000 patient days.⁵⁶ Adverse medical device event incidence rates per 1000 admissions, when different surveillance methods were tested at a tertiary teaching hospital, were found to be 1.6 for incident reports, 27.7 for computer flags, and 64.6 for ICD-9 discharge codes. The overall incidence of adverse medical device events detected by at least 1 of these methods was 83.7 per 1000 admissions.⁵⁷ A study conducted to investigate the frequency of medical device–associated adverse events that occur outside of hospitals, showed that in one year 454,383 visits to the emergency department were precipitated by adverse

⁵² Brown et al. “Medical Device Epidemiology and Surveillance” (2007) 23.

⁵³ Samore et al. (2004) 291 *JAMA* 325.

⁵⁴ Jha et al. (2010) 19 *Qual Saf Health Care* 42.

⁵⁵ Brown et al. (2007) 24.

⁵⁶ Bright and Shen “Use of a free, publicly-accessible data source to estimate hospitalizations related to adverse medical device events.” (2006) 325.

⁵⁷ Samore et al. (2004) 291 *JAMA* 325.

medical device events. Of these 58,396 were serious enough to require hospitalisation.⁵⁸

Developing countries may face additional challenges, WHO data indicate that equipment is often not sufficiently maintained or replaced, potentially submitting patients to unsafe care.⁵⁹ The overall picture in both developed and developing nations is still unclear, although the available data suggests that many patients are at risk.

Effective surveillance programmes are needed to detect the type, frequency and nature of adverse events associated with medical devices.⁶⁰ Medical devices are also a prime target for human factors engineering efforts.⁶¹ This interdisciplinary field specialises in the interaction between technology, people and their work environment.⁶² Novel approaches to adverse medical device events are needed, similar to those that have been adopted in order to improve anaesthesia safety.⁶³

3.3. INJURIES DUE TO SURGICAL AND ANAESTHESIA ERRORS

Surgical safety improvement has been one of the key priorities of the safety movement. It is estimated that 234.2 million major surgical procedures are undertaken every year worldwide, which amounts to one operation for every 25 people.⁶⁴ The literature has indicated that the majority of adverse events are associated with surgical care providers

⁵⁸ Hefflin et al. "Estimates of medical device--associated adverse events from emergency departments." *Am J Prev Med* (2004) 27 246.

⁵⁹ Pittet and Donaldson "Challenging the world: patient safety and health care-associated infection." *Int J Qual Health Care* (2006) 18 4.

⁶⁰ Amore and Ingram "Quality improvement report: Learning from adverse incidents involving medical devices" *BMJ: British Medical Journal* (2002) 325 272; Kramer et al. "Regulation of medical devices in the United States and European Union" (2012); Resnic and Normand "Postmarketing surveillance of medical devices—filling in the gaps" *New England Journal of Medicine* (2012) 366 875.

⁶¹ Wachter (2007) 54.

⁶² Wickens et al. "An introduction to human factors engineering" (1998); Lin et al. "Patient safety, potential adverse drug events, and medical device design: a human factors engineering approach" *Journal of biomedical informatics* (2001) 34 274.

⁶³ Pierce (2002) 11 *Qual Saf Health Care* 282.

⁶⁴ Weiser et al. "An estimation of the global volume of surgery: a modelling strategy based on available data." *Lancet* (2008) 372 139.

and 39.6% of all adverse events are operation-related.⁶⁵ A systematic review of retrospective studies showed that 14.4% of surgical patients experienced adverse events, and that 37.9% were preventable. A median of 3.6% of adverse events had fatal outcomes, and 10.4% were classified as severe.⁶⁶

Surgical adverse event rates could be up to five or 10 times higher in developing countries.⁶⁷ Studies have reported intraoperative mortality as high as 5% to 10%.⁶⁸ A shortage of trained staff, poor facilities, outdated or unmaintained technology and limited supplies of drugs and materials can all contribute to unsafe surgical care in developing countries.⁶⁹ Despite having the greatest burden of injury, violence, and maternal mortality, a disproportionately low volume of surgeries are observed in these countries, leading one to assume that a large unaddressed disease burden exists in lower-income parts of the world.⁷⁰

Annually, almost 7 million surgical patients experience major complications, and a million patients die during or immediately after surgery; making surgical safety a substantial global public-health concern. The inherent complexity, arduous workload, fatigue, and production pressures, involved with surgical care combine to make it particularly susceptible to adverse events.⁷¹

⁶⁵ de Vries et al. (2008) 17 *Qual Saf Health Care* 221.

⁶⁶ Anderson et al. "Surgical adverse events: a systematic review." *American journal of surgery* (2013) 206 253.

⁶⁷ Jha et al. (2010) 19 *Qual Saf Health Care* 44.

⁶⁸ Bickler and Sanno-Duanda "Epidemiology of paediatric surgical admissions to a government referral hospital in the Gambia." *Bull World Health Organ* (2000) 78 1330; McConkey "Case series of acute abdominal surgery in rural Sierra Leone." *World J Surg* (2002) 26 509; Yii and Ng "Risk-adjusted surgical audit with the POSSUM scoring system in a developing country. Physiological and Operative Severity Score for the enumeration of Mortality and morbidity." *Br J Surg* (2002) 89 110.

⁶⁹ Organization (2008a) 4.

⁷⁰ Weiser et al. (2008) 372 *Lancet* 139.

⁷¹ Vincent et al. "Systems Approaches to Surgical Quality and Safety: From Concept to Measurement" *Annals of Surgery* (2004) 239 475.

It has been proposed that a systems approach, which has shown promise in other industries, should also be applied to surgical practice.⁷² Results obtained by the WHO's Safe Surgery Saves Lives program, using the Surgical Safety Checklist have been promising. In one study, the rate of death decreased from 1.5% to 0.8% after implementation of the checklist, inpatient complications were also reduced from 11% to 7%.⁷³

Howell *et al.* conducted a systematic review of interventions used to reduce adverse events in surgery, they found that improving nurse to patient ratios, postoperative ICU physician involvement, team-training, subspecialisation, and submitting surgical outcome data to national audit reduced adverse events. The strongest evidence-based interventions and the ones that could be recommended for implementation were, however, identified to be care pathways and surgical safety checklists.⁷⁴

Anaesthesiology has been on the forefront of patient safety.⁷⁵ Technological improvements and advances in drugs and equipment have undoubtedly contributed to safer outcomes. Novel investigation techniques that examine, not only the incidence, but the nature of the mishap have also had a significant impact. These improvement efforts have included the 'critical incident' technique, which Cooper adapted from aviation⁷⁶, the analysis of closed malpractice claims⁷⁷, and the Australian incident monitoring study⁷⁸. The malpractice crisis galvanised many of the efforts. Standards and guidelines were implemented. Lessons learned from human factors engineering and the systems approach to safety have been adopted.

⁷² Calland et al. "A systems approach to surgical safety." *Surg Endosc* (2002) 16 1005.

⁷³ Haynes et al. "A surgical safety checklist to reduce morbidity and mortality in a global population" *N Engl J Med* (2009) 360 491.

⁷⁴ Howell et al. "Reducing the burden of surgical harm: a systematic review of the interventions used to reduce adverse events in surgery." *Ann Surg* (2014) 259 630.

⁷⁵ Gaba (2000) 320 *BMJ* 785.

⁷⁶ Cooper et al. (1984) 60 *Anesthesiology* 34.

⁷⁷ Cheney (1999) 91 *Anesthesiology* 552.

⁷⁸ Bhasale et al. "Analysing potential harm in Australian general practice: an incident-monitoring study." *Med J Aust* (1998) 169 73.

Gaba suggests that the most important contribution of anaesthesiology to patient safety has been the ‘institutionalisation and legitimisation of patient safety as a topic of professional concern’, the formation in 1985 of the Anaesthesia Patient Safety Foundation is a testament to this far-sighted commitment to safer care.⁷⁹

A meta-analysis of perioperative and anaesthetic-related mortality concluded that, despite an increase in patient baseline risk, perioperative and anaesthetic-related mortality rates have steadily declined over the past 50 years. This improvement may be due to the cumulative effect of the above-mentioned efforts to improve patient safety. Developed countries experienced greater and more consistent decline in mortality.

Rates of perioperative and anaesthetic-related mortality remain two to three times higher in developing countries. These countries require and would benefit from the implementation of evidence-based best practices; however, resource constraints remain a major impediment.⁸⁰

The evidence base is still very small in South Africa; however, it has recently started to receive increased attention.⁸¹

⁷⁹ Gaba (2000) 320 *BMJ* 785.

⁸⁰ Bainbridge et al. “Perioperative and anaesthetic-related mortality in developed and developing countries: a systematic review and meta-analysis.” *Lancet* (2012) 380 1075.

⁸¹ Hsia et al. “Access to emergency and surgical care in sub-Saharan Africa: the infrastructure gap” *Health policy and planning* (2011) 27 234; Cronje “A review of paediatric anaesthetic-related mortality, serious adverse events and critical incidents” *Southern African Journal of Anaesthesia and Analgesia* (2015) 21 147; Gebhardt et al. “Maternal death and caesarean section in South Africa: results from the 2011-2013 Saving Mothers Report of the National Committee for Confidential Enquiries into Maternal Deaths” *SAMJ: South African Medical Journal* (2015) 105 287; Nel and Farina “Anaesthesia and caesarean safety” *Obstetrics and Gynaecology Forum* (2015) 25 23; Biccard “Surgery and sedation is not safe in Africa” *Southern African Journal of Anaesthesia and Analgesia* (2016) 22 5; Biccard et al. “A meta-analysis of the efficacy of preoperative surgical safety checklists to improve perioperative outcomes” *SAMJ: South African Medical Journal* (2016) 106 592; Chawla et al. “Water availability at hospitals in low-and middle-income countries: implications for improving access to safe surgical care” *journal of surgical research* (2016) 205 169; Kong and Clarke “Analysis of 5 years of morbidity and mortality conferences in a metropolitan South African trauma service” *SAMJ: South African Medical Journal* (2016) 106 695; Krige et al. “Instilling a culture of safety for laparoscopic cholecystectomy” *South African Journal of Surgery* (2016) 54 2;

3.4. HEALTH CARE-ASSOCIATED INFECTIONS

A health care–associated infection (HCAI), also called a nosocomial or hospital-acquired infection, is defined by the WHO as: ‘An infection occurring in a patient in a hospital or other health care facility in whom the infection was not present or incubating at the time of admission. This includes infections acquired in the hospital but appearing after discharge, and also occupational infections among staff of the facility’.⁸²

Common types of HCAI include nosocomial pneumonia, catheter-related infections and surgical infections. Not only are these infections common, they are also highly preventable.⁸³ HCAI can result in lengthened hospitalisation, long-term disability, increased antimicrobial resistance, substantial additional financial burden, heavy toll on patients and their relatives, and excess mortality.⁸⁴ These infections are by far the most prevalent complication affecting hospitalised patients.⁸⁵

It has been widely reported that, at any time, more than 1.4 million people worldwide suffer from complications brought on by hospital acquired infections.⁸⁶ One in four intensive care patients are likely to acquire an infection in hospital, in developing countries the estimate could be twice as much.⁸⁷

Estimates suggest that nosocomial infections occur in approximately 4.6% to 9.3% of hospitalised patients in developed countries and between 25% and 40% in developing nations.⁸⁸ More recent national and multicentre studies in high-income countries, have shown the prevalence of hospitalised patients who acquired at least one HCAI, ranged

Naidoo et al. “The impact of a modified World Health Organization surgical safety checklist on maternal outcomes in a South African setting: A stratified cluster-randomised controlled trial” *SAMJ: South African Medical Journal* (2017b) 107 248.

⁸² Ducloux et al. “Prevention of hospital acquired infections: a practical guide.” (2002).

⁸³ Jha et al. (2010) 19 *Qual Saf Health Care* 44.

⁸⁴ Organization WHO *Guidelines on Hand Hygiene in Health Care* (2009) 6.

⁸⁵ Burke “Infection control - a problem for patient safety.” *N Engl J Med* (2003) 348 651.

⁸⁶ Pittet and Donaldson (2005) 366 *Lancet* 1246.

⁸⁷ Jha et al. (2010) 19 *Qual Saf Health Care* 44.

⁸⁸ Organization (2008a) 4.

from 3.5% to 12%.⁸⁹ In the same WHO report, HCAI pooled prevalence in mixed patient populations is reported to be 7.6 episodes per 100 patients.⁹⁰

The European Centre for Disease Prevention and Control reports that 4.2 million patients acquire a HCAI in the EU each year.⁹¹ A previous 2008 report found that HCAI directly contributed to around 37 000 deaths and 16 million extra days of hospital stay.⁹² In 2002 the estimated number of HCAI in US hospitals were approximately 1.7 million and almost 99 000 deaths were associated with HCAI.⁹³ A more recent study estimated that 648 000 patients acquired 721 800 health care–associated infections in US acute care hospitals in 2011.⁹⁴ High-risk populations, such as patients admitted to ICUs, burn and transplant patients, and neonates face a significantly higher burden of HCAI.⁹⁵ About 30% of patients in intensive-care units are affected by HCAI, resulting in substantial morbidity and mortality.⁹⁶ The financial toll is immense. Direct costs of HCAI in the EU could be between €13 and €24 billion per year.⁹⁷ A meta-analysis of costs and financial impact of HCAI on the US health care system, estimated that the total annual cost for the five major infections was \$9.8 billion.⁹⁸

Estimating the burden of HCAI in low- and middle-income countries remains a challenge, due to the lack of studies and national surveillance systems. In 2010, only 23 developing countries (less than 16%), had functioning HCAI surveillance systems

⁸⁹ Organization *Report on the burden of endemic health care-associated infection worldwide* (2011) 12.

⁹⁰ *Ibid.*

⁹¹ Control “Annual epidemiological report 2014” (2015) 1.

⁹² Control “Annual epidemiological report on communicable diseases in Europe 2008” (2008).

⁹³ Kleven et al. “Estimating Health Care-Associated Infections and Deaths in U.S. Hospitals, 2002” *Public Health Reports (1974-)* (2007) 122 160.

⁹⁴ Zimlichman et al. “Health care–associated infections: a meta-analysis of costs and financial impact on the US health care system” *JAMA internal medicine* (2013) 173 2039; Magill et al. “Multistate point-prevalence survey of health care-associated infections.” *N Engl J Med* (2014) 370 1198.

⁹⁵ Organization (2008a) 14.

⁹⁶ Vincent “Nosocomial infections in adult intensive-care units.” *Lancet* (2003) 361 2068.

⁹⁷ Organization (2008a) 6.

⁹⁸ Zimlichman et al. “Health care-associated infections: a meta-analysis of costs and financial impact on the US health care system.” *JAMA Intern Med* (2013) 173 2039.

and 66% had no published data on HCAI at all. The evidence that has been obtained more recently, suggests that prevalence rates are considerably higher than in developed countries, between 5.7% and 19.1%. With higher rates (15.5%) observed in better quality studies.⁹⁹ HCAI frequencies among high-risk populations, are several-fold higher than in developed countries, especially for device-associated infections.¹⁰⁰ Neonatal infections rates have been reported to be anywhere between three and 20 times higher than those of hospital-born babies in industrialised countries.¹⁰¹

Antimicrobial resistance poses a substantial threat to developing countries, where the burden of infectious disease is high and resource constraints impede containment efforts.¹⁰²

A systematic-review of HCAI studies conducted in Africa, highlighted the paucity of data from the continent, and found that prevalence rates are twice as high as the average European prevalence, which is reported to be 7.1%.¹⁰³ An overview of the evidence from sub-Saharan Africa also indicated that the burden of HCAI is high, significantly contributing to patient morbidity and mortality. Surgical site infections appear to be the leading type of infection acquired in the region. Nosocomial transmission of multidrug-resistant tuberculosis is another major concern.¹⁰⁴

The available evidence seems to indicate that HCAI can be prevented and that the burden of HCAI could potentially be halved. HCAI are frequently brought on by health-care delivery system failures and can, therefore, be addressed through the

⁹⁹ Allegranzi et al. (2011) 377 *Lancet* 228.

¹⁰⁰ Organization (2008a) 17.

¹⁰¹ Zaidi et al. "Hospital-acquired neonatal infections in developing countries." *Lancet* (2005) 365 1175.

¹⁰² Okeke et al. "Antimicrobial resistance in developing countries. Part I: recent trends and current status." *Lancet Infect Dis* (2005) 5 481; Hussein et al. "A review of health system infection control measures in developing countries: what can be learned to reduce maternal mortality" *Globalization and health* (2011) 7 14; Aiken et al. "Interventional studies for preventing surgical site infections in sub-Saharan Africa—A systematic review" *International Journal of Surgery* (2012) 10 242; Dramowski et al. (2016) 94 *Journal of Hospital Infection* 364.

¹⁰³ Bagheri Nejad et al. "Health-care-associated infection in Africa: a systematic review." *Bull World Health Organ* (2011) 89 757.

¹⁰⁴ Rothe et al. "Healthcare-associated infections in sub-Saharan Africa." *J Hosp Infect* (2013) 85 257.

implementation of effective evidence-based, infection prevention and control strategies.¹⁰⁵ Developing countries face unique challenges. Although, general determinants of HCAI are similar to developed countries, the risks of acquiring HCAI are exacerbated by certain factors, such as 'poor hygiene and sanitation, lack or shortage of basic equipment, inadequate infrastructures, unfavourable social background, and a population largely affected by malnutrition and other types of infection and/or diseases'.¹⁰⁶

HCAI is a pressing patient safety issue and has to be approached as such.¹⁰⁷ Structural, organisational, and management components that are critical to the effective implementation of infection-control programmes in hospitals have recently been identified.¹⁰⁸ A review of the literature on HCAI prevention has indicated that, in addition to a functional infection-control team, other factors, such as hospital organisation, bed occupancy, staffing, and workload all play an important role in combatting infection. Easy access to materials and optimised ergonomics, practical educational and evidence-based training, high-quality auditing and timely feedback, as well as the presence of institutional leaders that champion a positive organisational culture, were also found to have a positive impact on infection prevention.¹⁰⁹

3.5. UNSAFE INJECTION PRACTICES

Injections are one of the most common health-care procedures. Estimates indicate that between 8-12 billion injections are administered annually in health care settings worldwide.¹¹⁰ A more recent publication by the WHO indicates that at least 16 billion injections are given yearly.¹¹¹ The vast majority, 95% are administered for curative

¹⁰⁵ Allegranzi and Pittet "Role of hand hygiene in healthcare-associated infection prevention" *Journal of Hospital Infection* (2009) 73 305.

¹⁰⁶ Allegranzi and Pittet (2007) 28 *Infect Control Hosp Epidemiol* 1323.

¹⁰⁷ Organization (2008a) 20.

¹⁰⁸ Zingg et al. "Hospital organisation, management, and structure for prevention of health-care-associated infection: a systematic review and expert consensus." *Lancet Infect Dis* (2015) 15 212.

¹⁰⁹ *Ibid.*

¹¹⁰ Miller and Pisani "The cost of unsafe injections." *Bull World Health Organ* (1999) 77 808.

¹¹¹ Organization "WHO Guideline on the Use of Safety-Engineered Syringes for Intramuscular, Intradermal and Subcutaneous Injections in Health-Care Settings" (2015).

purposes, most of these are thought to be unnecessary.¹¹² In developing and transitional countries, each person receives an average of 3.4 injections per year.¹¹³ Prescribers overestimate patients' preference for injections and provider attitudes seem to drive injection overuse.¹¹⁴ Unsafe, and often unnecessary, injections are common in low-income countries, and place both staff and patients at risk of infection with blood-borne viruses.¹¹⁵ Approximately 6.7 billion or almost 40% of injections are given with reused equipment each year.¹¹⁶ In 2000, contaminated injections resulted in 21 million hepatitis B infections (32%), 2 million hepatitis C infections (40%) and 260 000 HIV infections (5%).¹¹⁷ These unsafe practices lead to significant morbidity and mortality, it has previously been estimated that annually more than 1.3 million deaths and US\$535 million is incurred due to unsafe injections.¹¹⁸

Injections performed with used syringes and needles may explain a large part of Africa's AIDS crisis.¹¹⁹ In South Africa many health workers regard injections as safe when the needle is changed, whilst the syringe is reused. South African health workers in public maternity and paediatric wards under direct observation in 2005 reused syringes; 30% of those surveyed did not see the need to use a new needle for each patient.¹²⁰

Fortunately, considerable progress has been made under the leadership of the Safe Injection Global Network (SIGN).¹²¹ SIGN was established with the goal of reducing

¹¹² Simonsen et al. "Unsafe injections in the developing world and transmission of bloodborne pathogens: a review." *Bulletin of the World Health Organization* (1999) 77 789.

¹¹³ Hauri et al. "The global burden of disease attributable to contaminated injections given in health care settings." *Int J STD AIDS* (2004) 15 7.

¹¹⁴ Hutin et al. (2003) 327 *BMJ* 1075.

¹¹⁵ Kermode "Unsafe injections in low-income country health settings: need for injection safety promotion to prevent the spread of blood-borne viruses." *Health Promot Int* (2004) 19 95.

¹¹⁶ Hutin et al. (2003) 327 *BMJ* 1075.

¹¹⁷ Hauri et al. (2004) 15 *Int J STD AIDS* 7.

¹¹⁸ Miller and Pisani (1999) 77 *Bull World Health Organ* 808.

¹¹⁹ Reid "Injection drug use, unsafe medical injections, and HIV in Africa: a systematic review." *Harm Reduct J* (2009) 6 24.

¹²⁰ Shisana and Mehtar *HIV Risk Exposure Among Young Children: A Study of 2-9 Year Olds Served by Public Health Facilities in the Free State, South Africa* (2005)

¹²¹ Network, WHO *The SIGN alliance*, <http://www.who.int/entity/injection_safety/sign/en/>.

the number of unsafe injections worldwide. It seeks to achieve this by promoting behavioural change among patients and healthcare workers, increasing the availability of necessary and good quality injection devices and the proper management of sharps waste.

A recent study attempted to review the impact that these global efforts have made. The results were very encouraging. The study found that, the average number of injections per person per year in developing and transitional economies decreased from 3.40 to 2.88, between 2000 and 2010. Due to the concerted efforts of SIGN and other stakeholders, there was a substantial decrease in the number of unsafe injections over the same period, unsafe injections decreased by 88%, from 1.35 to 0.16. In 2010, approximately 874 million unsafe injections were administered. The proportion of injections performed with re-used devices dropped from 39.8% to 5.5%.¹²²

Substantial progress was also made in reducing the burden of HIV, HCV and HBV infections transmitted through injections: 'Despite a 13% population growth, there was a reduction of respectively 87% and 83% in the absolute numbers of HIV and HCV infections transmitted through injections. For HBV, the reduction was more marked (91%) due to the additional impact of vaccination.'¹²³

The WHO has called on governments to: transition to safety-engineered injection devices with re-use and sharps injury prevention by 2020; to implement policies and standards for procurement, use and safe disposal of disposable syringes where they remain necessary; focus on the training and education of health workers and the development of sound waste management strategies; and provide targeted communications programmes as well as the creation of frameworks for evaluating overall progress.¹²⁴

¹²² Pépin et al. "Evolution of the global use of unsafe medical injections, 2000-2010." *PLoS One* (2013) 8 e80948.

¹²³ Pépin et al. "Evolution of the global burden of viral infections from unsafe medical injections, 2000-2010." *PLoS One* (2014) 9 e99677.

¹²⁴ Organization *Making all injections safe* (2015) 6.

A guideline on the use of safety-engineered syringes was published by the WHO in 2015.¹²⁵

3.6. UNSAFE BLOOD PRODUCTS

Blood transfusions are a critical component of health care and save millions of lives annually.¹²⁶ Up to 112.5 million blood donations are collected worldwide.¹²⁷ Approximately half of these are collected in high-income countries, home to only 15% of the global population.¹²⁸ Data obtained through the WHO Global Database on Blood Safety (GDBS) for the year 2013 shows that access to blood between low- and high-income countries varies significantly. The median blood donation rate in high-income countries is 33.1 donations per 1000 people. Compared to 11.7 in middle-income countries, and 4.6 in low-income countries.¹²⁹ Blood usage patterns also differ greatly between developed and developing nations.¹³⁰ In the latter, demand is mostly driven by obstetric complications, road traffic accidents, sickle cell disease, childhood anaemia, malnutrition, HIV, malaria, and parasitic infections.¹³¹

The WHO recommends that national blood policies, legislative frameworks and infrastructure should be put in place to promote the usage of safe blood and blood products.¹³² In 2013, 73%, or 122 out of 167 countries, had a national blood policy. Specific legislation covering the safety and quality of blood transfusions have been

¹²⁵ Organization (2008a); Harb et al. "Safety engineered injection devices for intramuscular, subcutaneous and intradermal injections in healthcare delivery settings: a systematic review and meta-analysis." *BMC Nurs* (2015) 14 71; Tarabay et al. "Knowledge, attitudes, beliefs, values, preferences, and feasibility in relation to the use of injection safety devices in healthcare settings: a systematic review." *Health Qual Life Outcomes* (2016) 14 102; Ballout et al. "Use of safety-engineered devices by healthcare workers for intravenous and/or phlebotomy procedures in healthcare settings: a systematic review and meta-analysis." *BMC Health Serv Res* (2016) 16 458.

¹²⁶ Organization "Universal access to safe blood transfusion" (2008b).

¹²⁷ Organization, *WHO Blood safety and availability*, <<http://www.who.int/mediacentre/factsheets/fs279/en/>>.

¹²⁸ Organization *Global Database on Blood Safety: Summary Report 2011* (2012).

¹²⁹ Organization (2008b).

¹³⁰ Schantz-Dunn and Nawal "The use of blood in obstetrics and gynecology in the developing world" *Rev Obstet Gynecol* (2011) 86.

¹³¹ Bloch et al. "Blood transfusion safety in Africa: a literature review of infectious disease and organizational challenges" *Transfusion medicine reviews* (2012) 26 164.

¹³² Organization *Global priorities for patient safety research* (2009a).

enacted in 65% of countries.¹³³

World Health Assembly resolution WHA63.12 urged all Member States to develop national blood systems based on voluntary unpaid donations. Well-organised voluntary blood donation programmes and effective assessment procedures, to verify suitable donors, can lower the prevalence of infections.¹³⁴ Between 2008 and 2013, an increase of 10.7 million blood donations from voluntary unpaid donors had been reported by 159 countries. The highest increase of voluntary unpaid blood donations (85%) during that period has been observed in Africa.

The prevalence of transfusion-transmissible infections in high-income countries is considerably lower than in the developing world.¹³⁵ Adverse transfusion-event reporting systems are present in 92% of hospitals in high-income countries and just 40% of hospitals in middle- and low-income countries. Further compounding the problem, is the fact that only 28% of middle- and low-income countries have national haemovigilance systems, compared to 72% of high-income countries.

Developing countries face additional challenges, including a lack of funding, insufficient training, poor management, and an inadequate supply of reagents and consumables. These factors contribute to unnecessary and unsafe transfusions, exposing patients to the risk of serious adverse reactions and infections.¹³⁶ The HIV epidemic emphasised the importance of blood safety. Since 2000, extensive investment has gone into providing HIV, hepatitis B surface antigen, and hepatitis C virus tests in Africa.¹³⁷ Notwithstanding, the transmissibility of disease, the supply of safe blood has the

¹³³ Organization (2015).

¹³⁴ Organization (2008a) 5.

¹³⁵ Laperche “Multinational assessment of blood-borne virus testing and transfusion safety on the African continent” *Transfusion* (2013) 53 816.

¹³⁶ Thursz and Fontanet “HCV transmission in industrialized countries and resource-constrained areas” *Nature Reviews Gastroenterology & Hepatology* (2014) 11 28.

¹³⁷ Roberts et al. “Problems and Approaches for Blood Transfusion in the Developing Countries.” *Hematol Oncol Clin North Am* (2016) 30 477.

potential to significantly reduce mortality in developing countries, especially among women and children.¹³⁸

Substantial progress has been made with regard to blood safety, though many challenges remain, especially in the African region where economic and organisational problems have aggravated the prevalence of transfusion-transmitted infections.

The WHO, through its Blood and Transfusion Safety programme, aims to assist countries in improving blood safety and availability. It recommends an integrated strategy, which includes: establishing national blood systems with well-organised and coordinated blood transfusion services, policies and regulation; strengthening donation systems, and ensuring effective donor management to procure blood from low-risk voluntary unpaid donors; quality-assured screening of all donated blood for transfusion-transmissible infections; reducing unnecessary transfusions and minimising the risks associated with transfusion through good clinical practices and blood management; and the implementation of effective quality systems.¹³⁹

3.7. SAFETY OF PREGNANT WOMEN AND NEWBORNS

Improving patient safety among pregnant women and new-borns is essential to reducing maternal and neonatal morbidity and mortality rates. Although the annual number of maternal deaths decreased by 44% since 1990 (532 000), the most recent global estimate still suggests that 303 000 women die each year, many from preventable causes.¹⁴⁰ Approximately 99% (302 000) of global maternal deaths occur in developing countries.¹⁴¹ The estimated lifetime risk of maternal mortality in low-income countries is 1 in 41, compared to 1 in 3300 in high-income countries. Out of all maternal deaths, 1.6% are thought to be AIDS-related. South Africa has the highest

¹³⁸ Bloch et al. (2012) 26 *Transfusion medicine reviews* 164.

¹³⁹ World "Strategic framework for blood safety and availability 2016–2025" (2017).

¹⁴⁰ Organization "Trends in maternal mortality: 1990-2015: estimates from WHO, UNICEF, UNFPA, World Bank Group and the United Nations Population Division: executive ..." (2015).

¹⁴¹ Alkema et al. "Global, regional, and national levels and trends in maternal mortality between 1990 and 2015, with scenario-based projections to 2030: a systematic analysis by the UN Maternal Mortality Estimation Inter-Agency Group." *Lancet* (2016) 387 462.

percentage of AIDS-related indirect maternal deaths – 32%.¹⁴² Between 1990 and 2015, 10.7 million women worldwide died from maternal causes.¹⁴³

The reduction of maternal mortality continues to be a global health priority, long after the launch of the worldwide campaign at the Safe Motherhood Conference in Nairobi in February 1987.¹⁴⁴ Maternal health was included as MDG 5 in the UN Millennium Development Goals framework and is listed under Goal 3 of the 17 Sustainable Development Goals. It is also a key concern of the updated Global Strategy for Women’s, Children’s and Adolescents’ Health, which was launched in 2015.¹⁴⁵

Maternal mortality is defined as ‘the death of a woman whilst pregnant or within 42 days of delivery or termination of pregnancy, from any cause related to, or aggravated by pregnancy or its management, but excluding deaths from incidental or accidental causes’. A systematic review was published in 2014 to analyse the causes of maternal death.¹⁴⁶ Nearly 73% of all maternal deaths between 2003 and 2009 were due to direct obstetric causes. Overall, 52% of maternal deaths are attributable to three leading preventable causes – haemorrhage (27.1%), hypertension (14%) and sepsis (10.7%). Up to 28% of maternal mortality results from indirect causes such as malaria, HIV, diabetes, and cardiovascular disease.

Strategies to address preventable maternal mortality can broadly be grouped into two categories: 1) interventions aimed at promoting health and well-being by ensuring adequate access to quality health care and information, within an enabling framework of human rights, equity and legal protection; and 2) universal health coverage that provides quality antenatal, perinatal and postnatal care, as well as emergency obstetric care where necessary.¹⁴⁷ In the 2015 report, *Strategies Toward Ending Preventable*

¹⁴² Organization (2015) 1.

¹⁴³ Alkema et al. (2016) 387 *Lancet* 462.

¹⁴⁴ Organization “Time to Respond: a Report on the Global Implementation of Maternal Death Surveillance and Response” (2016) 1.

¹⁴⁵ Woman and Child “The Global Strategy for Women’s, Children’s and Adolescents’ Health (2016–2030): Survive, Thrive, Transform” (2015).

¹⁴⁶ Say et al. “Global causes of maternal death: a WHO systematic analysis.” *Lancet Glob Health* (2014) 2 e323.

¹⁴⁷ Organization (2016) 6.

Maternal Mortality, the strategy is concisely enunciated as: ‘a shift from a system focused on emergency care for a minority of women to wellness-focused care for all’.¹⁴⁸

The Global Strategy for Women’s, Children’s and Adolescents’ Health lists a number of proven health interventions, specifically aimed at improving maternal health and outcomes.¹⁴⁹

These have been synthesised into five priority objectives: 1) effective care around the time of birth is critical, the quality of care and service integration needs to be improved; 2) invest in health systems and resources to enhance the healthcare delivery; 3) reduce inequities in access and coverage of care for women and new-borns; 4) family, community and societal engagement; 5) improve information systems and data collection to strengthen decision making and accountability.¹⁵⁰

Substantial progress has been made over the past 15 years. It may even be possible to completely eradicate preventable maternal deaths within a generation, if governments and policymakers implement effective interventions and strategies with the objective of improving quality and access of care.¹⁵¹

Developed nations have recognised the value of optimally organising systems and teams for pregnancy care and have started to adopt quality improvement tools such as morbidity and mortality reviews, triggers, bundles, protocols, and checklists in order to improve health maternal outcomes.¹⁵²

Neonatal mortality has seen a substantial decline in the last two decades, however, there are still an estimated 2.7 million neonatal deaths and 2.6 million stillbirths every

¹⁴⁸ Organization *Strategies towards ending preventable maternal mortality (EPMM)* (2015).

¹⁴⁹ *Woman and Child* (2015).

¹⁵⁰ Chou et al. “Ending preventable maternal and newborn mortality and stillbirths.” *BMJ* (2015) 351 h4255.

¹⁵¹ *Ibid.*

¹⁵² D’Alton et al. “The national partnership for maternal safety” *Obstetrics & Gynecology* (2014) 123 973; Arora et al. “Triggers, bundles, protocols, and checklists—what every maternal care provider needs to know.” *Am J Obstet Gynecol* (2016) 214 444.

year.¹⁵³ Many of these deaths can be prevented with evidence-based interventions.¹⁵⁴ Three main causes contribute to neonatal death: infections (0.6 million), intrapartum conditions (0.7 million), and preterm birth complications (1.0 million).¹⁵⁵ Small birth size has been found to be the biggest risk factor in neonatal deaths (80%) and also increases the risk of post-neonatal mortality.¹⁵⁶

Many resource-deficient countries still lack effective civil registration and vital statistics systems, hampering the calculation of the true burden of mortality.¹⁵⁷ Worldwide, half of all new-born babies do not receive birth certificates, and death certificates are non-existent in most neonatal deaths and almost all stillbirths.¹⁵⁸ This poses a significant problem as information on the nature and causes of death would determine health system responses and resource distribution, interventions aimed at improving quality of care need to be informed by adequate data.¹⁵⁹ Although national and regional estimates of the number and causes of death are important, closer inspection of cases is required to identify the underlying reasons for individual deaths, so as to enable providers of care

¹⁵³ Organization “Making Every Baby Count: Audit and Review of Stillbirths and Neonatal Deaths: Highlights from the World Health Organization 2016 Audit Guide” (2016); Blencowe et al. “National, regional, and worldwide estimates of stillbirth rates in 2015, with trends from 2000: a systematic analysis.” *Lancet Glob Health* (2016) 4 e98.

¹⁵⁴ Bhutta et al. “Can available interventions end preventable deaths in mothers, newborn babies, and stillbirths, and at what cost?” *Lancet* (2014) 384 347.

¹⁵⁵ Liu et al. “Global, regional, and national causes of child mortality in 2000–13, with projections to inform post-2015 priorities: an updated systematic analysis” *Lancet* (2015) 385 430.

¹⁵⁶ Lawn et al. “Every Newborn: progress, priorities, and potential beyond survival” *Lancet* (2014) 384 189.

¹⁵⁷ Kerber et al. “Counting every stillbirth and neonatal death through mortality audit to improve quality of care for every pregnant woman and her baby.” *BMC Pregnancy Childbirth* (2015) 15 Suppl 2 S9.

¹⁵⁸ Lawn et al. (2014) 384 *Lancet* 189.

¹⁵⁹ Gebhardt et al. (2015) 105 *SAMJ: South African Medical Journal* 287; Gebhardt “Preparing for caesarean delivery” *Obstetrics and Gynaecology Forum* (2015) 25 13; Fawcus et al. “Maternal deaths from bleeding associated with caesarean delivery: A national emergency (A review)” *SAMJ: South African Medical Journal* (2016) 106 472; Maswime and Buchmann (2016) 134 *International Journal of Gynecology & Obstetrics* 320; Maswime and Buchmann “Inequities in resources and preparedness for surgical complications of caesarean section in southern Gauteng hospitals” *South African Journal of Obstetrics and Gynaecology* (2016) 22 21; Gumede et al. “Attendance at antenatal clinics in inner-city Johannesburg, South Africa and its associations with birth outcomes: analysis of data from birth registers at three facilities” *BMC public health* (2017) 17 443.

to learn from adverse events and improve future practices.¹⁶⁰

Studies suggest that the majority of stillbirths, specifically during the intrapartum period, and up to three quarters of neonatal deaths are largely preventable.¹⁶¹ By providing effective care for all women and new-borns in facilities, an estimated 1 13 000 maternal deaths, 531 000 stillbirths, and 1.325 million neonatal deaths could be prevented annually by 2020. At a cost of approximately \$4.5 billion per year, or \$0.9 per person.¹⁶²

A substantial proportion of neonates admitted to hospital experience iatrogenic events, a significant proportion of which are preventable. One study indicates that a third of all iatrogenic events and more than a quarter of severe iatrogenic events are preventable. Nosocomial infections and respiratory events have been shown to be the most severe. Respiratory, along with drug events are also the most common adverse events. Error prevention strategies should be implemented and prospective, anonymous incident reporting systems have been recommended.¹⁶³

A systematic review of avoidable factors in global maternal and perinatal deaths was conducted by employing mortality audits in low-resource settings. It identified several avoidable factors, spanning those related to the behaviour and practices of health workers and patients, administration, supply, referral and transport problems. Substandard practice by health care workers attributed to the most deaths and is therefore the most important avoidable factor. Training and safety initiatives must be sharpened to ensure that an adequate standard of care is provided at each delivery.¹⁶⁴

Less information has been recorded for neonatal deaths and stillbirths than for maternal deaths. Very limited information about each birth and death is available, and reviews concerning the outcomes are not common. The WHO advocates capturing as much

¹⁶⁰ Blencowe et al. (2016) 4 *Lancet Glob Health* e98.

¹⁶¹ Akseer et al. "Ending preventable newborn deaths in a generation." *Int J Gynaecol Obstet* (2015) 131 Suppl 1 S43.

¹⁶² Bhutta et al. (2014) 384 *Lancet* 347.

¹⁶³ Ligi et al. "Iatrogenic events in admitted neonates: a prospective cohort study" *Lancet* (2008) 57 501.

¹⁶⁴ Merali et al. "Audit-identified avoidable factors in maternal and perinatal deaths in low resource settings: a systematic review." *BMC Pregnancy Childbirth* (2014) 14 280.

information as possible about why these deaths occurred in order to try and understand the underlying contributing causes and avoidable factors. In doing so, health-care providers, managers, administrators and policy-makers can endeavour to prevent future deaths and implement health care improvement strategies.¹⁶⁵ They recommend establishing a system to address the burden of stillbirths and neonatal deaths similar to the maternal death surveillance and response (MDSR) approach–The WHO application of ICD-10 to deaths during the perinatal period: ICD-perinatal mortality (ICD-PM):

‘The WHO application of ICD-10 to deaths during the perinatal period: ICD-perinatal mortality (ICD-PM) is modelled on The WHO application of ICD-10 to deaths during pregnancy, childbirth and the puerperium: ICD-maternal mortality (ICD-MM). ICD-PM, in the same vein as ICD-MM, is based on the 10th revision of the International Statistical Classification of Diseases and Related Health Problems (ICD-10) and its coding rules. It is intended to facilitate the consistent collection, analysis and interpretation of information on perinatal deaths. Improved reporting will also facilitate the coding of conditions.’

‘ICD-PM is intended to be used by those who assist health-care providers and those charged with death certification, to guide them in correctly documenting the pertinent information by clarifying which conditions should be considered underlying causes of death, thus improving accurate death attribution. As a result, it will improve the information available to coders, programme managers, statistical offices and academics/ researchers.’¹⁶⁶

3.8. SAFETY OF THE ELDERLY

The 2015 United Nations World Population Ageing report, indicates that almost all the countries in the world are experiencing an increase in the number and proportion of older persons in their population. Between 2015 and 2030, the number of people in the world aged 60 years or over is projected to grow by 56%, from 901 million to 1.4 billion,

¹⁶⁵ Organization (2016).

¹⁶⁶ Organization “The WHO application of ICD-10 to deaths during the perinatal period: ICD-PM” (2016) 1.

and the pace of world population ageing is projected to accelerate in subsequent decades. By 2030, older persons are projected to account for 1 in 6 people globally, compared to 1 in 8 now. People are also living much longer, in 2010-2015, 60-year-old persons globally could expect, on average, to live an additional 20.2 years. It is predicted to be one of the most significant social transformations of the twenty-first century, with far reaching implications, particularly for health care. Health systems will have to adapt to meet the specific needs of the elderly, if care is to be provided to a growing number and proportion of older persons.¹⁶⁷

Several of the large retrospective record review studies have found that older patients experience significantly more adverse events than younger patients in hospital. Patients over the age of 65 have more or less double the risk of experiencing an adverse event.¹⁶⁸ In the Harvard Medical Practice Study, when specific categories of injuries were examined, older patients faced a higher risk in all the groupings, ranging from a 2.2-fold increase for perioperative complications to a 10-fold increase for falls.¹⁶⁹ The incidence rate of preventable adverse events is also substantially higher amongst the elderly.¹⁷⁰ The consequences of these adverse events are likely to be much more severe as well.¹⁷¹ Most of the available data suggest that the elderly are more susceptible to unsafe care and repercussions thereof.¹⁷² This is of particular concern in light of the population ageing trends described above.¹⁷³

The underlying causes of the higher incidence of adverse events in older people probably has to do with the general frailty of elderly patients and comorbidity, as well

¹⁶⁷ World World report on ageing and health (2015); Publications "World Population Ageing 2015" (2016).

¹⁶⁸ Aranaz-Andres et al. "What makes hospitalized patients more vulnerable and increases their risk of experiencing an adverse event?" *International Journal for Quality in Health Care* (2011) 23 705.

¹⁶⁹ Rothschild et al. "Preventable medical injuries in older patients." *Arch Intern Med* (2000) 160 2717.

¹⁷⁰ Lefevre et al. "Iatrogenic complications in high-risk, elderly patients." *Arch Intern Med* (1992) 152 2074; Thomas and Brennan "Incidence and types of preventable adverse events in elderly patients: population based review of medical records." *BMJ* (2000) 320 741.

¹⁷¹ Lefevre et al. (1992) 152 *Arch Intern Med* 2074; Thomas and Brennan (2000) 320 *BMJ* 741.

¹⁷² Sari et al. "Incidence, preventability and consequences of adverse events in older people: results of a retrospective case-note review." *Age Ageing* (2008) 37 265.

¹⁷³ Szlejf et al. "Medical adverse events in elderly hospitalized patients: A prospective study" *Clinics* (2012) 67 1247.

as the complexity involved with such care, rather than age alone.¹⁷⁴ The number of exposures to potentially iatrogenic actions could also explain the higher incidence rate.¹⁷⁵ In one study knowledge-based errors were often found to contribute to adverse events, especially when confronted with multiple simultaneous diseases, uncertainty regarding medication use and complex medical histories.¹⁷⁶

The complicated nature of adverse events found among older people requires further attention. The impact of adverse events and geriatric syndromes upon the elderly, necessitates the collection of more measurement data.¹⁷⁷ Targeted interventions to improve the safety of the elderly are required, training in geriatric medicine and a better understanding of the complex care required for this particularly vulnerable group is needed to prevent future errors.¹⁷⁸

3.9. INJURIES DUE TO FALLS IN HOSPITALS

In hospital falls are the most common patient safety injury for the older patients in developed nations.¹⁷⁹ Approximately, one third of persons over the age of 65 fall each year, and falls are recurrent in half of such cases.¹⁸⁰ Although, the risk of a fall increases significantly as you get older, falls cause injury and impairment for persons of all ages.¹⁸¹ Studies conducted in acute hospitals have reported rates ranging between 1.36 to 8.97 falls per 1000 occupied bed days.¹⁸² NHS organisations in England and

¹⁷⁴ Long et al. "What is known about adverse events in older medical hospital inpatients? A systematic review of the literature." *Int J Qual Health Care* (2013) 25 542.

¹⁷⁵ Aranaz-Andres et al. (2011) 23 *International Journal for Quality in Health Care* 705.

¹⁷⁶ Merten et al. "Scale, nature, preventability and causes of adverse events in hospitalised older patients." *Age Ageing* (2013) 42 87.

¹⁷⁷ Long et al. (2013) 25 *Int J Qual Health Care* 542.

¹⁷⁸ Merten et al. (2013) 42 *Age Ageing* 87; Merten et al. "High risk of adverse events in hospitalised hip fracture patients of 65 years and older: results of a retrospective record review study." *BMJ Open* (2015) 5 e006663.

¹⁷⁹ Schwendimann et al. "Falls and consequent injuries in hospitalized patients: effects of an interdisciplinary falls prevention program." *BMC Health Serv Res* (2006) 6 69.

¹⁸⁰ Tinetti "Preventing Falls in Elderly Persons" *N Engl J Med* (2003) 348 42.

¹⁸¹ Dykes et al. "Fall prevention in acute care hospitals: a randomized trial." *JAMA* (2010) 304 1912.

¹⁸² Oliver et al. "Preventing falls and fall-related injuries in hospitals." *Clin Geriatr Med* (2010) 26 645.

Wales report almost 250 000 falls to the National Reporting and Learning System every year.¹⁸³ The number of falls in US hospitals could exceed 1 million per year.¹⁸⁴

Falls can have serious physical, psychological and legal consequences.¹⁸⁵ Between 30% and 50% of in-facility falls result in injuries.¹⁸⁶ Serious injuries occur in 4% to 6% of falls, and include fractures, subdural hematomas, profuse bleeding, and even death.¹⁸⁷ Injuries resulting from falls are associated with increased health care utilisation, in the form of additional resource requirements and lengthened hospital stays, which lead to significantly higher costs.¹⁸⁸ An Australian study indicated that patients who had an in-hospital fall had their hospital stay lengthened by 8 days, and incurred additional hospital costs of \$6669.¹⁸⁹

Despite the fact that over 70% of the world's older population, the group most at risk when it comes to falls, live in developing countries, information regarding falls and their prevalence has been scarce.¹⁹⁰ There is some evidence to suggest that there are significant differences between developed and developing countries with regard to the scope of the problem and the nature of fall risk.¹⁹¹ Nationally representative standardised data collected from adults aged 50 years and over participating in the World Health Organization (WHO) Study on global AGEing and adult health (SAGE), showed that the proportion of injuries that were fall-related across six developing

¹⁸³ Agency *Slips, trips and falls* (2010).

¹⁸⁴ Hughes *Patient safety and quality: An evidence-based handbook for nurses* (2008) 195.

¹⁸⁵ Hempel et al. "Hospital fall prevention: a systematic review of implementation, components, adherence, and effectiveness." *J Am Geriatr Soc* (2013) 61 483.

¹⁸⁶ Miake-Lye et al. "Inpatient fall prevention programs as a patient safety strategy: a systematic review." *Ann Intern Med* (2013) 158 390.

¹⁸⁷ Hitcho et al. "Characteristics and circumstances of falls in a hospital setting: a prospective analysis." *J Gen Intern Med* (2004) 19 732.

¹⁸⁸ Morello et al. "The extra resource burden of in-hospital falls: a cost of falls study." *Med J Aust* (2015) 203 367.

¹⁸⁹ *Ibid.*

¹⁹⁰ Stewart Williams et al. "Prevalence, risk factors and disability associated with fall-related injury in older adults in low- and middle-income countries: results from the WHO Study on global AGEing and adult health (SAGE)." *BMC Med* (2015) 13 147.

¹⁹¹ Kalula et al. "Falls and fall prevention programmes in developing countries: Environmental scan for the adaptation of the Canadian Falls prevention curriculum for developing countries" *Elderly Falls* (2011) 42 461.

countries, including South Africa, was 65.7%. The study aimed to address the gap in epidemiological falls research available in developing countries. It indicated that women, persons living in rural areas, those with depression, severe sleeping problems and chronic conditions had a significantly higher risk of fall-related injuries.¹⁹²

Despite the global scale the problem, the prevention of falls in acute hospitals has not been subjected to much high-quality research.¹⁹³ Researchers in the largest randomised controlled trial to date, applied a “6-PACK” approach to at risk patients. The “6-PACK” interventions include: “falls alert” sign, supervision of patients in the bathroom, ensuring patients’ walking aids are within reach, a toileting regimen, use of a low-low bed, and use of a bed/chair alarm. Although, implementation of the 6-PACK programme improved completion of a fall risk tool and use of fall prevention interventions recommended by best practice guidelines, it was ineffective at preventing falls or injuries, compared to usual care in the control wards.

Barker *et al.* concluded by calling for further investigation into system level interventions and environmental interventions, that may provide novel solutions to the problem of in-hospital falls.¹⁹⁴

Patients who fall in acute hospitals almost invariably suffer from diminished mobility, cognitive impairment, incontinence, drugs that may contribute to the likelihood of falls, orthostatic hypotension, impaired vision, or delirium. Targeting these specific risk factors seems to be the way forward.¹⁹⁵

3.10. PRESSURE ULCERS

Decubitus, or pressure ulcers are a common and largely preventable problem that results in substantial morbidity and mortality. It is estimated that pressure ulcers affect 2.5 million patients annually in the United States alone, and that 60 000 deaths are

¹⁹² Stewart Williams et al. (2015) 13 *BMC Med* 147.

¹⁹³ Healey “Preventing falls in hospitals” *BMJ* (2016) 17 424.

¹⁹⁴ Barker et al. “6-PACK programme to decrease fall injuries in acute hospitals: cluster randomised controlled trial.” *BMJ* (2016) 352 h6781.

¹⁹⁵ Healey (2016) 17 *BMJ* 424.

caused by complications related to hospital acquired pressure ulcers.¹⁹⁶ It is also the costliest of all hospital-acquired conditions. In 2006, hospital costs for adult patients diagnosed with pressure ulcers was \$11 billion.¹⁹⁷ In the United Kingdom the cost of treating pressure ulcers varies between £1 064 to £10 551, depending on ulcer grade, healing time and complications involved. The total annual cost is £1.4–£2.1 billion, which accounts for 4% of total NHS expenditure.¹⁹⁸ The amounts were more recently updated to reflect 2011 prices. Depending on severity, treatment costs are anywhere between £1 214 to £14 108.¹⁹⁹ The treatment cost in Australia was estimated to be A\$983 million per annum in 2012-13, representing approximately 1.9% of all public hospital expenditure.²⁰⁰ These figures do not take the legal consequences into account.²⁰¹ For example, failure to prevent pressure ulcers in long-term care settings has resulted in increasing litigation, with up to 87% of cases are settled in favour of the complainants.²⁰²

Vulnerable groups, that are more at risk of developing pressure ulcers are: the elderly, persons with cognitive or physical impairment, and patients with comorbidities (such as urinary incontinence, oedema, impaired microcirculation, hypoalbuminemia, and malnutrition).²⁰³

Effective strategies that have been shown to prevent pressure ulcers include: use of support surfaces, repositioning the patient, better nutrition, and moisturising sacral

¹⁹⁶ Sullivan and Schoelles “Preventing in-facility pressure ulcers as a patient safety strategy: a systematic review.” *Ann Intern Med* (2013) 158 410.

¹⁹⁷ Russo et al., ‘Hospitalizations Related to Pressure Ulcers Among Adults 18 Years and Older, 2006: Statistical Brief #64’ in (eds.), *Healthcare Cost and Utilization Project (HCUP) Statistical Briefs*, Agency for Healthcare Research and Quality (US), Rockville (MD), 2006.

¹⁹⁸ Bennett et al. “The cost of pressure ulcers in the UK.” *Age Ageing* (2004) 33 230.

¹⁹⁹ Dealey et al. “The cost of pressure ulcers in the United Kingdom.” *J Wound Care* (2012) 21 261.

²⁰⁰ Nguyen et al. “Pressure injury in Australian public hospitals: a cost-of-illness study.” *Aust Health Rev* (2015) 39 329.

²⁰¹ Bennett et al. “The increasing medical malpractice risk related to pressure ulcers in the United States.” *J Am Geriatr Soc* (2000) 48 73.

²⁰² Voss et al. “Long-term care liability for pressure ulcers.” *J Am Geriatr Soc* (2005) 53 1587.

²⁰³ Chou et al. “Pressure ulcer risk assessment and prevention: a systematic comparative effectiveness review.” *Ann Intern Med* (2013) 159 28.

skin.²⁰⁴

Multicomponent initiatives for pressure ulcer prevention in acute and long-term care settings have been associated with improved processes of care and reduced pressure ulcer rates. Strategies that include several key interventions can be successfully implemented through: straightforward and standardised interventions and documentation, collaboration between multidisciplinary teams and leadership, designated skin exponents, continuous staff education, and constant auditing and feedback.²⁰⁵ Financial incentives have also been shown to reduce rates of hospital acquired pressure ulcers. These reductions could possibly be as a result of quality improvements associated with the implementation of hospital-wide evidence-based practices.²⁰⁶

A systematic review of the cost of prevention and treatment of pressure ulcers found that the cost of pressure ulcer prevention per patient per day varied between €2.65 to €87.57. While treatment costs per patient per day ranged from €1.71 to €470.49. Pressure ulcer prevention for at-risk patients does impact healthcare budgets, however, the evidence shows that the costs to treat a severe pressure ulcer are substantially higher.²⁰⁷

4. CONCLUSION

Following the landmark IOM report and its estimate of iatrogenic injury in the United States, several other countries have now conducted studies to ascertain the incidence of adverse events in their own health systems. A systematic review of the available evidence suggests that about 1 in 10 patients will suffer an adverse event and that approximately half of these are preventable. Unfortunately, almost all of the evidence

²⁰⁴ Reddy et al. "Preventing pressure ulcers: a systematic review." *JAMA* (2006) 296 974.

²⁰⁵ Sullivan and Schoelles (2013) 158 *Ann Intern Med* 410.

²⁰⁶ Padula et al. "Are Evidence-based Practices Associated With Effective Prevention of Hospital-acquired Pressure Ulcers in US Academic Medical Centers" *Med Care* (2016) 54 512.

²⁰⁷ Demarré et al. "The cost of prevention and treatment of pressure ulcers: A systematic review." *Int J Nurs Stud* (2015) 52 1754.

on structural and process factors that contribute to unsafe care come from a small number of developed countries, making it difficult to assess the underlying causes, frequency and harm of unsafe care in developing countries.

Most of what we know about the sources of harm also come from developed countries. An overview of 10 significant sources, shows that unsafe care comes at a significant cost, both in terms of patient suffering and resource expenditure. It also shows that there is substantial room for improvement and that some progress is being made. Although there is scant evidence available, patients in developing countries likely face an even greater risk of harm. Furthermore, due to the particular challenges posed by healthcare systems in these countries, improvement of patient safety may require different strategies, to those employed in developed nations.

A recent WHO sponsored study estimated that out of the 421 million hospitalisations in the world annually, approximately 42.7 million adverse events occur. These adverse events resulted in a loss of 23 million disability-adjusted life years (DALYs) per year. Approximately two-thirds of all adverse events and the DALYs lost from them, occurred in low-income and middle-income countries.

Clearly, adverse events caused by medical care represent a significant source of morbidity and mortality. The authors of the global patient safety evidence overview, summarised the situation as follows:

‘In conclusion, patients seek care to reduce their suffering. Based on research from the past two decades, we know that while the healthcare system cures disease and alleviates pain, it can also cause largely preventable harm and suffering. This evidence should not be interpreted as an acceptable cost of providing healthcare. Our review suggests that harm occurs too often and that much of it is avoidable. Reducing harm will require targeted, well-designed and appropriately managed research to gain greater understanding of its causes and contributing factors, especially in transitional and developing countries.’

How do we go about reducing and preventing harm? The following chapter provides an overview of the key concepts of medical error and patient safety.

CHAPTER 4. THE KEY CONCEPTS OF MEDICAL ERROR AND PATIENT SAFETY

1. INTRODUCTION

This chapter begins with a brief illustrative description of medical harm in the United States, as their estimates of unsafe care and the subsequent costs currently provide the most complete picture of the issue. However, as the previous chapter showed, patient safety is a global concern and developing countries likely face an even greater burden. This serves as background and contextualises the ensuing discussion of the key concepts of medical error and patient safety.

1.1. ESTIMATES OF MEDICAL HARM

After somehow eluding those involved in medicine for so many years the health profession, public and policy-makers have finally, to some extent, come to appreciate the type, scope and frequency of harm inflicted by medical care. The first estimate of medical error to gain widespread attention was provided by the Institute of Medicine.¹ The groundbreaking report 'To Err is Human', extrapolated from the rates of adverse events and death obtained by the Harvard Medical Practice Study and a follow-up study conducted in Utah and Colorado to get to their approximation that 44 000 – 98 000 deaths due to medical error, excluding errors of omission, occur in the United States each year.²

The Harvard Study with its larger sample of 30 000 discharges and estimate of 98 000 deaths is most often quoted. As the basis of this estimate is nearly three decades old, James developed an updated estimate from modern studies published between 2008 and 2011.³ In the authors' updated estimation, annually 210 000 deaths are associated with preventable harm in hospitals. Although, the actual number of premature deaths

¹ Kohn et al. (2000).

² Brennan et al. (1991) 324 *N Engl J Med* 370; Thomas et al. (2000) 38 *Medical Care* 261.

³ James (2013) 9 *J Patient Saf* 122.

could be more than 440 000 per year, if one was to factor in limitations in the search capability of the Global Trigger Tool and incomplete documentation in hospital medical records on which the Tool relies. Thus, according to the author, it's possible that medical error causes approximately one-sixth of all deaths that occur in the United States each year.

A recent analysis by Makary and Daniel brought renewed attention to medical error and the potential fatal consequences thereof.⁴ Their assessment made the headlines by asserting that medical error was the third leading cause of death in the US. The authors estimated that medical error accounted for about 251 454 deaths; causing more deaths than chronic lower respiratory diseases (147 101), accidents (136 053), stroke (133 103), Alzheimer's (93 541) or diabetes (76 488). Only heart disease (614 348) and cancer (591,699) results in more mortality according to the list published by the Centers for Disease Control and Prevention (CDC).⁵

A big part of the problem is that we do not really know the extent of the problem, these estimates are just that, estimates.⁶ The CDC, which bases its yearly list on the underlying cause of death reported on death certificates, does not make provision for medical error to be recorded as the underlying cause, and even so, errors are hardly ever disclosed on death certificates. The ICD-10 coding system, used in 117 countries to code mortality statistics, also has limited ability to capture most types of medical error.

Only a fraction of these errors and deaths, with a view to prevention, are disclosed and discussed. And only in limited and confidential forums, such as a hospital's internal root cause analysis committee or a department's morbidity and mortality conference. This makes it highly unlikely that the lessons learnt would be disseminated anywhere beyond the particular hospital or specific department.⁷ Data are lacking and comprehensive reporting systems are needed to accurately measure the problem. Priorities in the

⁴ Makary and Daniel "Medical error-the third leading cause of death in the US." *BMJ* (2016) 353 i2139.

⁵ *Statistics Health, United States, 2015* (2016).

⁶ Abbasi "Headline-Grabbing Study Brings Attention Back to Medical Errors." *JAMA* (2016) 316 698.

⁷ Makary and Daniel (2016) 353 *BMJ* i2139.

health system may be set accordingly and at the least an accurate measure will allow any future progress to be assessed.⁸

Whilst, mortality figures grab the headlines, medical harm poses a significant risk of increased morbidity. The best available evidence suggests that 1 in 10 patients experience at least one adverse event during their hospitalisation, roughly half of which are preventable.

A recent study on perioperative medication errors indicated that approximately every second operation had a medication error, with more than one third of these errors leading to observed patient harm, and the remaining two thirds having potential for patient harm.⁹ More than 700 000 outpatients were treated for adverse drug events in emergency departments during one year, the events were serious enough that 1 in 6 required subsequent hospital admission.¹⁰

Diagnostic errors have until recently received relatively little attention, perhaps owing to difficulties in definition and measurement. However, Singh et al. estimate that approximately 12 million adults in the US experience outpatient diagnostic errors annually.¹¹ Quite concerning in light of the fact that previous research by the authors estimated that one-half of all diagnostic errors have the potential to cause severe harm.¹²

1.2. THE FINANCIAL COST OF HARM

A series of studies on adverse events affecting Medicare beneficiaries in different health settings found that around 30% of Medicare patients experienced adverse or temporary

⁸ Abbasi (2016) 316 *JAMA* 698.

⁹ Nanji et al. "Evaluation of Perioperative Medication Errors and Adverse Drug Events." *Anesthesiology* (2016) 124 25.

¹⁰ Budnitz et al. "National surveillance of emergency department visits for outpatient adverse drug events." *JAMA* (2006) 296 1858.

¹¹ Singh et al. "The frequency of diagnostic errors in outpatient care: estimations from three large observational studies involving US adult populations." *BMJ Qual Saf* (2014) 23 727.

¹² Singh et al. "Types and origins of diagnostic errors in primary care settings." *JAMA Intern Med* (2013) 173 418.

harm events.¹³ These events have immense cost implications. In acute-care hospitals the added costs equated to an estimated 3.5% of Medicare's expenditure during October 2008, which amounts to approximately \$4.4 billion in care associated with adverse events for the year.¹⁴ In skilled-nursing facilities more than half of the residents who experienced harm returned to a hospital for treatment, with an estimated cost to Medicare of \$208 million in August 2011, or approximately \$2.8 billion that year.¹⁵ Adverse events in rehabilitation hospitals cost Medicare at least \$7.7 million in one month, or at least \$92 million in one year.¹⁶

A study commissioned by the Society of Actuaries' Health Section estimated that the total cost of direct measurable medical errors in the United States was \$17.1 billion in 2008.¹⁷ The full economic impact is much higher when quality-adjusted life years (QALYs) are factored in. If the Institute of Medicine's estimate of 98 000 deaths is used, the total cost would be \$73.5 billion to \$98 billion.¹⁸ And should preventable death be ten times greater than previously measured, as a study which employed the Global Trigger Tool showed.¹⁹ The economic impact could be a staggering \$735 to \$980 billion.²⁰

¹³ US Department of Health and Human Services "Adverse Events in Hospitals: National Incidence Among Medicare Beneficiaries (OEI-06-09-00090; 11/10)" (2010) 1; US Department of Health and Human Services "Adverse Events in Skilled Nursing Facilities: National Incidence Among Medicare Beneficiaries (OEI-06-11-00370; 02/14)" (2014) 1; US Department of Health and Human Services "Adverse Events in Rehabilitation Hospitals: National Incidence Among Medicare Beneficiaries (OEI-06-14-00110; 07/16)" (2016) 1.

¹⁴ US Department of Health and Human Services (2010) 1.

¹⁵ US Department of Health and Human Services (2014) 1.

¹⁶ US Department of Health and Human Services (2016) 1.

¹⁷ Shreve et al. "The economic measurement of medical errors sponsored by society of actuaries' health section" *Milliman Inc* (2010); Van Den Bos et al. "The \$17.1 billion problem: the annual cost of measurable medical errors." *Health Aff (Millwood)* (2011) 30 596.

¹⁸ Andel et al. "The economics of health care quality and medical errors" *Journal of health care finance* (2012a) 39 39.

¹⁹ Classen et al. (2011) 30 *Health Aff (Millwood)* 581.

²⁰ Slawomirski et al. (2017).

1.3. THE KNOWN UNKNOWNNS

The preceding paragraphs illustrate the costs, financial and otherwise, associated with medical harm. A lack of information, especially in developing countries, constitutes one of the major challenges facing patient safety. Sufficient information regarding the aetiology and prevalence of medical errors, would be needed if error-reduction strategies, protocols and systems are to be successfully implemented. The illustrative selection of the US is deliberate, as their medically induced mortality and morbidity picture is currently the most complete. Yet, as shown, even the number of US deaths attributable to medical error, remains contentious.²¹

Patient safety is, however, a global concern. Jha *et al.* estimated the global burden of unsafe medical care and found that approximately 43 million adverse events occur each year, and that these adverse events result in an unsettling 23 million disability-adjusted life years (DALYs) lost.²² Inpatient adverse events represent a significant global burden of disability and premature death. If the global burden of unsafe injection practices were to be included in the estimate, a further 9.2 million DALYs lost per year, it would make unsafe care the 14th leading cause of morbidity and mortality in the world, comparable to the burden from tuberculosis or malaria.

1.4. EXPANDING ACCESS (TO SAFE CARE)

Even more concerning, is the fact that a large majority of these injuries and harm occur in developing and transitional countries. Two-thirds of all adverse events, and the DALYs lost from them, occur in low- and middle-income countries.²³ Not only does this lead to direct harm, distress and a waste of already scarce resources, unsafe care may also deter patients in low-income countries from utilising formal healthcare, which may present yet another barrier to access. Many of these countries are already plagued by

²¹ Shojania and Dixon-Woods “Estimating deaths due to medical error: the ongoing controversy and why it matters” *BMJ Qual Saf* (2016) 26 423. The authors caution against a reliance on unsound estimates of deaths, calling instead for a strengthening of the evidence base, especially in regard to epidemiology. Dubious statistics may do more to ‘erode the cause of patient safety than headline-friendly figures will do to help it.’

²² Jha *et al.* (2013) 22 *BMJ Qual Saf* 809.

²³ *Ibid.*

inadequate access to healthcare, and although this lack of access causes substantial harm, the evidence suggests that unsafe medical care experienced upon accessing health resources comes with its own substantial deleterious consequences.²⁴

It is evident that efforts to expand access, should be accompanied by initiatives aimed at improving quality and safety of care. A notion very relevant to our own context, particularly leading up to the implementation of the NHI scheme.²⁵ Delivering on the promise of universal health coverage comes with its own set of challenges, merely prioritising universal coverage at the expense of effective coverage might defeat the purpose, wasting precious resources without actually achieving improved health and wellbeing.²⁶ The successful implementation of effective universal health coverage largely depends on the underlying healthcare delivery system. Problems regarding safety, quality, and efficiency permeate most healthcare systems and ‘in many countries, especially those with scarce resources, the quality of the underlying healthcare delivery system is so poor that it is unclear whether increasing access to services will do more good or more harm’.²⁷ As governments necessarily have to reprioritise funds to achieve the goal of universal coverage, they would of course want to ensure that they receive the best value for their investment. In many instances, it remains difficult to determine what the best return on investment would likely be, however, considering the immense mortality, morbidity and excess costs that come about from poor quality care, one way to get the most value from such investment would certainly be to improve the quality and safety of the underlying healthcare delivery system.

²⁴ Flott et al. (2017) 389 *Lancet* 1279.

²⁵ Scott and Jha “Putting quality on the global health agenda.” *N Engl J Med* (2014) 371 3; Flott et al. (2017) 389 *Lancet* 1279.

²⁶ Jha et al. “Delivering on the promise of universal health coverage.” *BMJ* (2016) 353 i2216.

²⁷ *Ibid.*

2. CONFRONTING THE PROBLEM OF MEDICAL HARM – THE KEY CONCEPTS OF MEDICAL ERROR AND PATIENT SAFETY

2.1. INTRODUCTION

2.1.1. DEFINITIONS

The recognition that our understanding of the patient safety literature could be compromised by the inconsistent use of language prompted the World Alliance For Patient Safety of the World Health Organisation to propose an International Classification for Patient Safety.²⁸

The International Classification for Patient Safety (ICPS) provides a standardised set of concepts and terms organised into a conceptual framework to enable consistent organisation of the major events associated with patient safety.²⁹

Definitions for some of the more common concepts and terms are provided, for the sake of convenience, as they appear in the ICPS.³⁰

‘Patient Safety: the reduction of risk of unnecessary harm associated with healthcare to an acceptable minimum.’

An acceptable minimum refers to the collective notions of given current knowledge, resources available and the context in which care was delivered weighed against the

²⁸ References to these terms in the preceding chapters should be understood in this context and are subject to the specific methodology of their respective studies. The lack of consistency and standardisation in the usage of these terms is precisely why the International Classification for Patient Safety was undertaken and why it marks such an important step for the discipline.

²⁹ Thomson et al. “Towards an International Classification for Patient Safety: a Delphi survey.” *Int J Qual Health Care* (2009) 21 9; World et al. (2009) 21 *Int J Qual Health Care* 2.

³⁰ Organization *The conceptual framework for the international classification for patient safety* (2009b).

risk of non-treatment or other treatment.

‘Healthcare-associated harm: harm arising from or associated with plans or actions taken during the provision of healthcare, rather than an underlying disease or injury.’

‘Patient safety incident: an event or circumstance which could have resulted, or did result, in unnecessary harm to a patient.’

The use of the word ‘unnecessary’ in this definition recognizes that errors, violation, patient abuse and deliberately unsafe acts occur in healthcare.

‘Error: failure to carry out a planned action as intended or application of an incorrect plan.’

Errors may manifest by doing the wrong thing (commission) or by failing to do the right thing (omission), at either the planning or execution phase.

‘Violation: deliberate deviation from an operating procedure, standard or rule.’

Both errors and violations increase risk, even if an incident does not actually occur.

‘Risk: the probability that an incident will occur.’

An incident can be a reportable circumstance, near miss, no harm incident or harmful incident (adverse event).

‘Reportable circumstance: a situation in which there was significant potential for harm, but no incident occurred (i.e., a busy intensive care unit remaining grossly understaffed for an entire shift, or taking a defibrillator to an emergency and discovery it does not work although it was not needed).’

‘Near miss: an incident which did not reach the patient (e.g., a unit of blood being connected to the wrong patient’s intravenous line, but the error was detected before the infusion started).’

‘No harm incident: an incident which reached a patient but no discernible harm

resulted (e.g., if the unit of blood was infused, but was not incompatible).’

‘Harmful incident (adverse event): an incident which resulted in harm to a patient (e.g., the wrong unit of blood was infused and the patient died from a haemolytic reaction).’

‘Preventable: accepted by the community as avoidable in the particular set of circumstances.’

‘System failure: a fault, breakdown or dysfunction within an organization’s operational methods, processes or infrastructure.’

‘System improvement: the result or outcome of the culture, processes, and structures that are directed toward the prevention of system failure and the improvement of safety and quality.’

2.2. SAFETY - ‘THE HEART OF HEALTHCARE QUALITY’

Patient safety is, I would contend, the most critical component of quality care.³¹ In the Institute of Medicine’s ‘Crossing the Quality Chasm’ report, six aims for a quality health care system are described – safety being the first.³² It is of course important that any health system also be effective, patient-centred, timely, efficient and equitable. The foremost concern, however, from a patient’s point of view would most likely be the avoidance of harm, making patient safety ‘the heart of healthcare quality’.³³

Robert Wachter, a leading figure in the field, interviewed Lucian Leape, one of the authors of the seminal Harvard Medical Practice Study and regarded as the father of the patient safety movement, as part of the AHRQ WebM&M ‘Perspectives on Safety’ series.³⁴ When asked about the Harvard study, Leape recalled his dismay, at finding out that so many patients suffer adverse events and the surprise in discovering that such a large proportion had been caused by errors. That particular part of the interview

³¹ Vincent (2011) ix.

³² Institute (2001).

³³ Vincent (2011) ix.

³⁴ Network, *Perspectives on Safety: In Conversation with Lucian Leape, MD*, 2006.

is quoted here:

‘Wachter: As you were in the middle of that [Harvard Medical Practice] study, what was your sense of its potential?’

Leape: We always were convinced it was an important study, if nothing else, because of its magnitude. Looking at 30,000 patients gives you some clout. None of us had really thought much about the preventability issue, and nobody knew anything about systems, of course. We weren't completely surprised by our results, because earlier work had shown similar findings. But we were, shall we say, dismayed to find that 4% of patients had adverse events. The surprise for me was that two thirds of them were caused by errors. I'll never forget—I went to the library one day and did a literature search on what was known about preventing errors, and I didn't find anything. And I went to the librarian and said, "I'm interested in how you prevent medical errors, and I've found papers about complications, but nothing much about errors." And I asked her to look over my search strategy because I was not finding anything. She looked at it and she said, "Well, your strategy looks all right. Have you looked in the humanities literature?" And I sort of looked at her and said, "The what?" I know what humanities are, mind you. But it really never occurred to me. So she tried the same search strategy in the humanities literature, and boom, out came 200 papers. I started to read them and discovered James Reason and Jens Rasmussen and all those people. A year later, I came up for air and realized that we in health care could use this. If I didn't know how errors happen, most other people wouldn't know it either. So I decided to write a paper.’

That perspicacious paper, ‘Error in Medicine’, by Leape (with some initial assistance from a medical school librarian) set off the modern patient safety movement. Its publication was not without some resistance, as Leape explains in the interview:

‘Wachter: Talk for a moment about the "Error in Medicine" paper. Was there any sort of back story in getting that published?’

Leape: It was interesting because when I wrote the paper, I showed it to my

colleagues in the Harvard Medical Practice study, and they tried to talk me out of using the word "error." They said, "This is a red-flag word and you'll just turn people off." And I said, "But that's what it's about. You cannot write a paper about error and not talk about it." And sure enough, the New England Journal of Medicine bounced it so fast, I don't even know if they sent it out for reviews. But JAMA took it. George Lundberg [former JAMA Editor] got a lot of negative feedback. Interestingly enough, I got none—no hate mail. It was all directed towards the editor.'

George Lundberg, the editor at JAMA at the time, described the events surrounding its publication as follows:³⁵

'I published Lucian Leape's seminal paper, "Error in Medicine," in JAMA in 1994. Fearing reprisal by the American Medical Association (AMA), I deliberately tried, at the same time, to highlight the paper for the medical profession because of the glaring need, and hide it from the public, choosing a December holiday week for publication.

The strategy failed. National Public Radio and the Washington Post saw it and made a big deal out of it. Cries for my termination quickly arose from angry AMA members who did not believe it and cried out, "Whose side are you on?"

I replied, "The side of science, truth, and all patients."

2.3. LEAPE – ERROR IN MEDICINE

All physicians would like to believe that they are on the side of their patients, none want to see harm come to them, even less so by their own doing. But, that was exactly what was happening. So why then did the high error rates not raise more concern and lead to intensive prevention efforts? Leape posited that the culture of medicine in of itself may have constituted a barrier to acknowledgement of the problem and consequent

³⁵ Lundberg, *At Large at Medscape: Will Medicine Ever Become Safer?*, 2013, <<http://www.medscape.com/viewarticle/814699>>.

action.³⁶ Practitioners are inculcated to accept nothing less than perfection both in diagnosis as well as treatment.³⁷ During their formative years they are taught that mistakes are not tolerated, fostering the expectation of infallibility. An expectation often internalised, to such extent that failure to live up to error free practice is perceived as a moral failure or a defect in one's own character.

2.3.1. THE FLAW IN INFALLIBILITY

A commitment to excellence and the sense of responsibility for one's patient is laudable; however, the individual doctor is rarely directly responsible for all interventions to which a patient is subjected in the course of that patient's encounter with the health care system. Yet, as that patient's caregiver, doctors feel responsible for all errors and assume accountability for any harm that may arise, personally taking on a burden of sole responsibility, illogical as it may be. The most untenable consequence of the emphasis placed on infallibility is the disincentive it creates to be forthcoming about errors.³⁸ The pressure exerted by this unrealistic standard leads to intellectual dishonesty giving rise to an environment in which mistakes are concealed rather than admitted and disclosed. The organisation of medical practice perpetuates the convention. Errors are not revealed nor discussed among colleagues. The, often warranted, fear that admission may result in censure or that they might be deemed, by their peers, to be incompetent or careless, should the mistake come to light discourages voluntary disclosure. If there is anything learnt from the mistake, it is only for the individual doctor's benefit, no objective review takes place and if improvements are made, it is only in isolation.³⁹

The fear of reproach is compounded by the threat of malpractice litigation. It could be said that silence is incentivised. Even the slightest error, made by an otherwise typically diligent physician, can lead to serious injury. Failing to be faultless, in that one instance, can have severe long-lasting consequences. The damage a successful, or even

³⁶ Leape (1994) 272 *JAMA* 1851.

³⁷ Hilfiker "Facing our mistakes." *N Engl J Med* (1984) 310 118.

³⁸ Leape (1994) 272 *JAMA* 1851.

³⁹ *Id.* 1852.

unsuccessful, suit can inflict upon a career or professional reputation, could be devastating; not to mention the financial and emotional toll of such proceedings.⁴⁰

Leape called this paradox into question. All practitioners appreciate that errors are inevitable, yet somehow the standard of medical practice continues to be perfection. Anything less attracts disdain. Surely, most doctors would seize the opportunity to examine and subsequently learn from their mistakes. Unfortunately, adherence to an absurd principle of infallibility, fear of contempt—whether from colleagues or patients, and the threat of litigation, precluded any useful efforts to confront error in medicine.

2.3.2. THE PERFECTIBILITY MODEL

Error prevention in accordance with this approach, relies on, what Leape termed, the ‘perfectibility model’. Blame is assigned to the individual healthcare professional most proximate to the error: the surgeon who performed the surgery, the obstetrician involved with the delivery, the anaesthetist who put the patient under, the pharmacist who supplied the drugs, the nurse who administered the injection, et cetera. Those who are singled out as being responsible for the error, are then either disciplined or forced to submit to additional training. It was thought that training and the fear of professional condemnation and peer disapprobation alone would encourage flawless practice and prevent errors. If an error occurred, it necessarily followed that someone had to be at fault, and whether that fault was due to a lack of attention, skill or caring, someone had to be held accountable. In cases where such an error might be considered to be particularly reprehensible, accountability would be determined by the medical malpractice system, leaving it to the courts to decide whether the mistake amounted to negligence.⁴¹

There is now a growing awareness that this traditional ‘person approach’ to medical error is flawed, in that it fails to appreciate that most errors are made by well-meaning, hard-working and highly-trained professionals.⁴² Reprimanding, denigrating or

⁴⁰ *Ibid.*

⁴¹ *Ibid.*

⁴² Reason “Human error: models and management.” *BMJ* (2000) 320 768.

subjecting these individuals to malpractice litigation will in all likelihood not prevent most errors from occurring again. As Leape notes, those who study error and human performance reject this traditional approach. Instead, it is acknowledged that humans inevitably and frequently err, and systems that rely on faultless human performance are certain to fail. Furthermore, the traditional approach is reactive, as errors are typically only detected after the iatrogenic sequelae thereof have become apparent. Counteractive efforts intended to prevent the reoccurrence of errors, are then directed toward specific individuals so as to try and stop them from making the same mistake again. The underlying causes of the error are rarely examined when corrective measures are exclusively aimed at the professional nearest to the eventual outcome of the error.⁴³

2.3.3. ERROR PREVENTION IN OTHER HIGH-RISK INDUSTRIES

Leape rejected the traditional 'person approach' to medical error, drawing instead from lessons learned in psychological and human factors research that have found application in other high-risk environments and industries:

'...if physicians, nurses, pharmacists, and administrators are to succeed in reducing errors in hospital care, they will need to fundamentally change the way they think about errors and why they occur. Fortunately, a great deal has been learned about error prevention in other disciplines, information that is relevant to the hospital practice of medicine.'⁴⁴

Leape proceeded to provide a synopsis of some of the fundamental principles of cognitive psychology, particularly the contributions of Jens Rasmussen and James Reason, thereby succeeding in introducing their work to a broader medical audience.⁴⁵

⁴³ Leape (1994) 272 *JAMA* 1853.

⁴⁴ *Ibid.*

⁴⁵ *Ibid.*; Rasmussen and Jensen "Mental procedures in real-life tasks: a case study of electronic trouble shooting." *Ergonomics* (1974) 17 293; Reason "Human Error" (1990) 302.

3. EXPLAINING HUMAN ERROR

3.1. INTRODUCTION

Research into human error has proliferated over the past few decades.⁴⁶ Technological advances that emerged during and after World War II have introduced potential hazards, of such nature and scale, with consequences of accidents so devastating, that error-prevention had to be prioritised.⁴⁷ Public concern, following numerous high-profile accidents, also served as catalyst for the methodical investigation of human error.⁴⁸ Reason refers to a few of these tragic accidents: ‘the Tenerife runway collision in 1977, Three Mile Island two years later, the Bhopal methyl isocyanate tragedy in 1984, the Challenger and Chernobyl disasters of 1986, the capsizing of the Herald of Free Enterprise, the King’s Cross tube station fire in 1987 and the Piper Alpha oil platform explosion in 1988.’⁴⁹

Disasters have occurred throughout history, however, most of these events were confined and only affected those in the immediate vicinity thereof. These days, the aftermath of disasters can be catastrophic, especially in industries where more hazardous technologies are harnessed, such as nuclear power. A catastrophic human error at a nuclear power station, oil rig or chemical plant, for instance, could have an impact on entire continents for several generations. In the preceding pages, we have seen how many lives are affected by errors in medicine.⁵⁰

3.2. CAUSAL CLASSIFICATION OF ERROR

⁴⁶ Reason (1997) 266; Reason and Hobbs *Managing Maintenance Error: A Practical Guide* (2003); Woods et al. *Behind Human Error* (2012); Leveson *Engineering a Safer World: Systems Thinking Applied to Safety (Engineering Systems)* (2012); Amalberti “Navigating Safety” (2013) 132; Hollnagel *Safety-I and Safety-II: The Past and Future of Safety Management* (2014); Sidney “Safety Differently” (2014); Braithwaite et al. “Resilient Health Care, Volume 3” (2016) 236; Reason “Organizational Accidents Revisited” (2016) 160.

⁴⁷ Dekker *The Field Guide to Understanding ‘Human Error’* (2014b) 13.

⁴⁸ Reason (1990) 1.

⁴⁹ *Ibid.*

⁵⁰ *Ibid.*

Errors can be classified according to their consequences or by their presumed causes.⁵¹ Consequential classification has been widely used in medicine, whereby the most proximate action which contributed to the erroneous outcome is used as a descriptor. So, by way of illustrating, the error is described relative to the action, e.g. administration of an improper dose of medicine or a failed intubation. By contrast, causal classification is more concerned with discerning the psychological processes which produced the error. Errors almost always involve some kind of deviation in mental functioning. Reason quotes, Ernst Mach who described the relationship between error forms that have their origin in fundamentally useful psychological processes as follows: 'Knowledge and error flow from the same mental sources, only success can tell the one from the other'.⁵² Correct performance and systematic errors are two sides of the same 'cognitive balance sheet', as Reason puts it.⁵³ When one considers the variety of errors that can occur during relatively simple tasks (anyone that has ever attempted to make fudge would know) it comes as quite a surprise to learn that errors actually take an unexpectedly limited number of forms.

3.2.1. SLIPS, LAPSES AND MISTAKES⁵⁴

Errors can be divided into two causally determined groups: Slips and lapses, which are errors of action, and mistakes, errors of knowledge and planning.

Slips and lapses are failures of execution, in that the plan is adequate, but the related action did not follow as intended. Slips are observable actions, associated with failures of attention, whereas, lapses are more internal events and are associated with memory or recollection failures. In the case of slips and lapses, actions deviate from the intended progression. This deviation is mostly seen during the performance of routine tasks, in the course of automatic skill-based activities, usually taking place in familiar surroundings. The unintended acts that make up slips are almost always attributable to 'attentional capture', in the form of a distraction arising from the immediate surroundings or a preoccupation whilst having something else in mind. An unexpected change in plan

⁵¹ Reason "Understanding adverse events: human factors." *Quality and Safety in Health Care* (1995) 4 80.

⁵² Reason (1990) 1.

⁵³ *Id.* 2.

⁵⁴ *Id.* 12; Reason (1995) 4 *Quality and Safety in Health Care* 80.

or environment can induce a slip or a lapse. The most common example of an error falling under this group, is where you 'automatically' drive to work on a Sunday. In a healthcare setting, if you intend to write an order, but fail to do so due to another matter requiring your attention, such omission would constitute a slip. Slips are more likely to occur when attentional control is diverted, by factors such as: fatigue, sleep loss, stress, frustration, anxiety, heavy workload etc.

Mistakes on the other hand are failures of intention, in that the actions may go entirely as intended and according to plan, but the initial plan itself was wrong and will subsequently not have the intended outcome. The failure here lies at a higher level and involves incorrect choices. Mental processes associated with planning, formulating intentions, judging and problem solving, contribute to the error. Mistakes can ensue when practitioners have insufficient knowledge, experience, training, or information. So, for example, it would be a mistake if a doctor treats a patient with chest pain as if they have a myocardial infarction, when that is in fact not the case.⁵⁵

Mistakes can be further subdivided into two groups: rule-based mistakes and knowledge based mistakes. Rule-based mistakes occur when a person already possesses a previously assimilated solution, a rule or procedure acquired by way of training or experience. Experts, such as medical professionals, have a much larger collection of problem-solving rules than novices. A practitioner would be making a rule-based mistake if he or she applies the wrong rule, for instance, treating a patient for asthma when the guidelines for pneumonia should be followed. A rule-based mistake also occurs when a bad rule is applied (e.g. treating a patient in accordance with unsound practice guidelines), or where a good rule is not applied (e.g. not following the correct clinical procedure).

Knowledge-based mistakes occur in unfamiliar situations, where problems have to be resolved on the spot without the aid of pre-packaged solutions. These mistakes are much more complex and require 'slow, resource-limited but computationally-powerful

⁵⁵ Vincent (2011) 133.

conscious reasoning'. They are caused by a lack of knowledge or misinterpretation of the problem. Previously acquired 'mental models', rules or procedures cannot be relied on. For instance, a doctor might not know the clinical presentation of a specific illness, may not be able to distinguish between two or more possible diagnoses or may have to take speculative action in order to prevent haemorrhage during surgery.

3.2.2. VIOLATIONS⁵⁶

A distinction is also made between errors and violations. Violations are intentional deviations from safe operating practices, protocols, standards, procedures or rules.⁵⁷ Violations are deliberate, however, these actions are not intended to have a bad outcome, they are merely meant to circumvent the rules, usually for expediency. Violations fall into three groups. Routine violations, involve cutting corners whenever possible, perhaps to save time or in order to move on to another more urgent task. Optimising violations, further personal rather than task related aims, e.g. leaving work early, or performing a procedure without supervision so as to gain experience. Necessary or situational violations, occur when rules or procedures are judged to be inappropriate under the present circumstances, so a rule is flouted to get the job done.

Violations differ from errors in a number of significant respects. Whereas, errors occur largely due to informational problems (forgetfulness, deficient knowledge, etc.), violations have more to do with motivational problems (working conditions, low morale, inadequate incentives, etc.). Errors elucidate the thought processes of an individual, whereas violations are associated with the particular social context. Errors can be avoided by improving the quality and the way in which information is conveyed in the workplace, however, violations require interventions that address attitude and motivation, as well as organisational culture rectifications.

⁵⁶ Reason (1990) 195.

⁵⁷ Amalberti et al. "Violations and migrations in health care: a framework for understanding and management" *Quality and Safety in Health Care* (2006) 15 i66.

3.2.3. ACTIVE AND LATENT FAILURES⁵⁸

An important final distinction is made between active failures and latent failures. The difference essentially pertains to the period of time that elapses before the adverse consequences of the human error set in and affect safety. When an active failure occurs, the impact of the error is almost immediately apparent. Whereas, with latent failures the repercussions of the error may remain undetected within a system for an extended period, only becoming evident once combined with other factors to breach the system's defences.

Active failures occur at the so-called 'sharp end' of the system, they encompass unsafe acts (errors and violations) committed at the human-system interface (surgeon, anaesthetist, nurse) and often have immediate adverse outcomes.

Latent failures are removed, both in space and time, from the direct control interface. They are created at a different, frequently higher level in the system or organisation. Latent failures have their origins in activities or decisions of designers, managers, high-level policymakers, maintenance workers etc.

Analyses of recent accidents and disasters (i.e. Bhopal, Chernobyl, Challenger) have made it abundantly clear that latent errors pose the greatest threat to the safety of a complex system. Where accident investigations in the past have mostly focussed on operator error and equipment failures, it has come to be realised that the root-cause of many errors lie in defects that were integrated and present within the system long before the active operator error took place. Rather than being the main instigators of errors, those at the 'sharp end' of the system, are often inheritors of system defects created by poor design, incorrect installation, faulty maintenance and bad management decisions. In a healthcare context, such inherited system defects may include, excessive workloads, long shifts, understaffing, overcomplicated or unstandardized equipment etc.

⁵⁸ Reason (1990) 198.

It would be futile to target active errors or unsafe acts in isolation. System safety can only be improved if the underlying initiating causes of errors are identified and neutralised. Addressing latent failures will have much more of a beneficial impact on system safety than localised efforts aimed at averting active failures.

3.3. PERSON- VS SYSTEM APPROACH⁵⁹

Whereas, the 'person approach' focusses on the unsafe acts (errors and violations, resulting in active failures), believing their origin to be found in aberrant mental processes such as, forgetfulness, inattention, poor motivation, carelessness, negligence, and recklessness. The fundamentally different, 'systems approach' submits that safety is dependent on systems that anticipate errors (which are accepted as being inevitable), and are thus designed to prevent or catch errors before they cause harm.

Experts have realised that the human condition cannot be changed, but the conditions humans work under can be. It might be preferable, from an institutional responsibility or managerial standpoint, to impute the consequences of an unsafe act unto a specific individual. It is perhaps, also legally more convenient to single out a negligent individual who shall bear the damages. However, blaming and shaming those that erred, although perhaps emotionally satisfying, will almost certainly not be an effective safety improvement strategy. For this reason, system defences have been introduced in almost all high-risk industries. Healthcare is now coming around to this idea, recognising that the 'person approach' to human error is remarkably ill-suited to medicine and may very well be an impediment to safer care.

The 'person approach' impedes the establishment of a reporting culture, which is considered essential for effective risk management. A reporting culture allows for incidents to be analysed, possibly revealing recurrent errors and enabling organisations to implement defences, barriers and safeguards to counteract their reoccurrence. These defences, barriers and safeguards are the cornerstones of the 'system

⁵⁹ Reason (2000) 320 *BMJ* 768.

approach'. When an accident occurs, the foremost concern is not the individual that erred, but rather how and why the system defences failed.

3.4. REASON'S SWISS CHEESE MODEL⁶⁰

Reason's 'Swiss cheese model' of accidents causation was developed following numerous analyses of preventable accidents in industries as varied as nuclear energy and commercial aviation, and has come to be widely embraced as a mental model for system safety.

During his investigations, Reason found that isolated 'sharp end' errors committed by individuals in complex safety-conscious systems are rarely the cause of catastrophic safety failures. Instead, harm materialises when a number of smaller, less severe errors breach underlying flawed system defences. These system defences are often layered and can be dependent upon engineered barriers (alarms, automatic shutdowns, barcodes, automation, etc.), 'sharp end' operators (surgeons, anaesthetists, nurses, etc.), protocols and administrative controls.

Reason uses the image of slices of Swiss cheese to illustrate this concept. The protective layers (slices of Swiss cheese) include their own flaws (holes in the cheese, active failures and latent conditions), when these flaws in the defensive layers (or holes in the Swiss cheese slices) align, it allows for the error to pass through, causing the adverse event.

The model's lucid simplicity, enables one to quickly visualise and grasp system safety, giving it immense explanatory power. What this model clearly demonstrates, is that there should be less of an emphasis on achieving human infallibility (a futile endeavour) and more of an emphasis placed on identifying holes in the Swiss cheese slices, ensuring that the holes can be shrunk and the layers overlapped so that the holes subsequently never line up (eliminating the error trajectory). The 'root causes' of medical errors, or the underlying conditions that precipitated the unfortunate outcome,

⁶⁰ Reason (1990) 208; Reason (2016) 2.

must be dissected. Unlike active failures, these underlying or latent conditions can be identified and rectified before an adverse event occurs. Thereby, allowing for proactive rather than reactive risk management.

3.5. AETIOLOGY OF AN ORGANISATIONAL ACCIDENT

Reason summarised the aetiology of an organisational accident, paraphrased as follows:⁶¹

‘The adverse event progression begins with fateful consequences of organisational processes (e.g. decisions on planning, scheduling, forecasting, policy-making, designing, rostering, specifying, communicating or maintaining). The latent failures instigated thereby are passed on along various organisational and departmental avenues to the workplace (the pharmacy, operating room, ward or intensive care unit), where they produce the local conditions that promote the commission of errors and violations (e.g. understaffing, fatigue, technical problems, poor human equipment interfaces, heavy workload, poor communication, inadequate supervision, training deficiencies, inexperience, poor teamwork and unnecessary distractions). Although errors occur often, the majority are without consequence and are caught by defences, barriers and safeguards. However, in very few instances, they can breach these defences to produce harmful outcomes. The more deficient the defences are, the greater the chance that proximal errors will cause harm.’

Although it might seem that this model merely attributes blame to those at the ‘blunt-end’ of the system, exculpating the operators at the ‘sharp end’ and shifting the blame, it is not the case, as the decisions made at the higher levels are also subject to financial, political and operational compromises. It is inevitable that many of these organisational constraints will have negative safety consequences, introducing latent conditions or ‘pathogens’ into the system. This model appreciates that accidents may have their roots

⁶¹ Reason (1995) 4 *Quality and Safety in Health Care* 82; Reason “A systems approach to organizational error” *Ergonomics* (1995) 38 1708.

in flaws outside of the confines of the healthcare organisation, regulatory, political and economic factors can create a conducive environment and affect patient safety. While it may be impossible to eliminate the underlying ‘pathogens’, it is possible to detect them before they combine with local triggers to penetrate the system’s defences.⁶²

3.6. ‘ROOT CAUSES’-FRAMEWORK⁶³

Vincent *et al.* derived their widely-used framework from Reason’s model of organisational accidents, adapting it to the healthcare context. They have classified error producing conditions and organisational factors into a single broad ‘root causes’-framework. It consists of seven factors or levels of safety:

Patient Factors – The patient’s condition will be the most important determinant of clinical practice and outcome. The complexity and severity of the disease will have a significant impact on treatment. Additional factors, related to the patient, such as language, personality and psychological problems, can affect communication with healthcare personnel and increase the likelihood of an adverse event.

Task and Technology Factors – Clearly structured and designed tasks, coupled with readily available, straightforward protocols and accurate test results, assist in the provision of quality care.

Individual Staff Member Factors – Experienced, skilled, competent and motivated staff members influence patient outcomes. A lack of knowledge, fatigue and stress can obviously have dire healthcare consequences.

Team Factors – Individual staff members are part of teams, both within their unit and the broader organisation of the hospital or health service. Clinical care is constrained and influenced by other members of the team. The way in which team-members communicate, assist and supervise each other will impact the provision of care.

⁶² Reason (1995) 4 *Quality and Safety in Health Care* 83.

⁶³ Vincent et al. “Framework for analysing risk and safety in clinical medicine.” *BMJ* (1998) 316 1154.

Work environmental factors – Decisions made at higher levels in the organisation will in turn have consequences for the team. Management decisions affect staffing levels, skills mix, shifts and workload, as well as the availability and maintenance of equipment. Administrative support and policies regarding training and supervision are also critical to safety efforts.

Organisational and Management factors – Financial resources and constraints, the organisational structure, policy standards and goals, and a safety culture with the associated priorities, all have an effect on the wider work environment.

Institutional context factors – The organisation is affected by the institutional context: regulatory bodies, the prevailing medico-legal environment, as well as the overall economic and political climate. Problems that contribute to errors arise when regulators do not prioritise safety issues or if legal pressures prevent open discussion, hindering learning opportunities.

This framework provides the conceptual basis for the systematic investigation and analysis of clinical accidents. It considers accidents as a whole, taking into account a range of factors, those to do with clinical practice and those at higher organisational-levels that may have contributed to the adverse outcome. Information about the incident can be gathered from several sources, including medical records, witness-statements, and other relevant documents. Structured interviews with medical personnel are also important and very useful to establish the primary complication, sequence of events, as well as contributory factors from each team members point of view

3.7. ANALYSING ERRORS USING THE SYSTEM APPROACH

‘Error management has two components: limiting the incidence of dangerous errors and—since this will never be wholly effective— creating systems that are

better able to tolerate the occurrence of errors and contain their damaging effects.⁶⁴

In applying a system approach to error management, rather than a person approach that aims to make individuals less fallible, several aspects or components involved in health care delivery are targeted.⁶⁵ The system approach provides a framework for the analysis of errors and the improvement of safety. Several specific methods of error analysis exist, encompassing both retrospective (e.g. 'root cause analysis' or systems analysis) and prospective methods (e.g. failure modes effect analysis). These methods vary in orientation, theoretical basis and basic approach, but each one aims to uncover factors that contributed to the final accident. An extensive examination of all the different methods would be superfluous. A few methods are, nonetheless, considered here for purposes of the discussion.

3.7.1. RETROSPECTIVE METHODS

3.7.1.1. ROOT CAUSE ANALYSIS

In the United States, the Joint Commission's Sentinel Event Policy requires accredited health care organisations to conduct a 'comprehensive systematic analysis' after the occurrence of a sentinel event.⁶⁶ A sentinel event is defined as: 'a patient safety event (not primarily related to the natural course of the patient's illness or underlying condition) that reaches a patient and results in death, permanent harm, or severe temporary harm'. Root Cause Analysis is the most widely used analytical tool and the preferred

⁶⁴ Reason (2000) 320 *BMJ* 768.

⁶⁵ Reason "Comprehensive error management in aircraft engineering: A manager's guide" (1995); Helmreich et al. "The evolution of Crew Resource Management training in commercial aviation." *Int J Aviat Psychol* (1999) 9 19; Vincent *Clinical Risk Management* (1999); Helmreich "On error management: lessons from aviation." *BMJ* (2000) 320 781; Helmreich et al. "Culture, error and crew resource management" *Improving teamwork in organizations: Applications of resource management training* (2001) 305331; Youngberg "Principles of Risk Management and Patient Safety" (2010) 504; Spath *Error reduction in health care: A systems approach to improving patient safety* (2011); Müller et al. "Aviation Risk and Safety Management" (2014) 213; Merkle "Risk Management in Medicine" (2015) 159; Glendon and Clarke "Human Safety and Risk Management" (2015) 474.

⁶⁶ Commission *Root cause analysis in health care: tools and techniques* (2015).

method of the Joint Commission.⁶⁷ A Root Cause Analysis attempts to identify the basic or causal factors that led to the adverse outcome, with a primary focus on systems and processes, rather than individual performance.⁶⁸ It is designed to answer the following three questions: What happened? Why did it happen? And what can be done to prevent it from happening again?⁶⁹

3.7.1.2. THE YORKSHIRE CONTRIBUTORY FACTORS FRAMEWORK

Various other frameworks have been applied, including: the Eindhoven classification⁷⁰, WHO patient safety classification⁷¹, the London Protocol⁷², the Veterans Affairs Root Cause Analysis System⁷³, and the Australian Incident Monitoring System (AIMS)⁷⁴. Lawton *et al.* in their systematic review, have drawn attention to the fact that these frameworks either, lack an adequate empirical basis, or have been developed in non-healthcare environments and may, accordingly, not be entirely suited for use in the clinical context.⁷⁵ By reviewing the evidence, accumulated over the past two decades, they managed to identify a framework of contributory factors, consisting of 20 key domains, that could be applied to evaluate safety incidents in hospital settings. Although, this framework can be criticised for being more complex, as it is comprised of a greater number of domains compared to others, it does encompass a more comprehensive scope of contributory factors and places a greater emphasis on system, rather than individual failures. The authors suggest that the framework will allow for the

⁶⁷ Bagian et al. "The Veterans Affairs root cause analysis system in action" *The Joint Commission journal on quality improvement* (2002) 28 531; Joint and Inc *Root cause analysis in health care: tools and techniques* (2005).

⁶⁸ Bagian et al. "Developing and deploying a patient safety program in a large health care delivery system: you can't fix what you don't know about" *The Joint Commission journal on quality improvement* (2001) 27 522; Wu et al. "Effectiveness and efficiency of root cause analysis in medicine." *JAMA* (2008) 299 685.

⁶⁹ Andersen and Fagerhaug *Root cause analysis: simplified tools and techniques* (2006).

⁷⁰ Van Vuuren et al. *The development of an incident analysis tool for the medical field* (1997).

⁷¹ Organization (2009b).

⁷² Taylor-Adams et al. "Systems analysis of clinical incidents: the London protocol" *Clinical Risk* (2004) 10 211.

⁷³ Bagian et al. (2002) 28 *Jt Comm J Qual Patient Saf* 531.

⁷⁴ Runciman et al. "The Australian Incident Monitoring Study. Errors, incidents and accidents in anaesthetic practice." *Anaesth Intensive Care* (1993) 21 506.

⁷⁵ Lawton et al. "Development of an evidence-based framework of factors contributing to patient safety incidents in hospital settings: a systematic review." *BMJ Qual Saf* (2012) 21 369.

greater detection of contributory factors and substantially improve our ability to learn from them.

3.7.2. PROSPECTIVE METHODS

Error analysis can also be approached from a prospective perspective. This approach finds its origin in the field of Human Reliability Analysis (HRA)⁷⁶, which has been accepted and integrated into the safety management process in other industries for decades, and has now come to be used in healthcare.⁷⁷ Rather than examining an error and the events that led up to it after the incident had occurred, here we start with a process of care and systematically evaluate it to expose possible failure points. An understanding of the risks or latent conditions is required if effective mitigation strategies are to be implemented. The ultimate objective, is the improvement of reliability and safety. An important aspect of HRA is human error quantification, which can produce error probabilities, enabling us to estimate the likelihood of adverse consequences. This can be used as part of a probabilistic risk assessment (PRA), providing numerical estimates of error probability and giving us a complete picture of overall human and equipment failure. Quantification, promises more accurate prediction and ultimately safer systems. These techniques are rarely used in healthcare but have been utilised by the field of anaesthesia. There is considerable scope for wider application thereof.

Various techniques exist. One such technique, possibly the most well-known and most common in healthcare, Failure Modes and Effects Analysis (FMEA), was developed in 1949 by the US military and was used by NASA in the 1960s during the Apollo Space Program.⁷⁸

⁷⁶ HRA is defined as the application of relevant information about human characteristics and behaviour to the design of objects, facilities, and environments that people use.

⁷⁷ Lyons et al. "Human reliability analysis in healthcare: A review of techniques" *Int J Risk Saf Med* (2004) 16 223.

⁷⁸ Vincent (2011) 158.

3.7.2.1. FAILURE MODES AND EFFECTS ANALYSIS

The FMEA method of analysis is recommended by the UK National Patient Safety Agency (now part of NHS Improvement), the Joint Commission on Accreditation of Healthcare Organizations (Requirement LD.5.2) and the US Veterans Health Administration.

The Veterans Affairs National Center for Patient Safety has adapted this method specifically for healthcare, developing it into a hybrid prospective risk analysis system, known as Health Care Failure Mode and Effect Analysis (HFMEA).⁷⁹

‘HFMEA is a 5-step process that uses an interdisciplinary team to proactively evaluate a health care process. The team uses process flow diagramming, a Hazard Scoring Matrix, and the HFMEA Decision Tree to identify and assess potential vulnerabilities. The HFMEA Worksheet is used to record the team’s assessment, proposed actions, and outcome measures. HFMEA includes testing to ensure that the system functions effectively and new vulnerabilities have not been introduced elsewhere in the system.’

The idea behind prospective analysis and the promise it holds, is that incidents or failures can be prevented before they happen. Healthcare, with all its complexities and intricacies, abounds with opportunity for error, which stands to inhibit the effectiveness of such a resource intensive and expensive process, if it were to be performed in isolation. Vincent suggests that the judicious application of both prospective and retrospective methods of analysis would be most beneficial, offering a window into the system, by exposing vulnerabilities and providing guidance regarding factors, that would need to be confronted if we were to achieve a safer healthcare system.⁸⁰

These forms of analysis, whether Root Cause or FMEA, generally do seem sensible and are applied in other high-risk industries. However, there are concerns regarding

⁷⁹ DeRosier et al. (2002) 28 *Jt Comm J Qual Improv* 248.

⁸⁰ Vincent (2011) 165.

reliability, and efficacy in health care has yet to be fully demonstrated.⁸¹ The evidence is not yet clear, and would require further research, formal testing and evaluation.

4. CONCLUSION

The 'perfectibility model', which follows the 'person approach' pervades health care, however, in recent years it has come to be challenged, and we have begun to see a transition toward a 'system approach'. Medicine was slow to acknowledge the prevalence of error, and in instances where mistakes have been acknowledged, erring individuals were confronted and sanctioned, which has had a minimal effect on prevention. Much of our knowledge of error has come from other disciplines, including human factors and cognitive psychology. More recently, we have learned how to better manage error by turning to High-Reliability Organisations that function within hazardous industries, for guidance. Their reliance on 'mindful organisation' and especially their preoccupation with fostering a Safety Culture, may hold valuable lessons for healthcare. As such, High-Reliability Organisations, as a model for healthcare, and the all-important Safety Culture are discussed in the following chapter.

⁸¹ Wu et al. (2008) 299 *JAMA* 685; Percarpio et al. "The effectiveness of root cause analysis: what does the literature tell us" *Jt Comm J Qual Patient Saf* (2008) 34 391; Shebl et al. "Is failure mode and effect analysis reliable" *J Patient Saf* (2009) 5 86.

CHAPTER 5. HIGH-RELIABILITY ORGANISATIONS AND SAFETY CULTURE

1. INTRODUCTION

Our understanding of errors and how adverse events are caused greatly exceeds our knowledge of how they might be best avoided. We know more about failures than we do of successes. However, in recent years, researchers have examined organisations with exemplary safety records to gain insight into how they have managed to function so reliably even though they operate in particularly complex, hazardous domains.¹ A few of these ‘high-reliability organisations’, as they are known, have been studied, including aircraft carriers, air traffic control systems, and nuclear power plants.² Although seemingly far removed from medicine, these organisations embrace specific cultural attributes that could be of great value in healthcare settings.³ That these high-reliability organisations for extended periods of time, manage to meet their objectives without tragic failure or serious incident, makes the lessons that could be learned from them highly attractive and relevant to clinical practice, where risks are ever present and consequences just as dire.⁴

There are several parallels between Healthcare institutions and high-reliability organisations. Both are dynamic, complex, adaptive and interactive. Exacting tasks are often performed by highly trained individuals, in teams, under considerable pressure

¹ Weick “Organizational culture as a source of high reliability” *California management review* (1987a) 29 112; Weick et al. “Organizing for high reliability: Processes of collective mindfulness” *Research in organizational behavior* (1999) 21 23.

² Weick and Sutcliffe “Managing the Unexpected” (2015) 224.

³ Chassin and Loeb “The ongoing quality improvement journey: next stop, high reliability.” *Health Aff (Millwood)* (2011) 30 559.

⁴ Hudson “Applying the lessons of high risk industries to health care” *Quality and safety in health care* (2003) 12 i7.

and variable circumstances.⁵ Whereas high-reliability organisations frequently go years without suffering a significant accident, similar consistently high levels of safety have thus far eluded us in healthcare, instead, we are faced with an epidemic of preventable adverse events. Weick and Sutcliffe have identified five characteristics that high-reliability organisations share, which enable them to withstand demanding conditions and persistently have fewer than their fair share of failures.⁶ These five characteristics or hallmarks, make up what they have termed ‘mindful organising’:

2. MINDFUL ORGANISING – FIVE CHARACTERISTICS OF HIGH RELIABILITY ORGANISATIONS⁷

2.1. PREOCCUPATION WITH FAILURE⁸

In high reliability organisations, there is a need for continual awareness regarding irregularities, as these may be symptoms of larger problems in the system, precursors to failure. Everyone in the organisation is constantly mindful of the potential for failure. There is an active effort to detect small, emerging failures that could signal the presence of additional failures somewhere else in the system. They work hard to anticipate and prevent significant threats, avoiding mistakes they do not want to make.

People in these organisations also appreciate that they have incomplete knowledge about the situation, environment and their own group. They remain vigilant and refrain from ‘normalising the unexpected’, staying sceptical and wary instead. When ‘near-misses’ occur, they should be viewed as failures. One should not become complacent just because a safeguard happened to catch a potential mishap. A near miss should be interpreted as a ‘danger in the guise of safety rather than safety in the guise of danger’.

⁵ Sutcliffe “High reliability organizations (HROs)” *Best Practice & Research Clinical Anaesthesiology* (2011) 25 133.

⁶ Weick and Sutcliffe (2015) 224.

⁷ *Ibid.*

⁸ *Id.* 45.

2.2. RELUCTANCE TO SIMPLIFY⁹

Mindful organisation recognises the importance of variety and realises those actions and descriptions that can obscure or diminish complexity. The authors note that: ‘Simplification obscures unwanted, unanticipated, unexplainable details and in doing so, increases the likelihood of unreliable performance.’ This includes anomalies and finer-details that may contain warning signs which may be concealed when one relies on generalisations, types and categories. The authors cite the misidentification of the West Nile virus as an example, of where the smoothing over of fine-grained distinctions managed to veil unexpected trouble. The simplification of an unusual assortment of symptoms, resulted in a tentative diagnosis of St. Louis Encephalitis (SLE), which proved to be incorrect. The initial diagnosis disregarded evidence contrary thereto. Muscle weakness, one of the most notable symptoms, had never been associated with SLE. Birds and horses were also affected, which would not be the case with SLE. By simplifying early on, the investigators missed relevant information which would have made the overall picture much clearer.

Mindfulness, emphasises context and detail, slowing down our tendency to view things as similar, allowing us to detect differences more readily. By identifying more differences, we can anticipate more varied consequences, which can shed light on a greater number of warning signs, enabling us to take additional precautions.

The Columbia shuttle disaster serves as another cautionary example of the dangers of simplification. NASA were criticised by the Columbia Accident Investigation Board for making themselves guilty thereof. A section titled ‘Avoiding Oversimplification’ was included in their final report. The authors suggest that to organise for reluctant simplification, would entail organising for more process variety, more openness to argumentation, and more capability and willingness to act in order to understand.

2.3. SENSITIVITY TO OPERATIONS¹⁰

⁹ *Id.* 62.

¹⁰ *Id.* 77.

Interdependence is linked to limited concepts. When you do something, you change yourself and the context around you. This realisation and the extent to which you realise this, determines your sensitivity to the fact. Sensitivity to operations, pertains to the work itself, what is actually occurring regardless of intentions, designs, and plans. The two basic reliability mandates of operations are: keep the events flowing and protect the system (e.g. deal with a haemorrhage during surgery, whilst performing the intended operation).

Sensitivity to operations has to do with what is going on right now, in the present, what is sometimes referred to as 'situational awareness'. It is the ever-present awareness about the state of the systems and processes that influence patient care. Hospital managers and clinicians who understand the 'big picture' are able to detect errors in a timely manner and implement improvements before an adverse event occurs. They consider all the components and aspects of the work, the interdependence within the larger organisation, and how failure in one part of the system can spread to another.

This principle also emphasises the threat that small changes in the organisation's operations can pose, and that those on the front lines who are immediately involved are best placed to report any deviations from expected performance. To counter this threat, high reliability organisations ensure that staff are not hesitant to disclose any concerns, free and open communication is instead valued. In fact, personnel are obliged to report potential problems, considering that such information allows the organisation to operate safely, which is the highest priority.

2.4. COMMITMENT TO RESILIENCE¹¹

'The signature of a high reliability organization (HRO) is not that it is error-free, but that errors don't disable it.' Resilience refers to the capacity of a system to, maintain its processes and operations, absorb disturbances and remain resolute, and effectively adjust after a disruption, allowing it to continue functioning in the face of adverse

¹¹ *Id.* 94.

consequences. Put simply it involves: adapting to disruptions; maintaining critical operations or structures; and continuing to function, albeit to a lesser extent.

Resilience differs from anticipation. Anticipation entails accurate identification of potential problems, so that specific solutions can be put in place to avert any future damage. Whereas resilience has to do with what happens after the problems occurred and with how the damage is managed. It entails minimising the effects of errors, devising work-arounds to keep the system functioning, and absorbing change while persevering.

Resilience requires elasticity and recovery, which may call for improvisation. The better one is at improvising, the better one is able to react to a variety of surprises. When confronted with an unpredictable situation, the ability to improvise, increases the potential actions that one may take, possibly allowing for a better outcome. As an example, Weick and Sutcliffe cite the beneficial impact that the addition of a pharmacist, to a team of doctors and nurses making rounds in an intensive care unit, had upon medication errors. A reduction of 66% was observed. The authors contend that by expanding its arsenal of capabilities, the medical team were able to notice more mistakes and correct them before they led to adverse events.

Resilience is needed when there is a lapse in reliability. As was the case with United Airlines flight 232, where an engine, embedded in the tail, exploded; shrapnel from the fan blades severed and drained all three hydraulic systems. Through their combined resilience, the benefit of their Crew Resource Management (CRM) training, and richer repertoire of abilities they managed to bring the aircraft to the ground, 184 of 285 people survived. This situation called for rapid real-time learning, thus allowing individuals to manage unfolding volatile situations in ways that are not determined in advance. Resilient organisations recognise errors quickly and contain them even quicker. In so doing they manage to prevent the major repercussions that an amalgamation of minor errors may hold.

2.5. DEFERENCE TO EXPERTISE¹²

In reliable organisations decisions migrate to individuals with relevant expertise. The problem attracts and creates its own hierarchies. Those with specific knowledge are called upon to alleviate the problem. Formalised hierarchal constraints or chain of commands may stand in the way of a solution bearer, who may be the one closest to the problem, albeit, with a lower rank.

This does not mean that deference is the same as submission. Instead, there is a 'respectful yielding', individuals in high reliability organisations are aware of the limits of their knowledge or experience. Some skills are 'domain-specific' and may rely on first-hand experience or experienced-based knowledge, rather than a thorough theoretical understanding. When a new threat arises, these organisations have mechanisms in place to see to it that the individual with the greatest expertise regarding that particular threat is well-placed to deal with it. That individual then has decision-making authority. The organisation understands that the most senior or highest-ranked person will not necessarily be the most effective at dealing with the threat or problem.

Weick and Sutcliffe describe it as follows:

'organizations striving for higher reliability shift their decision dynamics, authority structures, and functional patterns to create the potential for a flexible response to changing circumstances. A flexible response is built partly from migrating decisions, but also from strong cultures and collective beliefs that the capabilities lie somewhere in the system and that problems will find them. When people defer to expertise, they remain alert to at least two assumptions that could be wrong: first, that authority equates to expertise; second, that the higher one goes in a hierarchy, the greater the expertise.'

¹² *Id.* 112.

3. ORGANISATIONAL CULTURE

The culture of an organisation is perhaps the one overriding factor that can predispose all its systems and processes to either failure or success.¹³ Schein defines the culture of a group as ‘a pattern of shared basic assumptions learned by a group as it solved its problems of external adaptation and internal integration, which has worked well enough to be considered valid and, therefore, to be taught to new members as the correct way to perceive, think, and feel in relation to those problems’.¹⁴

Organisational culture consists of the core values, beliefs, norms and shared basic assumptions that are developed and embraced within a specific group as it continually learns to manage and respond to its challenges. It can incorporate mindfulness; the five principles as individually discussed above, taken together as a whole.¹⁵

3.1. SAFETY CULTURE

One of the key recommendations of the IOM report was, that healthcare organisations must develop a ‘culture of safety’. The report stated that: ‘Safety should be an explicit organizational goal that is demonstrated by the strong direction and involvement of governance, management and clinical leadership’.¹⁶

Safety culture is a component of organisational culture. As a concept, it is difficult to define.¹⁷ A definition, first introduced by the Advisory Committee on the Safety of Nuclear Installations, is often quoted and is frequently used in the context of patient

¹³ Weick “Organizational culture as a source of high reliability” *California management review* (1987b) 29 112; Schulman “General attributes of safe organisations” *Quality and Safety in Health Care* (2004) 13 ii39; Weick et al. “Organizing for high reliability: Processes of collective mindfulness” *Crisis management* (2008b) 3 81.

¹⁴ Schein “Organizational Culture and Leadership” (2010) 18.

¹⁵ Weick and Sutcliffe (2015) 129.

¹⁶ Kohn et al. (2000) 15.

¹⁷ Guldenmund “The nature of safety culture: a review of theory and research” *Safety Science* (2000) 34 215.

safety by organisations such as the Agency for Healthcare Research and Quality (AHRQ).¹⁸ This definition succinctly captures the essential elements:

‘The safety culture of an organization is the product of individual and group values, attitudes, perceptions, competencies, and patterns of behaviour that determine the commitment to, and the style and proficiency of, an organization’s health and safety management. Organizations with a positive safety culture are characterized by communications founded on mutual trust, by shared perceptions of the importance of safety and by confidence in the efficacy of preventive measures.’¹⁹

The idea of a safety culture is derived from the studies of high reliability organisations. For instance, over the past 30 years the commercial aviation industry has gone to great lengths to completely change the culture of flight crews in order to improve airline safety. The catalyst for these efforts was a workshop sponsored by the National Aeronautics and Space Administration (NASA) in 1979. Research into the causes of air transport accidents, conducted and presented by NASA, showed that the majority of air crashes where human aspects were involved, were caused by failures of interpersonal communications, decision making, and leadership. Crew Resource Management was developed and crews were trained to better utilise human resources on the flight deck in order to promote a safety culture and reduce ‘pilot error’.

CRM is widely credited as having had a significant impact on safety improvements in the aviation industry.²⁰ The successful water landing or ‘ditching’ of US Airways Flight 1549, which came to be known as the ‘miracle on the Hudson’, serves as a recent example of the life-saving influence of CRM and the concerted effort to foster a culture of safety. Captain Chesley "Sully" Sullenberger, ascribes the ‘heroic’ outcome of that fateful day’s events to such a culture, he also relates his experiences in aviation to the developments he has observed in patient care:

¹⁸ Nieva and Sorra “Safety culture assessment: a tool for improving patient safety in healthcare organizations.” *Qual Saf Health Care* (2003) 12 Suppl 2 ii17.

¹⁹ Commission “Organising for safety: Third report of the ACSNI (Advisory Committee on the Safety of Nuclear Installations) study group on human factors” (1993).

²⁰ Helmreich et al. (1999) 9 *Int J Aviat Psychol* 19.

‘...the teamwork required to deliver hundreds of passengers to their destination safely is the same kind of teamwork needed to avoid life-threatening mistakes in hospitals. In the aviation industry, I was part of the effort to implement the safety methodology known as crew resource management (CRM) at US Airways. It was our CRM training that enabled my crew—which included my first officer, Jeff Skiles, and three flight attendants—to land on the Hudson River that frigid January day and then safely evacuate 150 passengers without a life-threatening injury or fatality...Our unscheduled landing was greatly assisted by the much-changed practices in our industry related to communication and cooperation among all members of the crew, regardless of their rank or job responsibility. As I have spoken with and observed those who work in the health care field, I have been struck by the many similarities between the early days of CRM formation and developments happening today in the patient safety movement.’²¹

Captain Sullenberger continues, referring to the specific case of Rory Staunton, who died at the age of twelve from undetected septic shock after being discharged by New York University Medical Center in summer 2012:

‘...some in the medical field regard such fatalities as an unavoidable consequence of delivering care in any complex, high-stress, high patient volume environment. In aviation, such rationalizations for avoidable human error were rejected long ago and replaced with the creation of a robust safety system that has now become the culture of the field.’²²

The shift toward a ‘culture of safety’, achieved in the aviation industry with the help of error management aides such as CRM, has been a development that many have suggested healthcare should endeavour to emulate. If a similar culture shift is to be achieved in medicine, an environment in which teamwork, clear communication, and openness about errors, both with other health care professionals and with patients,

²¹ Gordon et al. “Beyond the Checklist” (2012) vii.

²² *Id.* viii.

would have to become the norm.²³ As ‘safety culture’ is such a broad concept, strategies to foster a positive culture of safety have focused on developing teamwork and communication among medical personnel.²⁴

3.2. TEAMWORK AND COMMUNICATION

Much of healthcare relies on teamwork. One can justifiably say that ‘teams create safety’.²⁵ Considering how ubiquitous and vital teams are in the provision of care, it is regrettable that medical teams have up until very recently not been purposely designed with specific tasks in mind. For the longest time, the entire system relied upon the innate capacity, resilience and adaptability of individual staff members. Medicine has been very slow in adopting teamwork processes. A classic study which compared the attitudes of operating theatre and intensive care unit staff, to those of airline cockpit crew, regarding error, stress, and teamwork, showed that there were substantial differences between the two professions.²⁶ Medical staff were more likely to deny the effects of stress and fatigue, they found it difficult to discuss errors with colleagues, as not all staff accepted personal susceptibility to error, and there were great variations in teamwork perceptions that followed traditional hospital hierarchies.

There is a growing recognition that teamwork, and teamwork training principles originally developed in the aviation industry, can have a positive impact on clinical performance.²⁷ Team training seeks to prevent potential errors by training each team member to respond appropriately in clinical situations. Effective communication, cohesion among team members and an environment in which all personnel feel free to speak up if they have any misgivings, is promoted. Staff are trained to cross-check and verify the activities of their team, give guidance when required, and deal with errors in

²³ Goldman and Schafer *Goldman-Cecil Medicine* (2015) 44.

²⁴ Blegen et al. “Improving safety culture on adult medical units through multidisciplinary teamwork and communication interventions: the TOPS Project.” *Qual Saf Health Care* (2010) 19 346.

²⁵ Vincent (2011) 341.

²⁶ Sexton et al. “Error, stress, and teamwork in medicine and aviation: cross sectional surveys.” *BMJ* (2000) 320 745.

²⁷ Schmutz and Manser “Do team processes really have an effect on clinical performance? A systematic literature review.” *Br J Anaesth* (2013) 110 529.

a non-disparaging manner. Debriefing and feedback are critical elements of teamwork training. Human factors, such as fatigue, stress, expected or predictable perceptual errors (misreading monitors or misinterpreting instructions), and organisational culture, also play a significant part in team training.

Various frameworks or programs are used in teamwork training; most have been developed specifically for healthcare (programs adopted from other industries were initially utilised).²⁸ For example: the comprehensive Team Strategies and Tools to Enhance Performance and Patient Safety (TeamSTEPPS)²⁹ curriculum developed in collaboration by the United States Department of Defense and AHRQ, Veterans Affairs Medical Team Training program and crew resource management (borrowed from the aviation industry).³⁰

Team training has resulted in improved teamwork, safety attitudes and culture, communication, and reduced errors.³¹ CRM-based team training has also been associated with significant decreases in the frequency and severity of adverse events and malpractice claims.³² Evidence from various studies substantiate the notion that teamwork and communication are critical components of safe health care systems.³³

Reviews of closed malpractice claims have found that staff are particularly vulnerable to medical errors owing to teamwork failures. Communication breakdowns contributed

²⁸ Shekelle et al. (2013) *Evid Rep Technol Assess (Full Rep)* 472.

²⁹ King et al. "TeamSTEPPS™: team strategies and tools to enhance performance and patient safety" (2008)

³⁰ Helmreich (2000) 320 *BMJ* 781.

³¹ Williams et al. "Teamwork in emergency medical services." *Air Med J* (1999) 18 149; Grogan et al. "The impact of aviation-based teamwork training on the attitudes of health-care professionals." *J Am Coll Surg* (2004) 199 843; Leonard et al. "The human factor: the critical importance of effective teamwork and communication in providing safe care." *Quality and Safety in Health Care* (2004) 13 Suppl 1 i85; Awad et al. "Bridging the communication gap in the operating room with medical team training." *Am J Surg* (2005) 190 770.

³² Pratt et al. "Impact of CRM-Based Team Training on Obstetric Outcomes and Clinicians' Patient Safety Attitudes" *The Joint Commission Journal on Quality and Patient Safety* (2007) 33 720.

³³ Shekelle et al. (2013) *Evid Rep Technol Assess (Full Rep)* 472.

to error in one quarter of cases, in one analysis involving surgical errors.³⁴ Teamwork breakdowns were found to be one of the most prevalent contributing factors (70%) to medical error, in another study involving medical trainees.³⁵ Erroneous verbal communication between staff members was the root cause or contributed to more than half of all severe patient safety incidents.³⁶

A recent study provided quantitative evidence of a direct link between teamwork during the surgical case and subsequent patient outcome. Direct observation revealed that patients whose surgical teams exhibited less teamwork behaviours, were at a higher risk for death or complications, even after adjusting for preoperative risk.³⁷

A large retrospective health services study with a contemporaneous control group was conducted by the Veterans Health Administration (VHA) to assess the impact of their VHA Medical Team Training program on surgical outcomes. 74 Veterans Affairs hospitals underwent teamwork training, which included the use of preoperative and postoperative checklists. The decline in the risk-adjusted surgical mortality rate was about 50% greater in the training group than in group that had not yet implemented the training. Teamwork training was thus associated with a staggering reduction in mortality. A dose–response relationship was also demonstrated, as continuing training resulted in further reductions in mortality.³⁸

Team training, standardised communication protocols (e.g. briefing and debriefing checklists, and handoff protocols) and structural level changes (e.g. team composition, information systems support, and role clarification) are just some of the approaches that

³⁴ Rogers et al. “Analysis of surgical errors in closed malpractice claims at 4 liability insurers.” *Surgery* (2006) 140 25.

³⁵ Singh et al. “Medical errors involving trainees: a study of closed malpractice claims from 5 insurers” *Arch Intern Med* (2007) 167 2030.

³⁶ Rabøl et al. “Descriptions of verbal communication errors between staff. An analysis of 84 root cause analysis-reports from Danish hospitals.” *BMJ Qual Saf* (2011) 20 268.

³⁷ Mazzocco et al. “Surgical team behaviors and patient outcomes.” *Am J Surg* (2009) 197 678.

³⁸ Neily et al. “Association between implementation of a medical team training program and surgical mortality.” *JAMA* (2010) 304 1693.

have been employed in an attempt to improve teamwork and contribute to the realisation of a safety culture.³⁹ Medical professionals, more than ever, function as part of a larger system. Teamwork and communication training, might bring with it an enhanced awareness of the interdependencies that exist between individuals, with a diverse range of expertise, and team members, as healthcare providers. Thus, to a large extent, confirming the appropriateness and applicability of a systems approach to error management advocated by Reason.⁴⁰

3.3. DIMENSIONS OF A SAFETY CULTURE

A growing number of studies illustrate the importance of safety culture in healthcare safety improvement. The notion has also been bolstered by the Joint Commission, which has since 2009 required that the leadership of all health care organisations it accredits 'create and maintain a culture of safety'.⁴¹ However, little attention has focused on developing a common set of definitions, dimensions and measures. As researchers are yet to reach consensus on the dimensions that comprise a positive safety culture, a variance of combinations exists.

Except for teamwork and communication, other important dimensions of a safety culture that are most often cited in the literature, include: leadership commitment to safety; organisational learning; a non-punitive approach to adverse event reporting and analysis; and shared belief in the importance of safety.⁴²

³⁹ Salas and Rosen "Building high reliability teams: progress and some reflections on teamwork training." *BMJ Qual Saf* (2013) 22 369.

⁴⁰ Reason (2000) 320 *BMJ* 768.

⁴¹ Commission "Revisions to LD. 03.01. 01. Oakbrook Terrace, IL: The Joint Commission; 2012" (2012).

⁴² Halligan and Zecevic "Safety culture in healthcare: a review of concepts, dimensions, measures and progress." *BMJ Qual Saf* (2011) 20 338.

3.4. SAFETY CULTURE IMPLEMENTATION STRATEGIES

3.4.1. EXECUTIVE WALK ROUNDS AND MULTI-LAYERED IMPROVEMENT STRATEGIES

Strategies aimed at promoting a culture of patient safety may take the form of a single intervention or a package of multiple interventions. Team training, as discussed above, is one such intervention. Two additional common interventions have emerged: Executive walk rounds; and Comprehensive Unit-Based Safety Program (CUSP).⁴³

Executive walk rounds ensure that organisational leadership engage directly with front-line healthcare professionals. Executives or senior leaders visit front-line patient care areas to observe and discuss existing or potential threats to patient safety, they also offer support to address such threats. These walk rounds are intended to demonstrate an institutional commitment to safety, create an environment which promotes trust and psychological safety, and aid front-line care givers in dealing proactively with patient safety threats.

3.4.2. COMPREHENSIVE UNIT-BASED SAFETY PROGRAM

Improvement strategies that combine multiple interventions have also been employed. One such strategy, originally developed at Johns Hopkins Hospital by Pronovost and colleagues, is the Comprehensive Unit-Based Safety Program (CUSP):⁴⁴

‘CUSP is an 8-step program designed to impact safety climate by empowering staff to assume responsibility for safety in their environment. This is achieved through education, awareness, access to organization resources, and a toolkit of interventions.’

⁴³ Weaver et al. “Promoting a culture of safety as a patient safety strategy: a systematic review.” *Ann Intern Med* (2013) 158 369.

⁴⁴ Pronovost et al. “Implementing and Validating a Comprehensive Unit-Based Safety Program” *Journal of patient safety* (2005) 1 33.

The 8-steps of CUSP are:

- 'culture of safety assessment;
- sciences of safety education;
- staff identification of safety concerns;
- senior executives adopt a unit;
- improvements implemented from safety concerns;
- efforts documented/analyzed;
- results shared; and
- culture reassessment.'

'CUSP provides enough structure such that a health care organization can develop a broad strategy to improve safety, yet flexible enough to defer to the local concerns and wisdom of staff in individual care areas. As part of CUSP, a senior executive adopts a work area and actively participates in safety efforts with staff. Staff in each work area are asked to learn from one defect per month, and department and hospital leaders learn from one defect per quarter using a structured tool. The goal is to move away from just reporting and superficially reviewing multiple hazards to focusing intently on a few and mitigating the hazards (i.e., redesign the system in which work is performed). In addition, CUSP asks safety teams to implement tools, such as daily goals and morning briefings to help improve safety culture.'⁴⁵

CUSP is a multi-layered strategy for culture change, it includes adaptive interventions (e.g. continuous learning strategies or team training) and technical interventions (e.g. use of evidence-based clinical care algorithms) aimed at improving patient safety.⁴⁶ The

⁴⁵ Pronovost et al. "Creating High Reliability in Health Care Organizations" *Health Services Research* (2006) 41 1599.

⁴⁶ Weaver et al. (2013) 158 *Ann Intern Med* 369.

methodology includes aspects of executive engagement and team training, as well as specific strategies that aim to translate clinical evidence into practice.⁴⁷

The program has been implemented to great effect in a number of landmark patient safety initiatives. CUSP, along with preventative checklists, was one of the key components that contributed to the near elimination of central line–associated bloodstream infections (CLABSI) in intensive care units across the state of Michigan.⁴⁸

Analysis of the Michigan data showed that the CUSP intervention was as significant as the central line insertion checklist in reducing CLABSI.⁴⁹ Another recent study found that environments with a strong safety culture, achieved greater success in lowering CLABSI with CUSP. The authors observed a significant association between reduced CLABSI rates and communication openness, staffing, organisational learning, and teamwork.⁵⁰

The success of the Michigan initiative, prompted the AHRQ to subsequently sponsor an effort to expand the program, centred around CUSP, throughout America. Initial results, suggest that this expansion has been exceptionally successful, a 43% reduction in CLABSI rates across 1 100 participating ICUs has been achieved.⁵¹ This achievement is even more remarkable, considering that the baseline CLABSI rate was already lower than in prior studies. The reduction in CLABSI, and the part CUSP played therein, has

⁴⁷ Pronovost et al. “A practical tool to learn from defects in patient care.” *Jt Comm J Qual Patient Saf* (2006) 32 102; Pronovost et al. “Translating evidence into practice: a model for large scale knowledge translation.” *BMJ* (2008) 337 a1714.

⁴⁸ Pronovost et al. “Improving patient safety in intensive care units in Michigan.” *Journal of critical care* (2008) 23 207; Pronovost et al. “Sustaining reductions in catheter related bloodstream infections in Michigan intensive care units: observational study.” *BMJ* (2010) 340 c309.

⁴⁹ Dixon-Woods et al. “Explaining Michigan: developing an ex post theory of a quality improvement program.” *Milbank Q* (2011) 89 167.

⁵⁰ Richter and McAlearney “Targeted implementation of the Comprehensive Unit-Based Safety Program through an assessment of safety culture to minimize central line-associated bloodstream infections.” *Health Care Manage Rev* (2016) 43 42.

⁵¹ Berenholtz et al. “Eliminating central line-associated bloodstream infections: a national patient safety imperative.” *Infect Control Hosp Epidemiol* (2014) 35 56.

certainly been a success story that could inform other harm prevention efforts.⁵² A similar nationwide effort to implement CUSP, this time to reduce catheter-associated UTIs, has also been launched in U.S. hospitals.⁵³ This initiative, called ‘On the CUSP: Stop CAUTI’, involved an explicit focus on both the technical and socio-adaptive (which involves strategies shown to improve safety culture) aspects of prevention. The initiative has also achieved a notable sustainable clinical outcome improvement.

3.4.2. SURVEY TOOLS

Several validated survey tools are utilised to measure safety culture and teamwork climates, the AHRQ Surveys on Patient Safety Culture (SOPS)⁵⁴ and the Safety Attitudes Questionnaire (SAQ)⁵⁵ are the two most commonly used tools. Improved safety and teamwork climate, as measured by the SAQ, have been associated with decreased patient harm and severity-adjusted mortality.⁵⁶

3.4.4. CHECKLISTS

In the introduction to his book, Gawande, succinctly makes the case for the use of this seemingly facile tool:⁵⁷

‘Here, then, is our situation at the start of the twenty-first century: We have accumulated stupendous know-how. We have put it in the hands of some of the most highly trained, highly skilled, and hardworking people in our society. And, with it, they have indeed accomplished extraordinary things. Nonetheless, that know-how is often unmanageable. Avoidable failures are common and persistent, not to mention demoralizing and frustrating, across many fields—from medicine to finance, business to government. And the reason is increasingly evident: the

⁵² Pronovost et al. (2016) 25 *BMJ Qual Saf* 396.

⁵³ Saint et al. “A Program to Prevent Catheter-Associated Urinary Tract Infection in Acute Care.” *N Engl J Med* (2016) 374 2111.

⁵⁴ Quality, *Surveys on Patient Safety Culture*, <<http://www.ahrq.gov/professionals/quality-patient-safety/patientsafetyculture/index.html>>.

⁵⁵ Sexton et al. “The Safety Attitudes Questionnaire: psychometric properties, benchmarking data, and emerging research.” *BMC Health Serv Res* (2006) 6 44.

⁵⁶ Berry et al. “Improved Safety Culture and Teamwork Climate Are Associated With Decreases in Patient Harm and Hospital Mortality Across a Hospital System.” *J Patient Saf* (2016).

⁵⁷ Gawande “The Checklist Manifesto” (2010) 13.

volume and complexity of what we know has exceeded our individual ability to deliver its benefits correctly, safely, or reliably. Knowledge has both saved us and burdened us.

That means we need a different strategy for overcoming failure, one that builds on experience and takes advantage of the knowledge people have but somehow also makes up for our inevitable human inadequacies. And there is such a strategy—though it will seem almost ridiculous in its simplicity, maybe even crazy to those of us who have spent years carefully developing ever more advanced skills and technologies.

It is a checklist.’

Checklists, which are closely related to team training, heavily dependent on a culture of safety, and have been a cornerstone of safety management in HROs for decades, have played a remarkable role in some of the most significant successes achieved in the patient safety movement. In high-hazard industries, stress and fatigue can often lead to compromised cognitive functioning, potentially leading to increased error of judgment, deviation from standard procedure and diminished proficiency.⁵⁸ Hales *et al.* describe the checklist as, ‘an organized tool that outlines criteria of consideration for a particular process. It functions as a support resource by delineating and categorizing items as a list—a format that simplifies conceptualization and recall of information’.⁵⁹ Checklists have been adopted as an error management tool in aviation, aeronautics, product manufacturing, and more recently, in healthcare. It essentially has two primary duties; it aids adherence to protocol and reduces the frequency of human error.

⁵⁸ Hales and Pronovost “The checklist--a tool for error management and performance improvement.” *J Crit Care* (2006) 21 231.

⁵⁹ Hales et al. “Development of medical checklists for improved quality of patient care.” *Int J Qual Health Care* (2008) 20 22.

Certain medical specialities, such as anaesthesiology and emergency medicine, have expeditiously embraced the use of checklists and memory-aids.⁶⁰ The use of checklists, have more recently (as discussed above) been associated with remarkable reductions in morbidity and mortality when used during the placement of central lines.⁶¹ Although, the existence of a strong prevailing safety culture cannot be discounted.⁶² The successful implementation of a checklist could also mitigate factors that contribute to malpractice claims. A retrospective claim record review showed that nearly one-third of all contributing factors in accepted surgical malpractice claims of patients that had undergone surgery, might have been intercepted by using a comprehensive surgical safety checklist.⁶³ Checklists could potentially prevent a considerable amount of damage, both physical and financial.

Checklists and pre-operative briefings embed the idea of open communication, and help to promote teamwork. Simple checklist mandated acts, such as introductions among team members and discussing concerns about an operation, may have a considerable positive impact on team functioning.⁶⁴

3.4.4.1. SURGICAL SAFETY CHECKLIST

Certainly, the most well-known and influential implementation of checklists, has been by the WHO World Alliance for Patient Safety, led by Gawande. In 2008 the WHO launched 'Safe Surgery Saves Lives: The Second Global Patient Safety Challenge'.⁶⁵ This initiative was centred around the implementation of a 19-item Surgical Safety

⁶⁰ Harrahill and Bartkus "Preparing the trauma patient for transfer." *J Emerg Nurs* (1990) 16 25; Hart and Owen "Errors and omissions in anesthesia: a pilot study using a pilot's checklist." *Anesth Analg* (2005) 101 246.

⁶¹ Pronovost et al. "An intervention to decrease catheter-related bloodstream infections in the ICU." *N Engl J Med* (2006) 355 2725.

⁶² Richter and McAlearney (2016) *Health Care Manage Rev* 42.

⁶³ de Vries et al. "Prevention of surgical malpractice claims by use of a surgical safety checklist." *Ann Surg* (2011) 253 624.

⁶⁴ Thomas "Improving teamwork in healthcare: current approaches and the path forward." *BMJ Qual Saf* (2011) 20 647.

⁶⁵ Organization (2008) *World Health Organization ; Safety The Second Global Patient Safety Challenge* (2008).

Checklist.⁶⁶ The accompanying implementation manual provides a brief description of how the checklist procedure should be conducted:⁶⁷

‘In order to implement the Checklist during surgery, a single person must be made responsible for checking the boxes on the list. This designated Checklist coordinator will often be a circulating nurse, but it can be any clinician or healthcare professional participating in the operation.

The Checklist divides the operation into three phases, each corresponding to a specific time period in the normal flow of a procedure — the period before induction of anaesthesia (Sign In), the period after induction and before surgical incision (Time Out), and the period during or immediately after wound closure but before removing the patient from the operating room (Sign Out). In each phase, the Checklist coordinator must be permitted to confirm that the team has completed its tasks before it proceeds further. As operating teams become familiar with the steps of the Checklist, they can integrate the checks into their familiar work patterns and verbalize their completion of each step without the explicit intervention of the Checklist coordinator. Each team should seek to incorporate use of the Checklist into its work with maximum efficiency and minimum disruption, while aiming to accomplish the steps effectively.’

Hailed as one of the great success stories of the patient safety movement, eight hospitals in eight cities, representing a variety of economic circumstances and diverse populations of patients, participated in the World Health Organization's Safe Surgery Saves Lives program, and saw marked improvements in surgical outcomes.⁶⁸

‘Postoperative complication rates fell by 36% on average, and death rates fell by a similar amount. All sites had a reduction in the rate of major postoperative complications, with a significant reduction at three sites, one in a high-income location and two in lower-income locations.’

⁶⁶ Organization (2008) 1.

⁶⁷ *Safety Implementation Manual Surgical Safety Checklist (First Edition)* (2008) 1.

⁶⁸ Haynes et al. (2009) 360 *N Engl J Med* 491.

The remarkable observed reduction in rates of death (47%) and complications, suggested that the checklist initiative could potentially improve the safety of surgical patients, even in diverse clinical and economic circumstances.⁶⁹ The authors acknowledged that the underlying reasons for the improvements were ‘most likely multifactorial’, they cited the Hawthorne effect, existence of a formal pause or preoperative briefing, Increased uptake of safety technologies and a broad change in safety culture and teamwork at the sites, as other possible factors.

There was great initial enthusiasm about the ability of the WHO’s surgical safety checklist to prevent harm, and checklist use proliferated after publication of the Safe Surgery study. The WHO has fully endorsed their use, likening their life-saving potential to that achieved in aviation:⁷⁰

‘The WHO Surgical Safety checklist and other checklists have improved reliability and helped to standardize care for thousands of patients globally. Checklists allow complex pathways of care to function with high reliability by giving users the opportunity to pause and take stock of their actions ensuring that nothing has been omitted before proceeding to the next step. The checklist approach has the same potential to save lives and prevent morbidity in medicine that it did in aviation over 70 years ago by ensuring that simple standards are applied for every patient, every time.’

The use of such checklists has been mandated or strongly encouraged by several organisations and governments, including those of the United Kingdom, the Netherlands, and Ontario, Canada.⁷¹ Initial enthusiasm regarding the effectiveness of checklists has been slightly tempered, following a recent study conducted in Ontario, where the Ministry of Health and Long-Term Care mandated public reporting of

⁶⁹ *Ibid.*

⁷⁰ Organization, *The checklist effect.*

<http://www.who.int/patientsafety/implementation/checklists/background/en/>.

⁷¹ Shekelle et al. (2013) *Evid Rep Technol Assess (Full Rep)* 134.

adherence to surgical safety checklists for hospitals.⁷² The rapid implementation of surgical safety checklists in Ontario offered an opportunity to evaluate the impact of mandatory checklists. In contrast to other studies, the authors reported that their population-based study of surgical safety checklists in 101 Ontario acute-care hospitals showed no significant reduction in operative mortality or surgical complications after checklist implementation.

3.4.4.2. THE CHECKLIST CONUNDRUM

Clearly, checklists are not a simple panacea, they cannot be implemented in isolation. Leape addressed the 'checklist conundrum' in an accompanying editorial.⁷³ Leape provided perspective by restating some of the surrounding issues regarding checklist implementation: First, 'it is not the act of ticking off a checklist that reduces complications, but performance of the actions it calls for', a checklist is merely a tool to ensure that team communication happens; Second, the thorough implementation of a checklist is difficult. It requires successful system change, engaged institutional leadership, data collection, and most importantly, 'training in teamwork so that everyone feels respected and accountable'; Third, hospitals need help to implement the checklist. Many lack the resources or expertise to organize and lead a checklist-implementation'; Fourth, a checklist only works if it is used, and is heavily dependent on compliance; Lastly, 'full implementation takes time: time for the team to get it right and time for all units in an institution to get on board', positive results have shown to increase coinciding with the implementation period.⁷⁴

Using a stepped wedge cluster randomized controlled trial methodology in two Norwegian hospitals, a carefully structured implementation program, and measurement of actual checklist use, Haugen *et al.* conducted the most rigorous study of surgical safety checklists to date.⁷⁵ They confirmed substantial patient benefit can be derived

⁷² Urbach et al. "Introduction of surgical safety checklists in Ontario, Canada." *N Engl J Med* (2014) 370 1029.

⁷³ Leape "The checklist conundrum." *N Engl J Med* (2014) 370 1063.

⁷⁴ *Ibid.*

⁷⁵ Haugen et al. "Effect of the World Health Organization checklist on patient outcomes: a stepped wedge cluster randomized controlled trial." *Ann Surg* (2015) 261 821.

from a formalised checklist approach to team planning and communication in the operating room. The study showed substantial improvements in surgical outcomes. Across 2 hospitals, including 5 surgical specialties, complication rates fell by 42% on average when the checklist was introduced, in-hospital length of stay and potentially mortality across a wide range of patients was also reduced.

The authors concluded, that the use of the WHO Checklist prevents complications and reduces in-hospital length of stay and potentially also mortality across a wide range of patients undergoing simple or complex surgical procedures in hospitals.

Another recent study has been published in which the authors attempted to determine whether an association exists between the degree of checklist completion and clinical outcomes.⁷⁶ Significant variability in checklist usage was found. When all 3 components of the checklist were completed, compared with not completing the checklist, patients had a 43% less chance of experiencing a complication. Commenting on the public health policy opportunity, the authors noted that: 'Routinely completing all 3 components of the WHO checklist, which is actually mandatory in the operating room in England and Wales, could have an important public health impact and could potentially prevent 14% of the complications in surgical patients'.

Mayer *et al.* perfectly describe the checklist in terms of the underlying safety culture it may represent, as the 'tip of an iceberg':

'Unlike a drug, a checklist will only ever be as effective as the personnel implementing it. From the perspective of evaluating the impact of checklists on care, therefore, we will always face the confounder of the quality of team working in operating rooms where a checklist is implemented as intended, or not (or it is not implemented at all). We would hypothesize that a well-running team, where the communications between the physician and nurse members are open and regular, has a better chance of implementing a checklist as one of many checks

⁷⁶ Mayer et al. "Surgical Checklist Implementation Project: The Impact of Variable WHO Checklist Compliance on Risk-adjusted Clinical Outcomes After National Implementation: A Longitudinal Study." *Ann Surg* (2016) 263 58.

they carry out routinely within their operating room. Compliance with interventions like a checklist can thus be a surrogate of an underlying positive team culture and mutually supportive team behaviors in the operating room. A key study by Neily *et al.* supports this point: substantial reduction in postoperative mortality and morbidity was demonstrated after operating room team training, which included use of checklists but also team briefings/debriefings, and offered coaching interviews. Checklists are thus only the tip of an iceberg in the operating room—the unseen part of the iceberg reflects how well operating room personnel work as a team.’

As is the case with much of the interventions aimed at improving patient safety, and as alluded to in the introduction to this section, checklists, teamwork, communication and the existence of a safety culture, are all likely interdependent. Systems must be geared toward the objective of high-reliability and safer care, there are no simple solutions.

4. CONCLUSION

Healthcare providers have turned to High-Reliability Organisations for guidance on how to better manage error. HROs, with their reliance on ‘mindful organisation’, inclusive of the critical safety culture, may hold valuable lessons for healthcare. That these HROs are able to meet objectives, for extended periods, without serious incidents, make them highly attractive to those involved in patient safety.

Utilising a system approach to error analysis, as employed in HROs, has enabled us to gain better insight into all the factors, active and latent failures, that may have contributed to the occurrence of the final accident. It has made us aware of the importance of designing systems that prevent or catch errors, team training and communication, redundancies, crosschecks, read-backs and standardised safety procedures (counting the number of sponges before and after surgery, marking a surgical site prior to an operation, asking patients their names before administering medication).

The use of checklists, which has managed to significantly reduce central-line infections, is one notable recent success story. We have also come to see the value of engineered solutions that decrease the likelihood of errors at the human-machine interface. 'Forcing functions', for instance, have been implemented in anaesthesiology, ensuring that gas nozzles and connectors are designed in a way that makes it impossible to mistakenly connect up and administer the wrong substance. Such interventions, that attempt to engineer errors out of medical devices, will become invaluable as medicine grapples with ever increasing complexity. The use of information technology, including computerised order entry systems, will also be critical to safety efforts going forward.

However, people remain responsible for the provision of safe care. Most interventions rely on the existence of an adequately trained, sufficiently staffed and well-rested workforce. Low nurse-to-patient ratios, fatigue, unorganised-handoffs, poor supervision and production pressures, have been associated with adverse outcomes. Safe systems cannot be created by overextended, poorly trained, unsupervised and uncommitted healthcare providers.

The impact of a safety culture cannot be understated, it underlies many of the proposed interventions and will, to a great extent, be pivotal to their successful implementation. Another fundamental safety culture principle (briefly touched upon, and more thoroughly explored in the following chapter) is that mistakes present learning opportunities. Errors are openly discussed, without fear of censure, in a non-punitive environment, so as to encourage disclosure, thereby allowing organisations to learn from their mistakes, and translate those lessons into preventative measures.

This approach goes against the 'blame and shame' tradition, that has historically been, and still is, rather dominant in the medical profession. A balance needs to be struck between the majority of errors, *bona fide* mistakes, that are appropriately dealt with, without attributing blame, and certain errors that do seem blameworthy and justify calls for accountability. The concept of a 'just culture' has been suggested as a means to reconcile the two positions. This concept is discussed in the following chapter.

CHAPTER 6. JUST CULTURE - BALANCING 'NO BLAME' AND ACCOUNTABILITY

1. INTRODUCTION

'The paradox is that the single greatest impediment to error prevention is that we punish people for making them.'

These words formed part of a statement Dr Lucian Leape delivered in his testimony before the US Congress in 1997.¹ The traditional approach to medical error, Leape referred to, consisted of blaming and shaming the individual practitioner most proximate to the consequences of the error, for what was considered to be 'their' mistake.² Although it may have been emotionally satisfying or legally convenient to impute culpability unto a single 'aberrant' healthcare worker, such a reactive response had proven to be ineffectual as a safety improvement strategy.³ As a matter of fact, this approach may have considerably harmed safety efforts, in that underlying contributing factors would have been overlooked, to focus instead on the inevitable failings of hardworking, committed professionals, whilst simultaneously disincentivising reporting of relevant safety information, owing to fear of censure.⁴

1.1. THE SYSTEM APPROACH

The fundamental intellectual contribution of the patient safety movement, has perhaps been that of James Reason—the notion that most errors are caused by bad systems, rather than bad people.⁵

¹ Leape (1997) 105-23.

² Leape (1994) 272 *JAMA* 1851.

³ Reason (1990) 302.

⁴ Reason (2000) 320 *BMJ* 768.

⁵ Reason (1995) 38 *Ergonomics* 1708.

Organisational accidents, or adverse events as they are known in the patient safety literature, are hardly ever caused by solitary, ‘sharp end’ *active failures* (errors or violations). Instead, they occur as a result of the ‘insidious accumulation of delayed-action failures’ that are incubated in the managerial and organisational spheres.⁶ These *latent conditions* are the ‘resident pathogens’ within the system and are effected by the negative consequences of organisational processes (i.e. decisions regarding planning, forecasting, designing, managing, communicating, budgeting etc.).⁷ The safety culture of an organisation is also an influential factor.⁸ Accidents are set into motion when active failures coalesce with latent conditions, in the company of local triggering factors, to breach or bypass system defences.⁹ Healthcare professionals at the human-system interface, rather than instigators, are inheritors of ‘accidents waiting to happen’.¹⁰ Their working environments have been infected with latent, error conducive, conditions (e.g. high workloads, time pressures, drug shortages, inadequate training and skills, unmaintained or unavailable equipment), that have been transmitted through departmental and organisational pathways.¹¹ Even though many unsafe acts are likely to occur (latent conditions combining with psychological error and violation tendencies), very few will penetrate the various defences and safeguards to produce bad outcomes.¹²

Reason sets out the ‘system approach’ as follows:

‘The basic premise in the system approach is that humans are fallible and errors are to be expected, even in the best organisations. Errors are seen as consequences rather than causes, having their origins not so much in the perversity of human nature as in “upstream” systemic factors. These include recurrent error traps in the workplace and the organisational processes that give rise to them. Countermeasures are based on the assumption that though we

⁶ Reason (2016) 9.

⁷ Reason (1990) 198.

⁸ Reason “Achieving a safe culture: Theory and practice” *Work & Stress* (1998b) 12 293.

⁹ Reason (2016) 9.

¹⁰ Whittingham *The blame machine: Why human error causes accidents* (2004) 131.

¹¹ Reason (2016) 10.

¹² Reason (1997) 266.

cannot change the human condition, we can change the conditions under which humans work. A central idea is that of system defences. All hazardous technologies possess barriers and safeguards. When an adverse event occurs, the important issue is not who blundered, but how and why the defences failed.¹³

These layered system defences, and the active failures and latent conditions that might one day combine, and align to permit a breach, are simply, yet profoundly, illustrated by the ‘Swiss Cheese’ model of accident causation.¹⁴ It captures the importance of effective, successive layers of defences, barriers, and safeguards and the crucial role they play in the system approach. Defences consist of engineered safety features (alarms, physical barriers, automatic shutdowns, etc.), protocols, standardised procedures, administrative controls and people. Their function is to protect potential victims (patients) from local harm.¹⁵

An unfortunate reality, particularly in healthcare, is that little slips can cause immense tragedies.¹⁶ Patients are vulnerable, and medicine is an inherently, highly error-provoking, undertaking. This calls for an even greater effort to identify the holes (or systemic weaknesses), shrink their size and create enough overlap, so as to prevent them from ever lining up in the future.¹⁷

1.2. THE ‘NO BLAME’ MODEL

Until recently, doctors have known very little about the nature and varieties of human error, and even less about effective prevention strategies.¹⁸ The same goes for those who have been tasked with holding fallible healthcare professionals accountable for their mistakes. Errors have predominantly been equated with incompetence, met with

¹³ Reason (2000) 320 *BMJ* 768.

¹⁴ Reason (1997) 9.

¹⁵ *Id.* 7.

¹⁶ Reason (2016) 77.

¹⁷ Reason “Beyond the organisational accident: the need for “error wisdom” on the frontline.” *Qual Saf Health Care* (2004) 13 Suppl 2 ii28.

¹⁸ Reason (2016) 77.

stigmatisation, marginalisation and sanction.¹⁹ This has meant that golden opportunities have been lost, errors could have been treated as valuable learning experiences (as they do in other hazardous industries).²⁰ Erring individuals have often also been isolated from their context, thereby squandering chances to examine the system at large for contributing latent conditions.²¹

The system approach, advocated by the patient safety movement, views the question, 'who is at fault?' as a distraction.²² This has, perhaps misleadingly, been called a 'no blame' model. In that it is considered more constructive to identify error-conducive situations and settings, and to implement systems that prevent healthcare professionals from committing errors, than merely blaming 'culpable' individuals; Intercepting errors before they cause harm or mitigating harm if errors do reach the patient. This 'no blame' model has undoubtedly been vindicated, for instance, rather than trying to perfect doctors' penmanship and memories, computerised order-entry systems catch and alert practitioners to medication errors before they are able to cause patient harm. The implementation of simple checklists, that aid evidence-based best practices, has also been responsible for remarkable improvements in rates of surgical complications and central line-associated bloodstream infections.²³

2. BALANCING 'NO BLAME' AND ACCOUNTABILITY

The 'no blame' model has served a valuable purpose. Besides the numerous safety improvements (including: computerised order entry and bar coding systems, electronic medical records, standardisation, simplified processes, error-resistant equipment

¹⁹ Leape (1994) 272 *JAMA* 1851.

²⁰ Reason (1995) 4 *Quality and Safety in Health Care* 80; Helmreich (2000) 320 *BMJ* 781; Chassin and Loeb (2011) 30 *Health Aff (Millwood)* 559; Chassin and Loeb "High-reliability health care: getting there from here." *Milbank Q* (2013) 91 459.

²¹ Reason (2016) 78.

²² Wachter and Pronovost "Balancing 'No Blame' with Accountability in Patient Safety" *N Engl J Med* (2009) 361 1401.

²³ Wachter and Pronovost (2009) 361 *N Engl J Med* 1401; Dekker and Hugh "Balancing "no blame" with accountability in patient safety." *N Engl J Med* (2010) 362 275; author reply 275.

design, etc.) it has been instrumental in engaging healthcare professionals in safety efforts. It is doubtful whether progress in the early stages of the patient safety movement would have been as rapid, if the 'no blame' aspect had not been as prominent. One can imagine that it would be quite difficult to get doctors to acknowledge and discuss the prevalence of 'medical error', in an exceedingly antagonistic malpractice climate. Errors were hardly ever discussed before, and if they were, it would involve the pointing of fingers or even possibly adversarial plaintiffs' attorneys. The 'no blame' model changed this error landscape. Doctors were finally able to admit that they sometimes make mistakes—not as an admission of guilt, rather an admission that they are human and all humans err. It was, thus, crucial to emphasise the no blame and systems approach in order to advance the patient safety movement and garner widespread support.²⁴

However, as is often the case, theory and practice has not always aligned. Non-punitive environments that encourage systematic approaches to safety are still habitually not observed, to the detriment of local safety cultures.²⁵ 'Learning not Blaming', a 2015 United Kingdom government response to three reports on system failures at the NHS, perfectly illustrates the problem.²⁶ It follows the public inquiry into Mid Staffordshire NHS Foundation Trust in February 2013, and considers the 'Freedom to Speak up' consultation, the Morecambe Bay investigation, and the Public Administration Select Committee's report, 'Investigating Clinical Incidents in the NHS'.²⁷ The salient points that emerge from the three reports are succinctly covered, the principal message being that: the NHS must embrace a learning culture, a culture that listens to patients, families and staff, the system must foster a supportive environment, that welcomes the open, transparent and honest discussion of errors. The publication stresses the importance

²⁴ Wachter "Personal accountability in healthcare: searching for the right balance." *Quality in health care : QHC* (2013) 22 176.

²⁵ Aaronson et al. "Morbidity and Mortality Conference in Emergency Medicine Residencies and the Culture of Safety." *West J Emerg Med* (2015) 16 810.

²⁶ Health "Learning Not Blaming" (2015) 102.

²⁷ *Inquiry Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry: Executive Summary (House of Commons Papers)* (2013); Committee "Investigating clinical incidents in the NHS" *London: House of Commons* (2015); Francis *Freedom to speak up: An independent review into creating an open and honest reporting culture in the NHS* (2015); Kirkup "The report of the Morecambe Bay investigation" (2015).

of a positive organisational culture, deeming it a vital component of patient safety. This challenge is described as follows:

‘In an organisation as large and as complex as the NHS – operating under pressure, under intense scrutiny and in which life or death decisions are made every day – no matter how strong the professional instinct to do the right thing, no matter how powerful the impulse to care, there are inevitably times when it might feel easier to conceal mistakes, to deny that things have gone wrong and to slide into postures of institutional defensiveness.

All large institutions operating in high risk environments are at risk of sliding into this behaviour, so it is vital that leaders are alert to the risks and actively work to promote the culture of openness, learning and professional and institutional humility which is the absolute bedrock of safe care.’²⁸

The ‘no blame’ culture that has been championed since the publication of ‘To Err is Human’, has recently come to be reconsidered.²⁹ A few prominent healthcare figures have called for a more nuanced balance between an outright blame free approach and individual accountability. Leape and Fromson have suggested that physicians exhibiting performance problems, which could include mental or behavioural issues, disruptive conduct, or impairment, should be more decisively addressed, albeit through a system-level intervention.³⁰ Performance failures do occasionally occur, posing a significant threat to patient welfare and safety. These situations are generally not well managed by healthcare institutions. The authors have proposed the establishment of better performance assessment methods and programs to help carers with deficiencies. The Joint Commission published a sentinel event alert concerning disruptive behaviours that undermine a culture of safety. It takes into account systemic factors which may

²⁸ Health (2015) 6.

²⁹ Wachter and Pronovost (2009) 361 *N Engl J Med* 1401; Wachter (2013) 22 *Quality in health care : QHC* 176; Driver et al. “Responding to clinicians who fail to follow patient safety practices: perceptions of physicians, nurses, trainees, and patients.” *Journal of Hospital Medicine* (2014) 9 99; McTiernan et al. “Patient safety is not elective: a debate at the NPSF Patient Safety Congress.” *BMJ Qual Saf* (2015) 24 162.

³⁰ Leape and Fromson “Problem doctors: is there a system-level solution” *Ann Intern Med* (2006) 144 107.

contribute thereto, such as productivity demands, cost containment requirements, embedded hierarchies, and fear of or stress from litigation. Nevertheless, it calls for accountability and 'zero tolerance', for staff members who transgress the recommended organisational code of conduct relating to such unacceptable conduct.³¹ In relation to poor hand-hygiene compliance, Goldman has noted: 'Curbing the alarming increase in the rate of antibiotic-resistant infections surely requires both systemic improvements and increased personal accountability'. If repeated violations occur, especially concerning a standard of care as simple, well-understood and widely accepted as hand-washing (when adequate systemic support is in place, i.e. antiseptic dispensers are easily accessible and reliable), one can no longer only lay the omission at the system's door.³²

There is some concern that a shift back to individual accountability for certain types of unsafe acts, would undo much of the progress made towards achieving a safety culture and impede further improvement, causing healthcare professionals to revert to unforthcoming behaviour and distracting from more beneficial system-based safety interventions.³³ The concept of a 'just culture', which first appeared in the aviation safety literature and has gained prominence in other hazardous industries, has been put forward as a response to these concerns.³⁴ It aims to rebalance the system approach with accountability.

³¹ Commission *Behaviors that undermine a culture of safety (Sentinel Event Alert, Issue 40)* (2008).

³² Goldman "System failure versus personal accountability--the case for clean hands." *N Engl J Med* (2006) 355 121.

³³ Dekker *Just Culture* (2007) 1; Dekker and Hugh (2010) 362 *N Engl J Med* 275; author reply 275; Dekker "The criminalization of human error in aviation and healthcare: A review" *Safety science* (2011a) 49 121; McTiernan et al. (2015) 24 *BMJ Qual Saf* 162.

³⁴ Reason (1998b) 12 *Work & Stress* 293; Khatri et al. "From a blame culture to a just culture in health care." *Health Care Manage Rev* (2009) 34 312.

3. JUST CULTURE

3.1. MARX'S ALGORITHM

In 2001, David Marx, wrote a primer for healthcare executives describing the concept of a Just Culture.³⁵ The concept is often attributed to Marx and frequently mistakenly regarded as a counterpoint to Reason's model. However, this is not at all true, Reason wrote about the importance of a just culture in his 1997 book 'Managing the Risks of Organizational Accidents', stressing the value of voluntary reporting and how it is influenced by organisational approaches to blame and punishment:

'A 'no-blame' culture is neither feasible nor desirable. A small proportion of human unsafe acts are egregious...and warrant sanctions, severe ones in some cases. A blanket amnesty on all unsafe acts would lack credibility in the eyes of the workforce. More importantly, it would be seen to oppose natural justice. *What is needed is a just culture, an atmosphere of trust in which people are encouraged, even rewarded, for providing essential safety-related information—but in which they are also clear about where the line must be drawn between acceptable and unacceptable behaviour.*³⁶ [emphasis added]

Marx's construction of a just culture is similar to that of Reason, however he structures his discussion around four key behavioural concepts, and tailors it to the disciplinary challenges facing healthcare organisations.³⁷ His report specifically grapples with the implementation of a disciplinary approach that would encourage individuals to report information that would previously have been regarded as self-compromising. Marx notes that the effectiveness of a medical event reporting system, such as MERS-TM, which provides for a standardised means of organised data collection and the analysis of errors, adverse events, and near misses, absolutely depends on the willingness of staff to report such information.

³⁵ Marx "Patient safety and the "just culture": a primer for health care executives" *Trustees of Columbia University* (2001).

³⁶ Reason (1997) 195.

³⁷ Marx (2001) *Trustees of Columbia University* 5.

‘Advances in patient safety, especially when involving the management of human error, depend upon our collective ability to learn from our mistakes – whether they are near misses or mistakes resulting in actual harm to a patient. To promote a culture in which we learn from our mistakes, organizations must re-evaluate just how their disciplinary system fits into the equation. Disciplining employees in response to honest mistakes does little to improve overall system safety. Yet, mishaps accompanied by intoxication or malicious behaviour presents an obvious and valid objection to today’s call for blame-free error reporting systems’³⁸

Marx’s report addresses the balance that must be found between the need to learn from mistakes and the need to take disciplinary action, and aims to help answer the following questions: Where must the disciplinary line be drawn? What effect does censure have on the safety of the healthcare system? And does the threat or application of punitive sanction, in response to human error, help or hinder safety efforts? This is especially vital considering the chronic underreporting of incidents.³⁹ Leape, in his testimony before congress, indicated that only 2-3% of major errors are reported through hospital reporting systems. Healthcare professionals seem to report only what they cannot conceal.⁴⁰

3.1.1. THREE CATEGORIES OF HUMAN FALLIBILITY

Marx’s just culture algorithm, is intended to guide and standardise organisational responses to errors. It identifies three categories of human fallibility: Human error; ‘At-risk’ behaviour; and Reckless behaviour.⁴¹

³⁸ *Id.* 3.

³⁹ Barach and Small “Reporting and preventing medical mishaps: lessons from non-medical near miss reporting systems” *BMJ : British Medical Journal* (2000) 320 759; Leape “Reporting of adverse events.” *N Engl J Med* (2002) 347 1633; Kaldjian et al. “Facilitating and Impeding Factors for Physicians’ Error Disclosure: A Structured Literature Review” *The Joint Commission Journal on Quality and Patient Safety* (2006) 32 188; Mitchell et al. “Patient safety incident reporting: a qualitative study of thoughts and perceptions of experts 15 years after ‘To Err is Human’.” *BMJ Qual Saf* (2016) 25 92.

⁴⁰ Leape (1997) 105-23.

⁴¹ Marx “The just culture algorithm” *Outcome Engineering* (2008).

Human error, consists of inadvertent mistakes, slips and lapses. This category of fallibility is predictable (humans are error-prone) and does not attract censure or punishment. Managing this behaviour, involves re-engineering processes, designing effective defences, barriers, or redundancies, and training. Latent conditions in the system are thus addressed.

‘At-Risk’ and Reckless behaviour, increase the likelihood of error or removes defences that are meant to intercept errors. Individuals make themselves guilty of such behaviour when they consciously choose to bypass established safety practices. To distinguish between these two categories the just culture algorithm considers system level design, barriers to compliance and individual motivation.

‘At-risk’ behaviour, consists of a choice that increases risk, either, by not recognising the risk, perceiving it as insignificant, or mistakenly believing that the risk is justified. This category is managed by, removing incentives for at-risk behaviour, creating incentives for good behaviour, and improving situational awareness. Coaching is a more appropriate response than punishment.

Reckless behaviour, involves the conscious disregard of a substantial and unjustifiable risk. This category of behaviour warrants either, remedial, or punitive action

3.1.2. ERROR, NOT OUTCOME

A defining feature of the just culture model, is that it is more concerned with the origins of the error (human error, at-risk or reckless behaviour), than the severity of the outcome.⁴² The intent of the individual and the conscious risk of patient harm it creates, would rather be the deciding factor. A healthcare professional that acts recklessly, must be held accountable, even if no harm comes to the patient. The inverse is also true, we cannot, for the most part, control the outcomes of our errors. If a healthcare professional

⁴² Marx (2001) *Trustees of Columbia University* ; Marx “How building a ‘just culture’ helps an organization learn from errors.” *OR manager* (2003) 19 1.

makes an honest, inadvertent mistake, that reaches the patient undetected, leading to severe impairment or death, the consequences cannot be squarely imputed to that professional. The flaw lies not with the human error, but rather the system that allowed a simple mistake to penetrate its defences and cause substantial harm. The defect in the system is addressed to prevent a similar outcome, not the individual who made the mistake. After all, safer care can only be achieved if organisational leaders are made aware of such flaws in the system; and that requires that staff are encouraged and feel comfortable to come forward with information regarding 'error-traps'. Dekker, epigrammatically describes it as follows: 'A learning culture is a culture that allows the boss to hear bad news'.⁴³

Organisations that have adopted a reporting culture in order to learn from mistakes and have raised the threshold for possible disciplinary action to reckless conduct.⁴⁴ Disciplinary action is only taken to deter intentional or knowing unsafe acts. Most corporate disciplinary systems, however, have set their threshold at negligence.⁴⁵ If the employee should have been aware of the risk they were creating, disciplinary proceedings may be implemented. Negligence is also the threshold for compensation in the civil liability system. It is, however, crucial to distinguish between compensatory and punitive objectives, although they are often inter-related in a civil malpractice suit.⁴⁶

Negligence is a grey area in disciplinary-decision making. If one considers negligent conduct from a safety perspective: Would it advance safety efforts more if a punitive approach is taken, in hopes that the prospect of sanction will deter an individual from engaging in similar future behaviour? Or is it more beneficial to allow the negligent employee to come forward, so that the system may learn from the individual's negligence? High-risk industries outside of healthcare have preferred and reaped the benefits of the latter approach. Healthcare leaders need to determine whether disciplinary policies are supportive or detrimental to system safety efforts, whether

⁴³ Dekker *Patient safety: a human factors approach* (2011) 187.

⁴⁴ Marx (2001) *Trustees of Columbia University* 14.

⁴⁵ *Id.* 16.

⁴⁶ *Id.* 18.

human factors learning, outweighs the deterrent effect of punishment against negligent employees.⁴⁷

3.2. MEASURED AND REFINED

Multiple well-known instruments exist to measure an organisation's overall patient safety culture.⁴⁸ The growing popularity of the just culture concept, a subset of patient safety culture, has prompted the development of an assessment tool which specifically focusses on the aspects important thereto. The authors of the assessment tool have also proposed a formal definition of just culture, synthesising existing definitions and descriptions into one, which is universally applicable across healthcare settings:⁴⁹

‘a just culture for safety describes an environment where professionals believe they will receive fair treatment if they are involved an adverse event and trust the organization to treat each event as an opportunity for improving safety.’

Just culture, as a construct, is made up of six dimensions. Petschonek *et al.* conducted a review of the literature and have described these dimensions as follows:⁵⁰

- Balance - One's perceptions of fair treatment within the hospital as it relates to errors, error reporting, and its systems approach to medical error.
- Trust - The extent to which individuals trust the organisation, their supervisors, and their co-workers.
- Openness of communication - The willingness of individuals to communicate event information upward to supervisors and hospital administrators, for example, willingness to reveal events, share events information, and make suggestions for improvement within the unit or the organisation.

⁴⁷ Marx (2001) *Trustees of Columbia University*; Marx "Just Culture" *Outcome Engenuity* (2012) 1.

⁴⁸ Pronovost and Sexton "Assessing safety culture: guidelines and recommendations." *Qual Saf Health Care* (2005) 14 231; Morello et al. "Strategies for improving patient safety culture in hospitals: a systematic review." *BMJ Qual Saf* (2013) 22 11.

⁴⁹ Petschonek et al. "Development of the just culture assessment tool: measuring the perceptions of health-care professionals in hospitals." *J Patient Saf* (2013) 9 190.

⁵⁰ *Ibid.*

- Quality of the event-reporting process - One's perceived quality of the event reporting system (which includes the process of entering reports and the ability to follow up on these reports), whether employees are given time to report and to what extent the employees believe the reporting system is monitored and maintained.
- Feedback and communication about events - One's beliefs regarding whether the organisation does an effective job of sharing event information about the events and the outcome of evaluating events.
- Overall goal of continuous improvement - One's belief that the organisation demonstrates a goal of continuous improvement, characterised by a willingness to learn from events, and make improvements to the hospital system.'

The Just Culture Assessment Tool (JCAT) is the first of its kind, developed to measure various aspects of a just culture, following more research and refinement, it could be employed to ensure that resources are directed toward improving such a culture and overall patient safety.

4. HIGH-RELIABILITY AND JUST CULTURE

As the science behind patient safety develops, the strategies to effectuate mindfulness and high reliability are becoming clearer.⁵¹ High-risk industries have realised that a culture of safety requires, above all, the promotion of trust, reporting and improvement.⁵² The existence of a safety culture, which incorporates just culture principles, is often cited as a cornerstone of high-reliability and patient safety efforts.⁵³ High-reliability organisations balance accountability and learning by cultivating a just

⁵¹ Chassin and Loeb (2011) 30 *Health Aff (Millwood)* 559; Chassin and Loeb (2013) 91 *Milbank Q* 459.

⁵² Hudson "Applying the lessons of high risk industries to health care." *Qual Saf Health Care* (2003) 12 Suppl 1 i7.

⁵³ Frankel et al. "Fair and just culture, team behavior, and leadership engagement: The tools to achieve high reliability." *Health Serv Res* (2006) 41 1690; Leonard and Frankel "The path to safe and reliable healthcare." *Patient Educ Couns* (2010) 80 288; Chassin and Loeb (2011) 30 *Health Aff (Millwood)* 559.

culture, making sure that discipline is equably applied throughout the system.⁵⁴ They distinguish between blameless errors, that create learning opportunities, and blameworthy errors, that are met with, equitably applied, sanction.⁵⁵ This ensures that they are able to learn and improve by openly identifying and examining their own weaknesses.⁵⁶ As Frankel *et al.* put it: 'Ultimately, a Just Culture is about fair, enlightened, and reasonable assessment of behaviour and produces a work environment that supports high reliability'.⁵⁷ Healthcare organisations have begun to introduce explanatory documents and policies, that articulate the principles espoused by a just culture.⁵⁸ These documents convey organisational leaderships' commitment and responsibilities with regard to learning and safety improvement, predominantly in terms of a system approach. However, individual accountability and behaviour that would lead to sanction, as well as the disciplinary processes that will be followed, are also clearly delineated.⁵⁹

4.1. ALGORITHMS AND INCIDENT DECISION TREES

Investigations into adverse events are often conducted with the aid of 'incident decision trees' or algorithms, that see to it that just culture principles are applied practically and consistently. Incident decision aids were first developed in the aviation industry. Boeing utilised such an aid to assess maintenance errors.⁶⁰ Reason introduced a more general

⁵⁴ Oster and Braaten *High Reliability Organizations: A Healthcare Handbook for Patient Safety & Quality* (2016) 11.

⁵⁵ Chassin and Loeb (2013) 91 *Milbank Q* 459.

⁵⁶ Ruchlin et al. "The role of leadership in instilling a culture of safety: lessons from the literature" *Journal of Healthcare Management* (2004) 49 47; Clancy and Tornberg "TeamSTEPPS: assuring optimal teamwork in clinical settings" *American Journal of Medical Quality* (2007) 22 214; Connor et al. "Creating a fair and just culture: one institution's path toward organizational change" *The Joint Commission Journal on Quality and Patient Safety* (2007a) 33 617; Morris "Just culture-changing the environment of healthcare delivery" *Clinical Laboratory Science* (2011) 24 120; Karanikas and Chionis "Exploring the line between the preventive and punitive character of measures in the frame of a just culture" *Policy and Practice in Health and Safety* (2017) 1; McCall and Pruchnicki "Just culture: A case study of accountability relationship boundaries influence on safety in HIGH-consequence industries" *Safety science* (2017a) 94 143.

⁵⁷ Frankel et al. (2006) 41 *Health Serv Res* 1690.

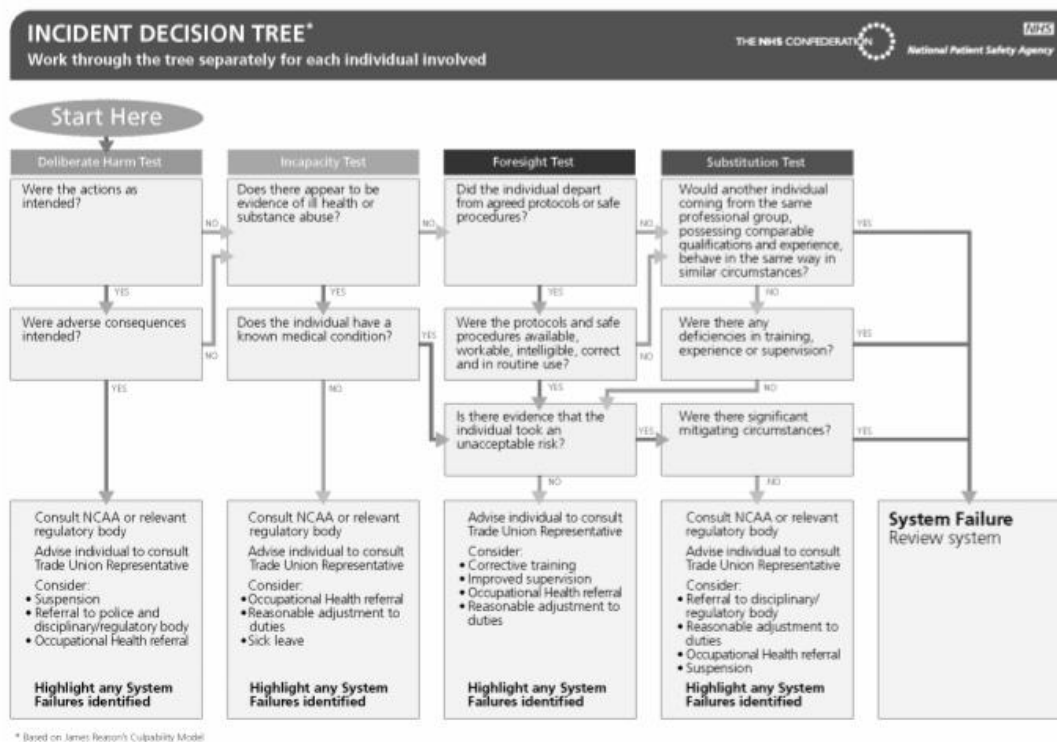
⁵⁸ Dekker and Nyce "Just culture: "Evidence", power and algorithms" *JHA* (2013) 2 73.

⁵⁹ Marx (2001); Marx (2008).

⁶⁰ Vincent (2011) 274.

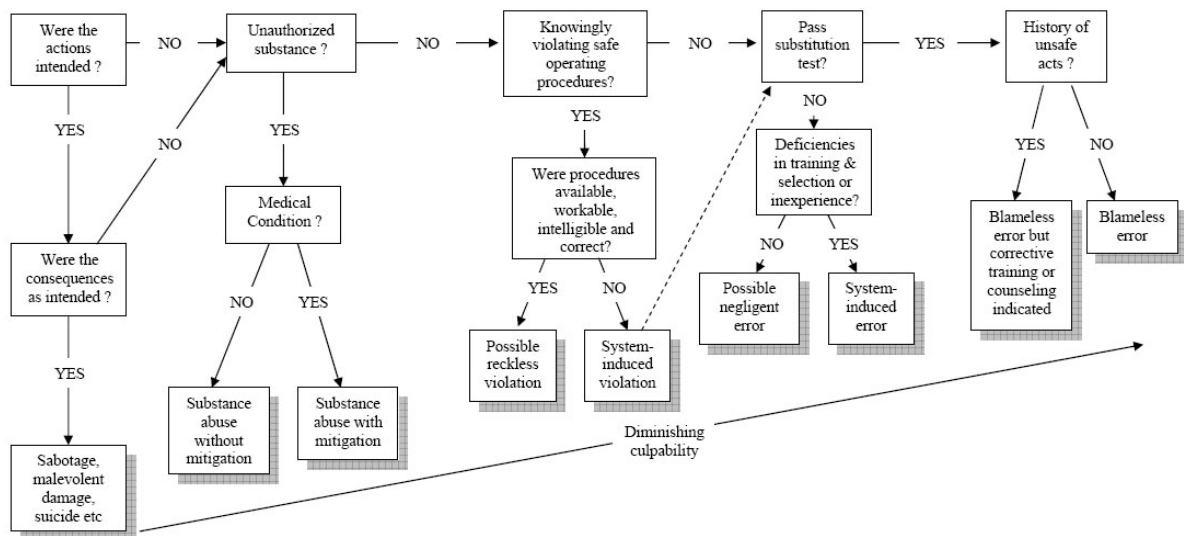
culpability decision tree in his 1997 book, *Managing the Risks of Organizational Accidents*.⁶¹

Reason's 'decision tree for determining the culpability of unsafe acts' or 'Unsafe Act Algorithm', has been adapted by the UK National Patient Safety Agency to create a NHS-specific model, known as the 'Incident Decision Tree'.⁶²



⁶¹ Reason (1997) 209.

⁶² Agency *The Incident Decision Tree* (2003); Meadows et al. "The incident decision tree: guidelines for action following patient safety incidents" (2005). Renamed to further disassociate it from unwarranted blame.



4.1.1. REASON'S 'DECISION TREE FOR DETERMINING THE CULPABILITY OF UNSAFE ACTS'

An effective reporting culture depends upon the existence of a just culture. These two concepts, when taken together and drawn on to create a learning culture, are critical subcomponents of a wider safety culture.⁶³ While it is important to always be mindful of situational and systemic factors, accidents do occasionally (though only on relatively rare occasions) occur as a result of the unreasonably negligent, reckless or even *mala fide* behaviour of certain individuals. Distinguishing between these few truly blameworthy behaviours and the clear majority of unsafe acts, to which the attribution of fault would be neither befitting nor productive, can be difficult. That is why Reason insists that a 'prerequisite for engineering a just culture is an agreed set of principles for drawing the line between acceptable and unacceptable actions'.⁶⁴

Reason's decision tree, which forms the basis for numerous others, attempts to grade unsafe acts according to their blameworthiness. It is utilised after an accident, serious

⁶³ Reason (1997) 196.

⁶⁴ *Ibid.*

incident or 'near-miss' has occurred. The decision tree is applied separately to each unsafe act that contributed to the adverse event.

Much in the same way as our legal understanding of culpability, Reason first differentiates between two forms of fault: *culpa* (negligence) and *dolus* (intention). If both the act and the consequences were intended, in other words committed with *mens rea* and *actus reus*, the conduct would most likely amount to criminal behaviour, which will probably be outside the purview of the organisation. This would be the most blameworthy of conduct.

If the act was intended, but the consequences were not, the conduct would amount to either a mistake or a violation. If the individual knowingly violated safe operating procedures, the conduct would possibly be reckless and, thus, blameworthy. This is because such a violation increases the risk of error and subsequent adverse effects. However, when assessing the blameworthiness of a violation, the quality, suitability and availability of the operating procedures that were not complied with, need to be considered. If the operating procedures are wrong, inappropriate or unworkable, as adjudged by the individual's peers, the violation could have been induced by the system and be considered 'necessary'.

Mistakes (and possibly system-induced violations) are subject to the substitution test: 'Could (or has) some well-motivated, equally competent and comparably qualified individual make (or made) the same kind of error under those or very similar circumstances?' If the answer given by a 'jury' of peers is 'yes', the error is likely blameless. If the answer is 'no', then it must be considered whether there were system-induced deficiencies in the individual's training, selection or experience. If that is found to be the case, the unsafe act would be considered a largely blameless system-induced error. If no such latent conditions are identified, the conduct could amount to negligence.

The final question examines whether the individual has a history of unsafe acts. Previous unsafe acts could signal a need for corrective training or career counselling. Some individuals are perhaps more prone to absentmindedness, slips or lapses. This

does not mean they are blameworthy, it is just a trait that must be dealt with, either through training or reassignment to other tasks in the organisation.

If neither the act, nor the consequences were intended, such conduct amounts to blameless slips or lapses.

Where does one then draw the line between acceptable and unacceptable behaviour? Malevolent damage and substance abuse without mitigation should obviously attract severe sanction, possibly by authorities rather than the organisation. Substance abuse with mitigation, reckless violations and negligent errors, are not as clear cut and require careful consideration, but are more than likely blameworthy, especially if there are aggravating factors involved. What remains are blameless errors. Reason indicates, that in his experience, 9 out of 10 errors fall in the blameless category. Punishing the few who commit serious blameworthy acts, reinforces the boundaries of acceptable behaviour. It fosters a safer work environment and strengthens the perception among colleagues that the organisational culture is just, that the truly reckless individuals will be identified and justifiably dismissed.

Frankel, distilled the algorithm into a short list of questions:⁶⁵

- Was the harm intentional?
- Was the individual knowingly impaired?
- Did the individual consciously decide to engage in an unsafe act?
- Did the caregiver make a mistake that individuals of similar experience and training would be likely to make under the same circumstances? (substitution test)
- And does the individual have a history of unsafe acts?

⁶⁵ Leonard and Frankel (2010) 80 *Patient Educ Couns* 288.

4.1.2. NHS INCIDENT DECISION TREE

The Incident Decision Tree employed by the NHS, is fundamentally the same as Reason's.⁶⁶ It is designed to be used by any manager dealing with staff involved in a patient safety incident. The Incident Decision Tree guides administrators through a series of structured questions regarding the individual's actions, motives and behaviour at the time of the incident.

The flowchart is comprised of four sequential 'tests':

- The Deliberate Harm Test
- The Incapacity Test
- The Foresight Test
- The Substitution Test

By applying each test, possible explanations for the individual's actions are considered and the most probable explanation is identified. The main point where the NHS decision tree diverges from that of Reason's, is the recommended management response options. These include, consulting relevant regulatory bodies and advising the individual to consult their trade union representative. Management can also then consider whether it would be appropriate to: suspend the individual, refer the matter to police and disciplinary/regulatory bodies, suggest an occupational health referral, reasonably adjust duties, grant sick leave, recommend corrective training or propose improved supervision.

The policy document acknowledges that in most cases, system failure will emerge as the cause of the incident. The focus should then shift to tackling the underlying problems found during an investigation, with the aim of improving practice and minimising the likelihood of recurrence. The NPSA document emphasises that: 'Research into patient safety shows that the majority of staff try to create a safe environment and prevent things from going wrong. Despite some high-profile cases, the overwhelming majority of incidents are not caused by malicious intent or even by lack of competence on the part of the individual delivering the care. The best people can make the worst

⁶⁶ Agency (2003).

mistakes'.⁶⁷ The document also addresses the important role of caregiver-support, no matter what the underlying cause of the incident might have been, the individual and their colleagues might still require support, coaching and assistance in coming to terms with the aftermath of the event.

4.2. UNIFORM APPLICATION OF ACCOUNTABILITY ALGORITHMS

These models help healthcare leaders to identify acts that merit an accountability approach. Leadership plays a crucial role, the realisation of a just culture will remain nothing more than a bureaucratic delusion if the rules are haphazardly applied, with frequent double-standards (e.g. nurses disproportionately targeted).⁶⁸

This has unfortunately, often been the case.⁶⁹ Hospital leaders have in the past been reluctant to hold physicians accountable to the same disciplinary standard as others.⁷⁰ One can speculate as to why. Perhaps, because doctors are not employed by hospitals (in the private sector). Furthermore, management at these hospitals try to attract these doctors (who are mostly specialists) to their facilities. Counting on them to bring their patients along, perform their operations in the hospital's theatres, with the help of the hospital's staff, and then check-up on their patients in the hospital's wards. These specialist doctors bring in a lot of revenue. While it might explain why disciplinary processes are more leniently applied, if applied at all, such an approach will definitely not bring about a just culture.

A tradition of non-accountability will instead be nurtured by arbitrary enforcement. With that in mind, Wachter and Pronovost have called for the uniform enforcement of accountability standards for all healthcare providers, and also suggested a number of

⁶⁷ *Id.* 50.

⁶⁸ Khatri et al. (2009) 34 *Health Care Manage Rev* 312; Wachter (2013) 22 *Quality in health care : QHC* 176.

⁶⁹ Von Thaden and Hoppes "Measuring a just culture in healthcare professionals: initial survey results" *Proceedings from safety across high-consequence industries conference. St Louis (MO)* (2005) 20.

⁷⁰ Ruchlin et al. (2004) 49 *Journal of Healthcare Management* 47.

prerequisites or conditions (also informed by Reason) that should be met before an individual accountability approach is considered:⁷¹

- Is the patient-safety problem that is being addressed important?
- Does the literature or expert consensus strongly support adherence to the practice as an effective strategy to decrease the probability of harm?
- Have clinicians been educated about the importance of the practice and the evidence supporting it?
- Has the system been modified, if necessary, to make it as easy as possible to adhere to the practice without disrupting other crucial work or creating unanticipated negative consequences; have concerns by providers regarding barriers to compliance been addressed?
- Have physicians, other providers, and leaders reached a consensus on the value of the practice and the process by which it will be measured; do physicians understand the behaviours for which they will be held accountable?
- Has a fair and transparent auditing system been developed, and are clinicians aware of its existence?
- Have clinicians who do not adhere to the practice once or perhaps twice been counselled about the importance of the practice, about the steps that have been taken to make it easy to adhere, and about the fact that further transgressions will result in punishment; have the consequences of failure to adhere been described?
- Are the penalties for infractions understood and applied fairly?

These prerequisites make a few things clear. They are very cognisant of system factors. Safety standards cannot be strictly followed or enforced, without first addressing the underlying system problems. Human-factors and systems engineering are thus, essential. Another prerequisite is that, carers should know what is expected of them, why it is expected of them, and how they will be audited according to those expectations. The prerequisites ensure that sanctions are only meted out against those

⁷¹ Wachter and Pronovost (2009) 361 *N Engl J Med* 1401.

who wilfully or habitually cross the line, despite education, exhortation and the existence of proper systems, not busy, distracted healthcare workers who make honest mistakes. Furthermore, sanctions must be proportional, fair, consistently applied, and just.

5. CONCLUSION

Healthcare has in recent years slowly transitioned from a traditional approach to medical error, where the most proximate individual practitioner would be blamed and sanctioned for their mistake, toward a system approach, that is more concerned with interventions aimed at reducing the fallibility of systems, than the impossible task of making humans less fallible. With its focus on identifying and addressing faults in systems that allow errors to transpire, rather than blaming individuals for their inevitable mistakes and lapses, the system approach has perhaps misleadingly been referred to as a 'no blame' model. This model has recently come to be reconsidered, with many calling for a more nuanced balance between the 'no blame', system approach and individual accountability.

The just culture concept has been advanced as a possible solution. It seeks to promote an environment in which errors can be reported, allowing the organisation to learn from its mistakes, but clearly stipulates that some unacceptable behaviour will result in disciplinary action. Early constructions of the just culture model have sought to draw a definitive disciplinary line, by categorising human fallibility. Marx's model, for instance, classifies conduct as either human error, at-risk or reckless. The concept has been refined and Algorithms and Decision-Trees have been developed to guide and standardise organisational responses to error. Reason's decision tree does this by attempting to grade behaviour according to blameworthiness. The NHS uses a similar tool.

However, these tools depend on the uniform application of accountability standards. Arbitrary enforcement by uncommitted leadership will defeat the purpose and would instead be severely detrimental to the establishment of a just culture.

This brings up another important consideration. Perhaps, more important than where

we draw the line is the question of who gets to draw the line. This question will be considered in the following chapter.

CHAPTER 7. JUST CULTURE – WHO DRAWS THE LINE?

1. INTRODUCTION

Dekker contends that ‘the critical question is not where to draw the line, but who gets to draw it’.¹ Accordingly, ‘where we draw the line’, is nothing more than an essentialist assumption, in that some behaviour is deemed to be inherently culpable, and there is a clear dividing line between what constitutes legitimate and illegitimate conduct.² This assumption underlies much of the current guidance on establishing a just culture. Such a construction of a just culture is problematic. By relying on an *a priori* cut-off point to distinguish between acceptable and unacceptable behaviour, it is easy to lose sight of the fact that culpability is conferred upon an act by our own assumptions and interpretation, it does not inhere in it.³ Decision trees are useful guides, however, that is all they are – guides.⁴ In attempting to categorise conduct, concrete lines can very easily become vague, as any classification invites new deliberations and judgements.⁵

2. ACCOUNTABLE TO WHOM?

Someone still has to make the difficult decision of whether the conduct under review, falls under, human error, at-risk behaviour or reckless behaviour (or any other variation of an algorithm or decision tree). The judgement itself is not the problem, after all, judgments will need to be made.⁶ The problem arises when one falsely assumes that blameworthy and blameless behaviour are intrinsic categories, capable of being defined

¹ Dekker “Just culture: who gets to draw the line” *Cogn Tech Work* (2009) 11 177.

² Cromie and Bott “Just culture’s “line in the sand” is a shifting one; an empirical investigation of culpability determination” *Safety science* (2016b) 86 258.

³ Dekker (2009) 11 *Cogn Tech Work* 177.

⁴ Dekker and Nyce (2013) 2 *JHA* 73.

⁵ Dekker “We have Newton on a retainer: Reductionism when we need systems thinking” *Joint Commission Journal on Quality and Patient Safety* (2010) 36 147.

⁶ Weiner et al. “The meaning of justice in safety incident reporting” *Social science & medicine* (2008) 66 403.

independent of context, interpretation, hierarchy or background.⁷ ‘Just-culture-by-algorithm’, as Dekker calls it, is the idea that hospital administrations can, by merely following a set of rules, come to an incontrovertible ‘right’ conclusion. Simply categorise the conduct as x and recommend corrective measure y. Justice cannot be separated from clinical and social interpretation, although some algorithms and decision trees give the impression that justice can be achieved through objective processes.⁸

3. POWER AND PERCEPTION

Dekker argues that categorising conduct is a matter of power. Someone has the power to conclude that an act is one thing and not the other, and that particular person has the power to decide on the consequences. Dekker submits that as soon as power is involved, categorisations and responses may quickly be seen as unjust, or unfair.⁹ Justice becomes a matter of perception.

What management perceives as at-risk behaviour, may be entirely logical and efficient to employees at the ‘sharp end’. It could be a practice adopted by everyone, as it is a reliable and good way to do complete a task.¹⁰ The task looks different from the employees’ perspective, who have first-hand experience, whose practices have evolved in response to certain shortcomings in technologies or processes, and who must deal with pressures and demands unfamiliar to administrators.¹¹ If such practices are met with punitive measures, it will show that managers are not in touch with the realities their employees face.¹² More importantly, it will be detrimental to the atmosphere of trust, that has to be fostered if a just culture is to be achieved.¹³

⁷ Karanikas and Chionis (2017) *Policy and Practice in Health and Safety* 1.

⁸ Dekker “The bureaucratization of safety” *Safety Science* (2014) 70 348.

⁹ Dekker (2011) 189.

¹⁰ Santomauro et al. “Second victims, organizational resilience and the role of hospital administration” *Journal of Hospital Administration* (2014) 3 95.

¹¹ Dekker (2011) 155.

¹² Boothman “Breaking Through Dangerous Silence to Tap an Organization’s Richest Source of Information: Its Own Staff” *Joint Commission journal on quality and patient safety* (2016) 42 147.

¹³ Reason (1997) 266; Burns et al. “Explicit and implicit trust within safety culture.” *Risk Anal* (2006) 26 1139.

Dekker emphasises that the same act, can be interpreted in a number of ways, depending on your perspective and perceptions.¹⁴ Social constructionism would argue that by viewing conduct one way, you have constructed an understanding of an event and explained it using only one language.¹⁵ If you regard that construction as true, you might overlook a multitude of other possibilities.¹⁶ For instance, by reading an act as inattentive, you might only see a careless individual. The same act can, however, be construed differently, depending on alternative readings and the questions asked. Ask organisational questions and you may see a system deficiency. Ask disciplinary questions and you may see a blameworthy act. Ask judicial questions and you may see a crime or a delict.¹⁷

These readings, in turn, have implications for accountability.¹⁸ Blameworthy acts face sanction, crimes are punished, and delicts attract liability.¹⁹ Here accountability is backward-looking and reactive.²⁰ However, an alternative reading of the act, might, instead, lead you to ask operational, technical, educational, political or, as mentioned, organisational questions. Accountability, then becomes forward-looking and proactive.²¹

One interpretation does not necessarily exclude others.²² There is no wrong or right account. But the person tasked with drawing the line, will have a perspective that might exclude certain aspects of some accounts.²³ That perspective will have implications for

¹⁴ Hugh and Dekker "Hindsight bias and outcome bias in the social construction of medical negligence: a review." *J Law Med* (2009) 16 846.

¹⁵ Burr *Social constructionism* (2015).

¹⁶ Dekker (2009) 11 *Cogn Tech Work* 177.

¹⁷ *Ibid.*

¹⁸ Stern et al. "Failure to learn from safety incidents: Status, challenges and opportunities" *Safety Science* (2018) 101 313.

¹⁹ Dekker *Just Culture* (2007) 85.

²⁰ Sharpe "Promoting patient safety. An ethical basis for policy deliberation." *The Hastings Center report* (2003) 33 10.

²¹ *Id.* 12.

²² Dekker "The psychology of accident investigation: epistemological, preventive, moral and existential meaning-making" *Theoretical Issues in Ergonomics Science* (2015) 16 202.

²³ Dekker (2009) 11 *Cogn Tech Work* 177.

how persons and organisations then deal with conduct that crosses the line.²⁴ If an act is perceived as blameworthy, it means that the line is drawn in accordance with that particular interpretation. Where it is then drawn, is determined by the social function it wishes to achieve. Is it meant to emphasise moral boundaries and enhance solidarity, deter unwanted conduct, protect financial interests, manage risks and liabilities, appease regulators, placate the public, etc.²⁵

One should bear in mind that administrators and managers have different concerns and expectations to contend with.²⁶ Budgets and operational realities have to be factored in.²⁷ From their perspective, practices that do not entirely align with protocol and instruction may negatively influence productivity, undermine authority or affect the financial performance of the organisation.²⁸ It might be more cost effective to remind employees to be careful and follow protocol, than make structural changes, procure better equipment, or invest in new technologies.²⁹ Categorising behaviour may offer the semblance of managerial control, as one falsely believes that such categorisation might mean the undesirable behaviour would cease.³⁰ However, problematic behaviour is often a product of the usefulness and rewards it offers, as determined by the circumstances and system in which one functions.³¹

Just-culture-by-algorithm might downplay how categories of culpability are constructed. Different perspectives and vested interests influence decisions.³² Categorising an act as blameworthy, might have more to do with risk manager's fears regarding liability, finances, or reputation. Rather than promoting trust, fairness and justice, an improperly

²⁴ Pellegrino "Prevention of medical error: Where professional and organizational ethics meet" *Accountability: patient safety and policy reform*. Georgetown University Press, Washington (2004) 83.

²⁵ Dekker and Nyce (2013) 2 *JHA* 75.

²⁶ Walton "Creating a "no blame" culture: have we got the balance right" (2004) 163.

²⁷ Reason (2016) 27.

²⁸ Dekker and Nyce "There is safety in power, or power in safety" *Safety Science* (2014) 67 44.

²⁹ Perrow *Normal accidents: Living with high risk technologies* (2011) 146.

³⁰ Catino "A Review of Literature: Individual Blame vs. Organizational Function Logics in Accident Analysis" *Journal of Contingencies and Crisis Management* (2008) 16 53.

³¹ Dekker (2011) 190.

³² Weiner et al. "The meaning of justice in safety incident reporting." *Soc Sci Med* (2008) 66 403.

applied algorithm may entrench and legitimate managerial control, whereby individuals become scapegoats at the expense of addressing more onerous system problems.³³

‘What is not widely acknowledged is that the algorithms that have emerged, the ones that control the process by which evidence appears and is weighted, are biased and slanted by a larger social matrix that encompasses hospital risk management, lawyers, quality control, the pharmaceutical industry, departmental managers and physicians. This web of influence and ideology benefits from portraying the achievement of justice-by-algorithm in healthcare as rationality and science. But what is represented as natural, objective, rational and common sense, is often anything but.’³⁴

4. WHO DRAWS THE LINE?

If we accept that the line cannot be drawn in isolation, that factors such as hierarchy may influence our clinical and social interpretation of events, and sway seemingly ‘objective’ decisions regarding accountability.³⁵ And we are cognisant of role that perception and power play in our formation of culpability categories and constructs.³⁶ The question then arises: who draws the line between unacceptable and acceptable behaviour?³⁷

4.1. THE ORGANISATION

Inevitably, a line has to be drawn.³⁸ In an organisation, that responsibility may fall upon a line functionary, either a supervisor or manager, or perhaps, even a separate division

³³ Dekker and Breakey “‘Just culture:’ Improving safety by achieving substantive, procedural and restorative justice” *Safety science* (2016) 85 189.

³⁴ Dekker and Nyce (2013) 2 *JHA* 76.

³⁵ von Thaden et al. “The perception of just culture across disciplines in healthcare” *Proceedings of the ...* (2006) 50 964.

³⁶ Dekker “Just Culture” (2012a) 32.

³⁷ Dekker (2009) 11 *Cogn Tech Work* 177.

³⁸ Driver et al. “Responding to clinicians who fail to follow patient safety practices: Perceptions of physicians, nurses, trainees, and patients” *Journal of hospital medicine* (2014) 9 99.

in the institution, such as the human resources or risk-management department.³⁹

In a just culture health workers expect to be treated fairly, and such fair treatment creates an environment of trust, thereby engendering a sense of psychological safety.⁴⁰ Individuals are more likely to report relevant safety information if they feel assured that they will not be exposed to unjustified treatment by administrators, managers, or colleagues. However, to protect patients from harm it may, occasionally, in some flagrant instances, be appropriate and fair to institute disciplinary proceedings.⁴¹ Still, a purely retributive just culture approach could be counterproductive, and inhibit openness and learning.⁴²

As mentioned, power and perception comes into play. A survey study conducted in 2006 into the perception of just culture across disciplines in healthcare, revealed differences in perceptions between physicians, management, nurses, and non-clinical staff.⁴³ Disparities were found between how different employee groups rated their organisation's culture. Particularly, where respondents were asked questions about accountability, such as: 'Are employees held equally accountable for their actions?', 'Is there blame or favouritism?', 'Does the organization recognize honest mistakes?'

Physicians tended to have the highest ratings, followed by management, then nurses and clinical staff. Groups with more power in the medical hierarchy had a different perception of accountability and were more likely to view their organisation's culture as just. If responses to errors are too hierarchical and punitively-focussed, employees will not come forward with information. Such a top-down approach will inhibit reporting and see to it that hazards go unidentified and unaddressed.⁴⁴

A retributive approach tries to determine, *who* made a mistake and how do we to deal

³⁹ Connor et al. "Creating a fair and just culture: one institution's path toward organizational change" *The Joint Commission Journal on Quality and Patient Safety* (2007b) 33 617.

⁴⁰ Weiner et al. (2008) 66 *Soc Sci Med* 403.

⁴¹ Leape and Fromson "Problem doctors: is there a system-level solution" *Annals of Internal Medicine* (2006) 144 107.

⁴² Shojania and Dixon-Woods "'Bad apples': time to redefine as a type of systems problem" (2013).

⁴³ von Thaden et al. (2006) 50 *Proceedings of the ...* 964.

⁴⁴ Dekker and Breakey (2016) 85 *Safety science* 187.

with *them*.⁴⁵ While, it must instead be determined, *what* was responsible for the occurrence of the mistake and how do we deal with *that*.⁴⁶ By focussing on the *who*, one can easily lose sight of underlying system problems and mitigating factors.⁴⁷ *What* (the problems and factors) caused the accident is then neither confronted, nor considered in disciplinary decisions.⁴⁸

These considerations are critical to the establishment of an effective just culture, where employees believe that they are treated fairly and not viewed as part of the unsafe care problem, but rather part of the patient safety solution.⁴⁹ Retributive just culture programs might not address all of these concerns. Other aspects of justice, that have been overlooked in some just culture constructions, may be required if an actual just culture is to be achieved.

Before we get to who draws the line, we must first consider who makes the rules, since the line is drawn where a rule is breached. This is a question of substantive justice, which relates to the morality and legitimacy of a rule's content.⁵⁰ If the rules are unfair, illegitimate or unworkable, culpability cannot be credibly determined in relation thereto. When rules are devised by persons who lack the required experience or who may be unfamiliar with operational realities, circumstances and pressures, 'violations' that get the job done are bound to take place. When certain rules are routinely disregarded by almost all conscientious employees, it may point to a disconnect between expectations and practical reality, thereby bringing the legitimacy of the rule into question.⁵¹ If substantive justice is ignored, good, hard-working healthcare professionals may be exposed to unfair sanction, which would be a death-knell for a just culture and

⁴⁵ Dekker "Reconstructing human contributions to accidents: the new view on error and performance" *Journal of Safety Research* (2002) 33 371.

⁴⁶ Stanton and Baber "A systems approach to human error identification" *Safety science* (1996) 22 215.

⁴⁷ Leveson "Applying systems thinking to analyze and learn from events" *Safety Science* (2011b) 49 55.

⁴⁸ Karanikas and Chionis (2017) *Policy and Practice in Health and Safety* 1.

⁴⁹ Hollnagel et al. "From Safety-I to Safety-II: A white paper" *The Resilient Health Care Net ...* (2015); Jeffrey et al. "Resilient Health Care, Volume 3" (2016); Jean and John "Resilience Engineering in Practice" (2017).

⁵⁰ Dekker and Breakey (2016) 85 *Safety science* 187.

⁵¹ Wachter and Pronovost (2009) 361 *N Engl J Med* 1401.

subsequently, severely inhibit reporting and safety.⁵²

Organisations that are truly concerned with fostering a just culture, and providing safer care, do not just leave the rules to the lawyers and risk-managers. Yet, some organisations, may cynically, do just that, in order to limit legal exposure and absolve the organisation and managers of liability.⁵³ Safety standards and the façade of a just culture program, conveniently allow for the identification of an individual scapegoat to shift blame to. Financially, it may make more sense to discipline an erring, overburdened nurse, than it would to implement a new computerised order entry system; or budget-constraints, might make it impossible to hire new staff to help ease the workload.

Luckily, the more ethical organisations and managers, that are actually interested in pursuing a just culture, can learn from other industries and involve frontline-workers, among other stakeholders, in the development of safety standards and rules. This adds to the legitimacy of the rules in the eyes of those who will have to comply with them. It gives a sense of ownership, knowing that their insights and experiences helped to shape the rules and will aid in creating a safer environment for their patients. By being part of the process, the workers can make sure that the rules correspond with the clinical realities they face. Their involvement ensures that the rules set out best practices currently achievable, whilst taking ‘sharp-end’ pressures and complicating factors into account.⁵⁴

Rules that are substantively just, will ring hollow if they are not married with legitimate processes for identifying transgressors, assessing their culpability and determining their sanction. Aspects of procedural justice become pertinent to the establishment of a just culture.⁵⁵ Especially, when stakeholders want to ensure that the rules are fairly

⁵² Hale and Swuste “Safety rules: procedural freedom or action constraint” *Safety science* (1998) 29 163; Dekker “Failure to adapt or adaptations that fail: contrasting models on procedures and safety.” *Appl Ergon* (2003) 34 233.

⁵³ Dekker and Breakey (2016) 85 *Safety science* 189.

⁵⁴ Dixon-Woods et al. “An ethnographic study of classifying and accounting for risk at the sharp end of medical wards.” *Soc Sci Med* (2009) 69 362.

⁵⁵ Dekker and Breakey (2016) 85 *Safety science* 190.

enforced. It is here where, 'who gets to draw the line', emerges as a key consideration.⁵⁶ Although, not quite in the formal legal sense, procedural justice, should perhaps still be an aspiration in organisations that wish to foster a just culture.

Such an aspiration could be meaningfully met, by introducing objective, independent adjudicators. Particularly, when disciplinary processes and decisions call for the use of discretion, since events can be construed in several divergent ways, depending on one's perspective and perception. Someone will have to grapple with negotiable notions, e.g., was 'reasonable care' exercised, was the 'expected standard' complied with, would another nurse have 'made a similar mistake under the circumstances'. And that someone will have to draw the line. If a line manager, that might have, or be seen to have a stake or vested interest, were to draw the line, it could taint perceptions of an institutions just culture amongst staff. It would, after all, be fair to presume that a line-manager, who imposes a sanction on an employee for a violation that may have occurred under his or her watch, may have an underlying agenda (e.g. a reputation to protect, career-related considerations, financial incentive, etc.) They may have an interest in the outcome, that may lead to actual or supposed bias.⁵⁷

An independent adjudicator would certainly be a step toward achieving procedural justice. However, there is another crucial step. As important as the independence of the decision-maker is, his or her experience and knowledge of the realities of clinical practice, and what it takes to get the job done, often despite severe time and resource constraints, is just as important. Decisions regarding accountability will be seen as more credible and just, if the person possesses a thorough understanding of the profession, practice and local circumstances. Finding an independent person with intimate knowledge of a particular clinical undertaking, could be difficult. A manager from a different unit would be a good start. Ideally, one would have an impartial safety department with a focus on system-based peer review.⁵⁸ Provision can also be made

⁵⁶ Dekker (2009) 11 *Cogn Tech Work* 177.

⁵⁷ *Ibid.*

⁵⁸ Edwards "The objective impact of clinical peer review on hospital quality and safety." *Am J Med Qual* (2011) 26 110; Hudson et al. "Toward improving patient safety through voluntary peer-to-peer assessment." *Am J Med Qual* (2012) 27 201; Pronovost and Hudson "Improving healthcare quality through organisational peer-to-peer

for an appeal process, as well as an opportunity to have a distinct sanction-phase, which would allow for the submission of mitigating factors and so forth, that can then be weighed by taking different factors into account.⁵⁹

4.2. PROFESSIONAL BOARDS

Outside of the organisation, the responsibility to draw the line may fall on Professional Boards or Associations.⁶⁰ Healthcare professionals who are affiliated to their respective boards or associations have to comply with certain rules and abide by guidelines that prescribe standards of ethical and professional conduct. These rules are by and large meant to safeguard the integrity and prestige of the profession, but may have the dual function of protecting the public. Professional Boards are usually legislatively empowered to investigate allegations of unprofessional conduct.⁶¹ To this end, Boards may institute disciplinary inquiries and impose sanctions, where practitioners are found to have been guilty. Statutory and regulatory provisions usually govern much of the procedural justice aspects of inquiries (as discussed above). Boards may delegate inquiries to disciplinary committees, that function as quasi-judicial administrative tribunals. As such, these disciplinary committees are legally obliged to conduct their inquiries in accordance with the principles of administrative justice. That is to say, it must act in a procedurally fair and reasonable manner, as well as provide adequate reasons for their decisions and sanctions.⁶²

assessment: lessons from the nuclear power industry." *Quality in health care : QHC* (2012) 21 872; Edwards "A longitudinal study of clinical peer review's impact on quality and safety in U.S. hospitals." *J Healthc Manag* (2013) 58 369; Kadar "Peer review of medical practices: missed opportunities to learn." *Am J Obstet Gynecol* (2014) 211 596; Reznik and Barton "Improved incident reporting following the implementation of a standardized emergency department peer review process." *Int J Qual Health Care* (2014) 26 278; Edwards "An Organizational Learning Framework for Patient Safety." *Am J Med Qual* (2017) 32 148.

⁵⁹ Dekker and Breakey (2016) 85 *Safety science* 191.

⁶⁰ Dekker (2009) 11 *Cogn Tech Work* 177.

⁶¹ The Health Professions Council of South Africa (HPCSA), through its Professional Boards and Committees, is authorized to exercise this function in terms of the Health Professions Act 56 of 1977.

⁶² Oosthuizen "An analysis of healthcare and malpractice liability reform: aligning proposals to improve quality of care and patient safety" *repository.up.ac.za* (2014) LLM See Chapter 1 for an overview of the HPCSA and Professional Conduct Enquiries.

Sanctions vary in severity, from a caution or reprimand, to the removal from the register, with the effect of being disqualified from practice. Due to the fact that disciplinary proceedings involve members of the profession, who know and appreciate the standards demanded of it, and would therefore be in the best position to consider and evaluate the standards it seeks to maintain, courts are reluctant to interfere with their decisions. Although, where interference is warranted by the principles governing appeals and review, courts will not hesitate to intervene. As to where the line is then drawn, despite the wide-ranging authority vested in the Professional Boards, the judiciary may still be called upon to make the final decision.

The purported objectives of Professional Boards may be undermined if an overly retributive stance is adopted in regard to what is deemed to be unprofessional conduct.⁶³ Legislators often entrust Professional Boards with expansive powers with which to internally administer justice. However, if such administration of justice merely falls back on a traditional view of medical error, and attempts to address error in accordance with that view by assigning blame and imposing penalties, it will not do the profession, it aspires to guide, or the public, it wishes to protect, any favours.⁶⁴ If human error is labelled unprofessional conduct, associated and treated with the same ignominy as other acts that trigger disciplinary action – fraud, substance abuse, receiving perverse incentives and engaging in unacceptable relationship – it is unlikely that practitioners would be very forthcoming about their mistakes.⁶⁵ No erring practitioner will provide information regarding a mistake, in the interest of safety, where the perception is that human error is on par with, what is undoubtedly, intentional, disreputable behaviour.⁶⁶

Professional Boards that fallaciously equate human error to unprofessional conduct, should instead alter their disciplinary standards to support patient safety. It may be difficult to achieve, being that professional inquiries inevitably follow a person approach,

⁶³ Shojania and Dixon-Woods (2013).

⁶⁴ Karanikas and Chionis (2017) *Policy and Practice in Health and Safety* 1.

⁶⁵ Lazarus “On the road to find out... transparency and just culture offer significant return on investment” *Journal of Healthcare Management* (2011) 56 223.

⁶⁶ Stanton and Baber (1996) 22 *Safety science* 215.

instead of a system approach to alleged unprofessional conduct. There may have to be more coordination between Professional Boards and the Ombud if system factors are to be meaningfully addressed. Although, rather cynically, it may be more expedient for Boards to stand by their ‘few bad-apples’ policy, ‘sacrificing’ individual practitioners for the good of the profession.⁶⁷ This might be done in an attempt to defend and distance the wider profession from medical error, as it could make practitioners feel less at risk if errors can be attributed to a colleague’s inattentiveness, unskillfulness or personal flaws. Admitting that we are just as vulnerable to error might increase our sense of uncertainty and give rise to anxiety. Medical errors and harm are relatively common, though the public might be unaware of the prevalence of unsafe care. If the profession can create the impression that the ‘few bad apples’ responsible for iatrogenic harm are being dealt with, the public can continue to feel secure and at ease. By avoiding public disapproval, the profession is able to keep outside interference to a minimum and continue their affairs unencumbered by regulatory, or judicial scrutiny.⁶⁸

4.3. HEALTHCARE REGULATOR OR OMBUD

Where complaints are received about healthcare organisations or healthcare providers, a regulator or ombud may be called upon to draw a line. The regulator, through its delegated ombud, exercises an oversight function, and aims to guide, monitor and enforce standards in the healthcare industry. The ombud will usually be a member of and have experience in the industry he or she oversees. The ombud’s history and knowledge of the specific domain, gives him or her a better understanding of its sources of safety. This allows the ombud to better balance concerns and interests when considering where to draw the line.⁶⁹ Being a healthcare professional and knowing the circumstances and pressures that practitioners face on a daily basis, furnishes the ombud with a ‘sharp-end’ perspective, non-domain experts may lack. This permits the

⁶⁷ Leape and Fromson (2006) 144 *Annals of Internal Medicine* 107; Shojania and Dixon-Woods (2013).

⁶⁸ Wachter and Pronovost (2009) 361 *N Engl J Med* 1401.

⁶⁹ Miller et al. “A Statewide Approach to a Just Culture for Patient Safety: The Missouri Story” *Journal of Nursing Regulation* (2010) 1 52; Dekker “The criminalization of human error in aviation and healthcare: A review” *Safety science* (2011b) 49 121; Gallagher and Mazor “Taking complaints seriously: using the patient safety lens” (2015); Gandhi et al. “Patient safety at the crossroads” *JAMA* (2016) 315 1829.

ombud to better evaluate nuances of individual performance in relation to wider systemic influences. By not being bound to a narrow investigation of specific conduct, the ombud can examine the organisation as a whole, and benefit from that contextual knowledge and insight when making decisions regarding healthcare standards.

It is, of course, also possible that a lack of oversight or the inadequate functioning of the ombud could contribute or factor in the occurrence of an incident. If the ombud does a poor job of prescribing or upholding standards, or the standards it enforces are innately inappropriate or unsound, it could increase the susceptibility of healthcare organisations to incidents or entrench rules that undermine the establishment of a just culture. An ombud is also at risk of governmental interference, especially, when he or she is appointed by a minister. The ombud could also be indirectly impeded in exercising its mandate, e.g. by not receiving adequate funding or support from government. Safeguards have to be put in place to ensure that the ombud can function independently and impartially, without succumbing to undue influence.

4.4. JUDICIARY

Finally, when a decisive line has, perhaps, been elusive, society has given the judiciary the authority to draw the line.⁷⁰ The justice system is after all meant to satisfy our notions of rationality, objectivity and impartiality. However, Dekker argues that there can be no real objective view, as it would have to be 'a view from nowhere', which does not exist.⁷¹ All views are shaped by values, interests and stakes. The best we can do, is acknowledge these values and interests, and try to keep them in check. When judgements are handed down, they are not conceived in isolation, free from external influences or factors – what Dekker refers to as the 'negotiated outcome of a social process'.⁷² Therefore, judicial findings are not unlike any other social process, in that they are guided, perhaps unknowingly, by history, tradition, culture, institutions,

⁷⁰ Dekker (2009) 11 *Cogn Tech Work* 177.

⁷¹ Dekker (2007) 86.

⁷² *Id.* 87.

personal interactions, background, values, hopes, fears and desires. The legal process endeavours to uncover the truth.⁷³ For this it relies on different stories or versions of events. Multiple versions of the ‘truth’ can compete and contradict each other, whilst remaining valid. Inevitably, courts have to settle upon one version of the ‘truth’ and ascribe that ‘story’ to the events that unfolded. This can sometimes prove to be an injustice to the real complexity that surrounded the events. Zealous legal advocacy in an adversarial system can also construe the ‘truth’ to support one side’s argument.⁷⁴

What impact is there on a just culture, if the judiciary steps in to draw the line? Rather paradoxically, when the justice system gets involved, things do not get any safer or more just. In fact, it might have the opposite effect. This is, in part, due to the difficulties involved with the retrospective evaluation of adverse events. The legal classification of conduct as negligent, is actually quite complex. It relies on a number of judgement calls regarding, what is essentially, an after-the-fact social construction.⁷⁵ Moreover, those called upon to evaluate the behaviour are invariably subject to ubiquitous bias, often unwittingly. Particularly, outcome and hindsight-bias. There is often limited awareness of the pervasive influence of these biases, not only in court, but wherever unintended patient harm is retroactively assessed in order to draw a line (thus, relevant to all the decision-makers discussed above). In the context of legal proceedings, outcome and hindsight bias, can affect everyone, from the experts that drafted the medico-legal reports, to the judge that will ultimately decide the matter.

4.4.1. HINDSIGHT BIAS

‘In situations where information is limited and indeterminate, occasional surprises—and resulting failures—are inevitable. It is both unfair and self-defeating to castigate decision makers who have erred in fallible systems without admitting to that fallibility and doing something to improve the system.’⁷⁶

⁷³ Laudan *Truth, error, and criminal law: an essay in legal epistemology* (2006).

⁷⁴ Dekker (2007) 88.

⁷⁵ Hugh and Dekker (2009) 16 *J Law Med* 846.

⁷⁶ Fischhoff “Hindsight is not equal to foresight: The effect of outcome knowledge on judgment under uncertainty.” *Journal of Experimental Psychology: Human perception and performance* (1975) 1 288.

These words are taken from a landmark study by Fischhoff, which first provided evidence of the cognitive phenomenon known as hindsight bias (Fischhoff first referred to it as 'unperceived creeping determinism'). The study consisted of three experiments, which demonstrated that finding out that an outcome has occurred increases its perceived likelihood. Furthermore, the judges that were informed of the outcome, were unaware of the effect that outcome knowledge had on their perceptions. This meant that they were inclined to believe that this relative inevitability was almost apparent in foresight, without the benefit of knowing what happened. Being unaware of your own hindsight bias, not only affects your impression of what you would have known without knowledge of the outcome, but, even more interestingly, it also biases your impression of what you yourself actually did know in foresight. The implication of this is, that unperceived hindsight bias can seriously impair our ability to judge the past or learn from it.

The impact of this bias on the judiciary, might entail that judges, as retrospective reviewers of an adverse event, possessing knowledge of the outcome, may have an inflated sense of their own potential to foresee the *ex ante* eventual harm. They would believe that they could have predicted or known what was going to occur. Thus, hindsight bias is observed in the anticipation of probabilities regarding prospective incidents. Once the outcome is known we start to causally link behaviour and events, suddenly confident that everything that came before the incident was clearly pointing to the end-result. Hindsight bias makes, what is in actual fact a complex attribution of fault to human error, seem simple. The immense convergence of pressures, factors, indeterminate events, uncertainties, and contributions, that had to be navigated by the practitioner at the time of the incident, are downplayed when the outcome is known. We tend to attach more weight to the significance of certain aspects or singular actions that could have probably prevented the eventual harm, ignoring the indeterminacy and complexity of the context surrounding the events leading up to the adverse event. We impute the outcome to, what we now clearly perceive as, a negligent misdiagnosis, oversight or unfulfilled duty of care.

Several authors have reflected on the influence of hindsight bias on legal decision-

making.⁷⁷ Considering that one of the key functions of the legal system, is the evaluation and attribution of blame after an outcome has occurred, those involved in the legal process are highly susceptible to the subtle sway of hindsight bias.⁷⁸ Investigations in the United States have shown, that information regarding the outcome, influences the amount of money jurors award to plaintiffs, it affects jurors' perceptions relating to foreseeability of adverse events, and even alters jurors' opinions about defendants' intentions and their state of mind.⁷⁹ Although, judges are experienced and well-trained decision makers, they are vulnerable to the same cognitive illusions, these biases may produce systematic errors in judgment.⁸⁰

4.4.2. OUTCOME BIAS

Negative outcomes have also been associated with increases in hindsight bias, as well as outcome bias. Outcome bias is closely related to, and often conflated with, hindsight bias. It pertains to the influence of outcome knowledge on perceptions regarding decision quality. The more severe the negative outcome, the larger the bias. This is particularly prevalent in medical malpractice lawsuits. In determining whether practitioners acted negligently, jurors have been found to not limit their assessments to the conduct of the defendant (i.e. did the practitioner adhere to the expected standard of care). Instead, jurors incorrectly allow their determination of negligence to be influenced by the medical outcome or damage suffered. Conduct, is therefore, more likely to be labelled negligent if the patient suffered serious harm or permanent impairment.

Outcome bias, is not confined to lay jurors – practicing healthcare professionals have also been observed to succumb to the same cognitive distortion, when evaluating the appropriateness of care provided by other practitioners.⁸¹ Caplan *et al.* asked 112

⁷⁷ Guthrie et al. "Inside the judicial mind" *Cornell L. Rev.* (2000) 86 777; Guthrie et al. "Blinking on the bench: How judges decide cases" *Cornell L. Rev.* (2007) 93 1.

⁷⁸ Harley "Hindsight Bias In Legal Decision Making" *Social Cognition* (2007) 25 48.

⁷⁹ LaBine and LaBine "Determinations of Negligence and the Hindsight Bias" *Law and Human Behavior* (1996) 20 501.

⁸⁰ Guthrie et al. (2000) 86 *Cornell L. Rev.* 777.

⁸¹ Caplan et al. "Effect of outcome on physician judgments of appropriateness of care." *JAMA* (1991) 265 1957.

practicing anaesthesiologists to judge the appropriateness of care in 21 cases involving adverse anaesthetic outcomes. The original outcome in each case was classified, according to severity, as either temporary or permanent. Matching alternate, yet identical, case histories were generated, original in every respect except that a plausible outcome of opposite severity was substituted. The reviewers were asked to rate the care in each case as appropriate, less than appropriate, or impossible to judge, based on their personal (implicit) judgment of reasonable and prudent practice. Despite identical case histories, and identical care given to the patients, care was rated as less appropriate when the outcome was changed from temporary to permanent (more severe outcome). Conversely, the reviewers rated the care more appropriate when the outcome was temporary or less severe.⁸²

Knowledge of the severity of outcome can thus, significantly influence our judgment regarding the appropriateness of care. Furthermore, the authors found that the severity of outcome affected not only the harshness of implicit judgments but also the willingness to render judgments. The extent to which practitioners are influenced by outcome bias, could have significant implications with respect to the findings of expert medico-legal reports in medical negligence claims.

Blendon *et al.* conducted parallel surveys of physicians and the public to learn their views on medical errors.⁸³ The questionnaires included a vignette, a hypothetical account of a patient who has an allergy to antibiotic drugs, which is noted on his medical record. Despite this allergy, a hospital nurse administers the antibiotic. To see if views on the appropriate consequences for the health professionals would vary depending on the severity of the error's outcome, the authors varied the health consequences for the patient. One group were told that the patient was harmed, the other group was told that the patient was unharmed.

The outcome of the vignette had a significant impact on views of appropriate consequences for those involved in the medical error. Physicians in the harm group were notably more likely to support malpractice lawsuits against the surgeon, nurse,

⁸² *Ibid.*

⁸³ Blendon et al. "Views of practicing physicians and the public on medical errors." *N Engl J Med* (2002) 347 1933.

and hospital. The public in the harm group were also substantially more likely to support lawsuits and suspension of the surgeon's license.

Judges rely heavily on expert opinions when deciding cases of medical negligence. These decisions can have far reaching consequences for plaintiffs, individual defendants, and now even entire medical specialities. Litigation in the field of obstetrics and the large amounts of damages that are awarded in such cases, has had severe repercussions for indemnity insurance premiums, as well as provincial health budgets.

It is common, in the aftermath of an adverse fetal outcome, to retrospectively review cardiotocographic (CTG) tracings. Delayed or inadequate responses to non-reassuring CTG tracings are frequently found to have contributed to fetal hypoxia/acidosis, often leading reviewers to believe that more appropriate clinical management could have avoided adverse outcomes. Studies have, however, found that CTG interpretation is subject to high inter-observer and intra-observer variability, particularly in non-reassuring cases.⁸⁴ Prior knowledge of an adverse fetal outcome has also been shown to result in a more severe clinical interpretation of CTG tracings.

In a recent international multi-centre study, knowledge of fetal outcome significantly influenced CTG interpretation and subsequent management recommendations. Hindsight and outcome bias were observed in senior clinicians and heads of department interpreting CTG and clinical decisions. Knowledge of a normal outcome led to an increase in 'normal' classifications and knowledge of an acidotic outcome led to an increase in 'pathologic' classifications. Interpretation of CTG tracings are highly susceptible to hindsight and outcome bias.

Intrapartum hypoxia remains a leading cause of obstetrical litigation and CTG interpretation plays a pivotal role during these proceedings. Expert court witnesses must therefore, endeavour to judge clinical situations *ex ante* and not *ex post*. Not doing so would mean that their biases would be passed on to judges who are almost entirely

⁸⁴ Ayres-de-Campos et al. "Knowledge of adverse neonatal outcome alters clinicians' interpretation of the intrapartum cardiotocograph." *BJOG* (2011) 118 978.

dependent on their expertise.⁸⁵

At the end of the day, judges draw the final line. They decide which evidence they will attach more weight to in their final judgement. This decision, as well as the evidence it relies on, could be tainted by hindsight and outcome knowledge. By focussing on the outcome, rather than the processes – the consequences that are often not proportionate to the cause – one can easily come to unjust conclusions. What is known as the illusion of cause–consequence equivalence.⁸⁶ These assessments can include counterfactuals, what people should or should not have done. But, this gets us no closer to understanding or explaining the human error, it merely describes a reality that did not occur.

Practitioners, almost always act according to what must have made sense to them at the time, given their objectives, situational indications, operational pressures, organisational norms and experience. This is the local rationality principle. As Dekker explains: ‘The challenge for patient safety is not why bad people produce adverse events but to understand why good people do.’⁸⁷ Behaviour can only really be understood, in the context and from the point of view of those who made, what from an outside perspective with the benefit of hindsight, turned out to be an error. To improve safety, one needs to determine why the decision that amounted to an error, seemed from the inside to be a normal, routine decision, rationally linked to the goal or task they wished to achieve. To gain such an understanding, it is necessary to reconstruct the situation as it unfolded from the practitioner’s view directly before the incident, not as it looks to us now. If we are only concerned with causally working backwards from the eventual outcome, we might be able to predict what we already know, but such delusional clarity will not teach us anything we don’t know.⁸⁸ Important patient safety lessons will remain unlearned.

⁸⁵ Reif et al. “Does knowledge of fetal outcome influence the interpretation of intrapartum cardiotocography and subsequent clinical management? A multicentre European study.” *BJOG* (2016) 123 2208.

⁸⁶ Dekker (2014b) 30.

⁸⁷ Dekker (2011) 55.

⁸⁸ Dekker (2007) 84.

4.4.3. THE NATURE OF MALPRACTICE LITIGATION SYSTEM

Besides the inherent and implicit biases that may be prevalent in retroactive determinations of negligence, medical malpractice litigation may very well be inimical to patient safety.⁸⁹ The way in which the legal system functions, deterrence through the attribution of blame and damage awards, is at odds with our current understanding of human error and effective prevention strategies. One can argue that two seemingly irreconcilable cultures collide when practitioners and their errors are subjected to medical malpractice suits.⁹⁰

The threat of litigation, proponents assert, incentivises safer care. However, very little evidence exists to substantiate such an assertion.⁹¹ Frakes and Jena, in a recent study, concluded that there is ‘at most, a modest degree of deterrence stemming from the present liability system’ and that ‘under existing liability standards, malpractice penalties generate little to no benefits in health care quality’.⁹² They did, however, find some evidence to suggest that medical liability may potentially influence physician behaviour. Altering the legal clinical standard to which physicians are held, i.e. locality rule abdications, may be effective in elevating the standard of care.⁹³ This only seems to apply to liability standards that establish a higher expectation of care, when liability standards change, possibly condoning lower-quality care, physicians did not respond by reducing the quality of their practices. It may however be that other factors besides the liability system influenced the improvements observed.⁹⁴

Another recent study by Bilimoria *et al.* examining the effect of the malpractice environment on outcomes and costs, found no evidence suggesting that liability is

⁸⁹ Donaldson *Making amends: a consultation paper setting out proposals for reforming the approach to clinical negligence in the NHS: a report by the Chief Medical ...* (2003).

⁹⁰ Studdert et al. “Medical Malpractice” *N Engl J Med* (2004) 350 283.

⁹¹ Avraham and Schanzenbach “Medical Malpractice Reform” *SSRN Journal* (2015).

⁹² Frakes and Jena “Does Medical Malpractice Law Improve Health Care Quality” *J Public Econ* (2016) 143 142.

⁹³ *Ibid.*; Frakes “The surprising relevance of medical malpractice law” *The University of Chicago Law Review* (2015) 317; Frakes et al. “Do Physicians Respond to Liability Standards?” *Journal of Institutional and Theoretical Economics (JITE)* (2015) 171 58.

⁹⁴ Prantl “Medical Liability Standards and Clinical Practice in the US: Comment” *Journal of Institutional and Theoretical Economics* (2015) 171 78.

effective in deterring negligent medical practice or in promoting better outcomes.⁹⁵ Adding to the body of existing literature exhibiting similar findings. Patients treated in high-malpractice risk states actually had higher risks of postoperative adverse events compared with patients treated in low-malpractice risk states. The authors, conjectured, that this could be explained by defensive medicine practices that increase the risk of patient harm.

Scant evidence exists to suggest that litigation incentivises safer practices. In fact, several studies have shown that it might incentivise undesirable practices.⁹⁶ The malpractice litigation system also follows an adversarial, individualistic and punitive approach, which is entirely inconsistent with the approach recommended by safety experts. These experts advocate for the adoption of a just culture, within the broader framework of a safety culture, whereby responses to errors are non-punitive, systems-orientated, cooperative, based on trust and accountability (as opposed to blame).

Transparency is also emphasised. Practitioners are encouraged to be forthright and open regarding their mistakes. Errors are seen as learning opportunities, and thus candidly reported. Practitioners that report honest errors are met with appreciation and support, rather than condemnation and sanction. Everyone in the organisation understands that most errors arise from the faulty systems, not from practitioners' incompetence or carelessness.

This is in stark contrast to the medical malpractice system. In the retrospective determination of negligence, individual practitioners are the focus, blame is assigned, and compensation is awarded on that basis, related to the damage suffered. Damages awarded, usually reflect the severity of the outcome, not the magnitude of the error. The threat of litigation and the adverse consequences thereof for the practitioner involved, ensures that errors are only reported if they cannot be concealed. Information regarding the error is then only shared with a defence attorney, and only for purposes of managing

⁹⁵ Bilimoria et al. "Association Between State Medical Malpractice Environment and Surgical Quality and Cost in the United States." *Ann Surg* (2016) 263 1126.

⁹⁶ Defensive medicine and other shortcomings of the malpractice litigation system will be further discussed in a following chapter.

liability. Patients might not even get an explanation or apology, for fear that it may be interpreted as an admission of guilt or used as evidence in a potential trial. The medical malpractice system engenders a climate of fear and silence, negatively impacting the establishment of a safety culture (encompassing just culture) in the healthcare system.

5. CONCLUSION

Where the line is drawn, may not be as important as *who* draws the line. Power and perception come into play, as soon as someone is called upon to draw a line. Vested interests could be furthered if just-culture-by-algorithm approaches are disingenuously implemented. Instead of promoting trust, fairness and justice, such approaches could entrench and legitimise hierarchical control, at the expense of real system safety improvements.

Despite these concerns, a line will inevitably have to be drawn. That responsibility may fall upon the organisation, professional boards, regulators and ombuds, and finally, the judiciary. These adjudicators can all have a significant influence on the preservation of a just culture. Issues surrounding procedural and substantive justice may arise. Financial and political factors carry immense weight. Hindsight and outcome biases can sway decisions. And the legal system, paradoxically, could very well be an impediment.

The next chapter will look at what happens after a line has been drawn.

CHAPTER 8. JUST CULTURE - WHAT HAPPENS AFTER THE LINE HAS BEEN DRAWN?

1. INTRODUCTION

There is a chasm between accountability and blame. Accountability plays a key role in patient safety, blame inhibits it.¹ If we are to achieve a safe and just culture, we need to rethink our conventional notion of accountability. What information do we adjudge to be relevant and what is it that we wish to accomplish by ascribing accountability?

2. TWO FORMS OF ACCOUNTABILITY

Sharpe makes a distinction between two types of accountability ascription: accountability in the backward-looking or retrospective sense, and accountability in the forward-looking or prospective sense. Retrospective accountability, is retributive, it focusses on outcomes; errors are met with blame and sanction. Prospective accountability, is restorative, it focusses on processes; errors are viewed as lessons and represent opportunities for improvement.²

The medical malpractice system (or an overly rigid organisational just culture algorithm) ascribes accountability in the backward-looking sense. Errors are only actionable or relevant when they cause harm, near-misses do not merit consideration. It seeks to deter further individual malpractice by imposing culpability and punishment.

Accountability can become forward-looking if, instead, a systems approach to error is followed.³ Errors are bound to occur in an environment as dynamic, complex, and high-

¹ Sharpe (2003) 33 *The Hastings Center report* S3.

² *Ibid.*

³ Leveson *Engineering a safer world: Systems thinking applied to safety* (2011); Leveson (2011b) 49 *Safety Science* 55.

risk as healthcare.⁴ Every participant in the system is cognisant of that fact, and subsequently constantly vigilant, practitioners and the organisation have an interdependent shared responsibility towards patients and their safety. Prospective accountability involves proactive preventative measures, that include: designing safety and safeguards into the system to catch errors before they can cause harm, improving poor organisational or operational processes, establishing adverse event and error reporting systems, investigating and analysing root causes of error, and fostering a safety culture where errors can be openly discussed and examined. Healthcare financing and delivery has changed significantly in the past century, it can no longer be said that a solitary physician bears the sole responsibility for the welfare of a patient.⁵

It could be argued that the duties practitioners have toward their patients, shaped by the ethical imperative ‘to help, or at least do no harm’, should be extended to those who have substantial control, albeit indirect, over decision-making that can significantly affect patient wellbeing.⁶ Whereas, practitioners have been held accountable to a certain standard of ethical behaviour and practice, administrators and healthcare managers, who can, arguably, influence the quality of care and outcome just as much, have not traditionally been held to the same exacting standards.⁷ If one accepts that patient safety is an interdependent shared responsibility, it calls for *prospective* collective accountability, or at least a more nuanced balance between individual and institutional accountability.⁸

Seeing as the complexities of institutionally delivered health care has altered the nature

⁴ Woods and Branlat “Basic patterns in how adaptive systems fail” *Resilience engineering in practice* (2011) 127.

⁵ Genovese et al. “A new paradigm on health care accountability to improve the quality of the system: four parameters to achieve individual and collective accountability” *Journal of global health* (2017) 7.

⁶ Sage et al. “Enterprise liability for medical malpractice and health care quality improvement” *Am. JL & Med.* (1994) 20 1; Sage “Enterprise liability and the emerging managed health care system” *Law and Contemporary Problems* (1997) 60 159; Havighurst “Vicarious liability: relocating responsibility for the quality of medical care” *Am. JL & Med.* (2000) 26 7.

⁷ Allen “Accountability for clinical governance: developing collective responsibility for quality in primary care” *Bmj* (2000) 321 608; Sorensen and Iedema “Redefining accountability in health care: managing the plurality of medical interests” *Health* (2008) 12 87; Bell et al. “Accountability for medical error: moving beyond blame to advocacy.” *Chest* (2011) 140 519.

⁸ Sharpe (2003) 33 *The Hastings Center report* S3.

and scope of responsibility, prospective accountability allows us to reassess medical error, in light of what we now know of safety and error in complex, high-risk systems (bad systems, not bad people).⁹

Prospective accountability aligns everyone who influences patient care (physicians, nurses, pharmacists, administrators, hospital managers and boards, technicians, information specialists etc.) toward safety improvement.¹⁰ Prospective accountability, ensures that healthcare professionals are seen as a solution to harness, not just as a problem to retrospectively control.¹¹ Accountability is the specified obligations that contribute to safer care. In terms of the systems approach, we now know that, in order to improve we will need to target latent conditions created at the organisational ‘blunt end’, system defects, and unsafe acts and psychological precursors at the ‘blunt end’. Fulfilling this obligation and being truly accountable means that errors are reported, assessed, learned from, so as to implement system reforms and prevent future harm.¹²

3. ERROR WISDOM AND FORESIGHT

If the recurrence of adverse events and patient harm cannot be prevented by blaming and punishing healthcare workers, in fact it may even be counter-productive in the prospective accountability sense, where does it leave us? Clearly, healthcare organisations should review their system defences regularly, bolstering safeguards wherever they exist or could be anticipated. However, it remains unlikely that all the latent conditions or ‘pathogens’ could be vanquished from the system, no matter how meticulously such a process is undertaken.

Physicians and nurses continue to be the last line of defence, owing to their proximity to patients. Reason submits, that these sharp-end workers should be provided with the

⁹ McCall and Pruchnicki “Just culture: A case study of accountability relationship boundaries influence on safety in HIGH-consequence industries” *Safety science* (2017b) 94 143.

¹⁰ Sharpe *Accountability: patient safety and policy reform* (2004).

¹¹ Professor “Safety-I and Safety-II” (2014); Braithwaite et al. “Resilient health care: turning patient safety on its head.” *Int J Qual Health Care* (2015) 27 418; Jeffrey et al. (2016).

¹² McCall and Pruchnicki (2017b) 94 *Safety science* 143.

mental skills that will help them recognise potentially harmful, error-prone situations.¹³ They should be made more error-wise, i.e., aware of the hazards and risks lurking within the system.¹⁴ The healthcare domain is unique, in that there is a diversity of complex activity and equipment, a high degree of uncertainty, and vulnerable subjects in direct contact with staff, purely systemic counter-measures are not enough to pre-empt adverse outcomes. Practitioners will have to be made more ‘mindful’ of dangers.

To enhance risk-awareness healthcare can learn from high-reliability organisations. One defining feature of these organisations, is their preoccupation with failure, both technical and human. In other words: ‘Individual mindfulness of danger needs to be sustained and supported by a collective mindfulness of the operational risks.’¹⁵ Healthcare professionals generally acquire an enhanced risk-awareness through years of experience in their field. This mental preparedness, over and above their technical proficiency, plays an important role in the attainment of excellence. Reason poses the following question in this regard: would it be possible to accelerate risk-awareness, which has in the past only been obtained through the experiential learning process, by providing frontline workers and inexperienced physicians with training in identifying high-risk situations?¹⁶

3.1. REASON’S THREE BUCKET MODEL

In another brilliantly simple mental model, Reason illustrates how frontline workers can help avoid errors if they are able recognise high-risk situations, by using ‘error-wisdom’ or ‘foresight’.¹⁷ Reason explains how healthcare practitioners can detect, assess and avoid potentially harmful outcomes by evaluating three aspects of their current situation or task. These aspects are depicted as three buckets:

‘One bucket reflects the well-being or otherwise of the front-line individual; the second relates to the error-provoking features of the situation; and the third

¹³ Reason (2016) 72.

¹⁴ Reason (2004) 13 Suppl 2 *Qual Saf Health Care* ii28.

¹⁵ Reason (2016) 89.

¹⁶ *Ibid.*

¹⁷ Reason (2004) 13 Suppl 2 *Qual Saf Health Care* ii28.

concerns the nature of the task – individual tasks and task steps vary widely in their error potential.¹⁸



The three buckets are filled with 'bad stuff', the more that goes into each bucket, the higher the probability of an error occurring becomes. Full buckets do not mean that an adverse event will occur, just as empty buckets do not ensure safety. The amount of 'bad stuff' in the buckets (each bucket scaled from 1 to 3, with a total cumulative score of 9 for all three) increases the likelihood of an unsafe act or error. If the situation is assessed to be between 6 and 9, red flags should immediately be raised (figuratively), as this could indicate a serious risk of an error occurring. Where possible, such an individual should rather take a step back and seek assistance.

According to Reason his three-bucket model seeks to emphasise the following aspects of mental preparedness: 1) Accept that errors are inevitable; 2) Stop to assess the 'bad stuff' before undertaking a task; 3) Be willing to seek more qualified help; 4) Establishing your immediate colleagues' knowledge and experience in relation to the patient, don't let professional courtesy get in the way; and 5) Appreciate that the path to adverse events is paved with false assumptions.¹⁹

Reason submits that frontline staff equipped with 'error wisdom' or 'foresight' would be able to act as 'harm-absorbers' between the system's weaknesses and the patient. The National Patient Safety Agency (NPSA) in the United Kingdom has adapted Reason's three-bucket model and developed a foresight training package in order to improve the

¹⁸ Reason (2016) 91.

¹⁹ *Id.* 92.

prospective risk analysis abilities of healthcare workers.²⁰ The foresight training package aims to develop the skills that would allow healthcare workers to individually assess the risks in any given situation. The training complements existing retrospective risk analysis tools, such as the incident decision tree and root cause analysis.²¹

3.2. EARLY WARNINGS AND COLLECTIVE FORESIGHT

In the aftermath of the disaster at Mid Staffordshire, Macrae published a paper that adapted Barry Turner's work on organisational accidents to healthcare systems.²² Turner, who is regarded as a pioneer in the realm safety and risk-management, introduced his 'Man-made Disaster' model nearly four decades ago.²³ This model included the concept of 'incubation'; Turner's best known and most important contribution. Organisational accidents, do not just happen, they develop over time. As Turner and Pidgeon state in the second edition of 'Man-made Disasters':

'...a disaster or cultural collapse occurs because of some inaccuracy or inadequacy in the accepted norms or beliefs but, if the disruption is to be of any consequence, the discrepancy between the way the world is thought to operate and the way it really is rarely develops instantaneously. Instead, there is an accumulation over a period of time of a number of events which are at odds with the picture of the world and its hazards represented by existing norms and beliefs. Within this 'incubation period' a chain of discrepant event, or several chains of discrepant events, develop and accumulate unnoticed.'²⁴

Organisations operate according to cultural beliefs, collective norms, and shared assumptions, that may be codified as standards or protocols or observed tacitly. A disaster occurs after there has been a continual critical divergence between these

²⁰ Foundation, *Foresight training*, 2008, <<http://www.nrls.npsa.nhs.uk/resources/?entryid45=59840>>.

²¹ Boakes "Using foresight in safe nursing care." *J Nurs Manag* (2009) 17 212.

²² Macrae "Early warnings, weak signals and learning from healthcare disasters." *BMJ Qual Saf* (2014) 23 440.

²³ Turner *Man-made disasters* (1978).

²⁴ Turner and Pidgeon *Man-made disasters* (1997) 72.

beliefs, norms, and assumptions and the real state of affairs in the organisation.²⁵ Discrepancies creep in, causing increasing underlying system vulnerability. These weaknesses accumulate over prolonged periods and then converge with concealed contributory preconditions ('pathogens', as Reason calls them) to defeat system defences or safeguards (if they were ever implemented). Turner states that: 'In this incubation stage the failure of foresight develops'.²⁶ In other words latent errors and events go unnoticed, or are culturally taken for granted, because of a collective failure of organisational intelligence.²⁷ The accumulation of unrecognised risk then becomes a gradual drift into failure.²⁸ It is very likely that the management system would have lost touch with the operational realities ahead of such failure.²⁹

Organisational accidents are usually preceded by systematic and protracted periods of time wherein warning signs and signals of harm go unnoticed or are either ignored or neglected. Macrae describes incubation in the healthcare context as follows:

'In healthcare organisations some of the key sources of missed, miscommunicated or misinterpreted signals of risk are closed professional cultures, competing and conflicting demands, and the inherent ambiguity of many forms of adverse event.'³⁰

Professional power relations, medical hierarchies, concerns about career advancement, perceived complicity, cultural censorship, and a fear of blame, can all keep professional concerns regarding safety issues and warning signs concealed. Common problems can also be played down as normal, attributed to an imperfect system. Healthcare workers are accustomed to working under severe time-pressures,

²⁵ Dekker *Drift into failure: From hunting broken components to understanding complex systems* (2012b); Dekker and Pruchnicki "Drifting into failure: theorising the dynamics of disaster incubation" *Theoretical Issues in Ergonomics Science* (2013) 15 534.

²⁶ Turner "The organizational and interorganizational development of disasters" *Administrative Science Quarterly* (1976) 21 378.

²⁷ Pidgeon and O'Leary "Man-made disasters: why technology and organizations (sometimes) fail" *Safety Science* (2000) 34 15.

²⁸ Dekker and Pruchnicki (2013) 15 *Theoretical Issues in Ergonomics Science* 534.

²⁹ Turner "Causes of Disaster: Sloppy Management" *British Journal of management* (1994) 5 215.

³⁰ Macrae (2014) 23 *BMJ Qual Saf* 2.

without sufficient equipment or supplies, keeping up with clinical demand despite inadequate staffing, or a general lack of resources. Whilst it may be thought of as acceptable, these ‘ordinary’ problems incubate organisational accidents.

Macrae suggests that we apply Turner’s thinking to healthcare systems:

‘Viewing healthcare disasters as the result of social and organisational processes of incubation—in which existing patterns of attention, interpretation and communication systematically blind people to the implications of adverse events—has many implications for healthcare organisations and their supervisors. In particular, it points to deeply practical implications regarding the use of information, the production of warning signs and the organisation of learning across healthcare systems.’³¹

Macrae argues that, since the process of ‘incubation’ occurs incrementally and over a considerable period of time, it provides the opportunity for early detection and prevention. In other words, if emerging problems and indications of failure can be discovered and addressed before they accumulate, eventual organisational disasters and subsequent patient harm can be avoided. To make the most of this ‘incubation’ opportunity, Macrae proposes three practical steps that organisations and regulators can take: 1) Actively endeavour to uncover and amplify warning signals of risk, by continually challenging assumptions and organisational ignorance relating to safety; 2) Instil vigilance across the entire organisation by defining and constantly updating a set of specified, focussed fears of failure they must seek to avoid; and 3) Establish an independent body to routinely investigate and publicise the systematic causes of major failures.³²

Macrae makes a critical observation about how healthcare and aviation investigate and learn from failures. The contrast is quite instructive and disconcerting. Accidents and serious incidents in the aviation industry are, as a rule, subjected to an extensive inquiry by an independent national safety investigation organisation:

³¹ *Ibid.*

³² *Id.* 3.

‘The investigations they conduct span the entire aviation system—from the work of regulators to the manufacture of equipment to the training of crew to the culture and practices within airlines. Critically, these national air safety investigators are not regulators, or commissioners, or performance managers, or providers. They have no stake in current regulatory or policy or commissioning agendas: they are simply investigators. They work to understand the causes of the failure, circulate this knowledge widely, recommend ways that systems should be improved, and then hold all organisations within the aviation system publicly accountable for making those improvements.’

As Macrae notes, these investigations are conducted by safety specialists with substantial expertise, working closely with stakeholders in their respective organisations and the industry as a whole. The cooperative nature of investigations ensures that safety capabilities and knowledge can be drawn upon and continually developed to the benefit of all involved. He believes that the absence of a similar mechanism in healthcare is a serious impediment to safety improvement:

‘A crucial piece of the safety and quality oversight puzzle is therefore missing in healthcare. Healthcare systems lack a routine and independent source of knowledge on the processes that lead to systemic failures of care, the kinds of warnings signs that managers and regulators should remain vigilantly attentive to and afraid of, and the location of potential pockets of ignorance in healthcare organisations and the system as a whole. When it comes to learning from systems-wide failures, the healthcare system is largely flying blind.’³³

Macrae’s recommendations, which include uncovering early signs of ignorance, actively avoiding specified clinical and organisational risks, and routinely conducting independent system-wide investigations, could foster a ‘collective foresight’. Thus, ensuring that managers and administrators of healthcare organisations, as part of a concerted effort involving the entire industry, actively anticipate accidents and put systems in place to support healthcare workers (exercising individual foresight as the

³³ *Id.* 5.

last line of defence and inheritors of systemic defects) in their tasks and in uncovering latent conditions and error traps during the incubation phase.³⁴

Detecting the early signs of failure is challenging and complex. It is ordinarily done by vigilant healthcare workers who notice and report potential problems.³⁵ These, warning signs will, however, only ever come to light and be addressed if healthcare workers are assured of the institutional commitment to a culture of safety and feel comfortable in providing relevant safety information, without fear of the consequences. Clearly, the existence of a just culture would be a prerequisite for the effective realisation of 'collective foresight'.³⁶

4. HEALING

Harmful medical errors can have a devastating impact on all involved.³⁷ This impact has often been exacerbated by inadequate responses in the aftermath of an adverse event.³⁸ Until very recently, healthcare organisations have been peculiarly appalling and inept in dealing with injured patients.³⁹ In the wake of an injurious outcome these harmed patients and their relatives would often be met with evasion and a lack of openness. They would not receive any support from the organisation or even a simple apology. In many instances, their only contact with the hospital would be through their risk managers and legal representatives. Much of this iniquitous behaviour would be aimed at limiting hospitals' liability in the face of potential litigation. Ironically, such an

³⁴ Macrae and Vincent "Learning from failure: the need for independent safety investigation in healthcare." *J R Soc Med* (2014) 107 439.

³⁵ Macrae "The problem with incident reporting." *BMJ Qual Saf* (2016) 25 71; Macrae "Remembering to learn: the overlooked role of remembrance in safety improvement." *BMJ Qual Saf* (2017) 26 678; Macrae and Vincent "A new national safety investigator for healthcare: the road ahead." *J R Soc Med* (2017) 110 90.

³⁶ It is encouraging to see recent developments on this front in the NHS (Healthcare Safety Investigation Branch) Also see the recent Competition Commission proposal on the subject.

³⁷ Gallagher et al. "Patients' and physicians' attitudes regarding the disclosure of medical errors." *JAMA* (2003) 289 1001.

³⁸ Gallagher and Levinson "Disclosing harmful medical errors to patients: a time for professional action." *Arch Intern Med* (2005) 165 1819.

³⁹ Gallagher et al. "Disclosing harmful medical errors to patients." *N Engl J Med* (2007) 356 2713.

opaque antagonistic response, coupled with the absence of an honest explanation or apology, owing to a fear of legal action, is exactly why patients resort to litigation.⁴⁰

Patients expect to be informed when they are harmed by care, especially if the harm was caused by medical error. Healthcare workers have struggled with this disclosure in the past. Practitioners may have wanted to be open with their patients, but have been fearful of professional censure or litigation, felt ashamed and embarrassed, or might not have known how to effectively engage with injured patients and their families.

Many healthcare workers are also deeply affected by medical errors. The negative emotional consequences are often profound and enduring. Practitioners can be emotionally and psychologically wounded by their errors too, becoming 'second victims'. Wu, a professor at the Johns Hopkins School of Public Health, coined the term in a *BMJ* article; where he described what some practitioners experience after making a medical error:

'Virtually every practitioner knows the sickening realisation of making a bad mistake. You feel singled out and exposed—seized by the instinct to see if anyone has noticed. You agonise about what to do, whether to tell anyone, what to say. Later, the event replays itself over and over in your mind. You question your competence but fear being discovered. You know you should confess, but dread the prospect of potential punishment and of the patient's anger. You may become overly attentive to the patient or family, lamenting the failure to do so earlier and, if you haven't told them, wondering if they know'⁴¹

The failure to deal with the repercussions of medical error and patient harm in a caring manner could perhaps be explained, by having regard to how our responses to the consequences of errors had been shaped by our traditional conception and understanding of the causes of errors.

Our retributive approach to medical error, has done very little to ensure safer care, and

⁴⁰ Vincent et al. "Why do people sue doctors? A study of patients and relatives taking legal action." *Lancet* (1994) 343 1609.

⁴¹ Wu (2000) 320 *BMJ* 726.

even less to ensure healing after unsafe care. Leveson concisely describes the need for a system approach as follows: 'Blame is the enemy of safety. Focus should instead be on understanding how the entire system behavior led to the loss and not on who or what to blame.'⁴²

To improve safety we must acknowledge that errors are an indication of an organisational, operational, educational, or political problem – and therefore safety is everyone's responsibility. This does not diminish accountability, quite the opposite. Rather than only attributing responsibility and accountability to the healthcare worker at the 'sharp end', those responsible for creating operational pressures or providing inadequate oversight and those who create flawed systems that contribute to mistakes, are also held collectively accountable.

In a just culture, accountability is implemented and understood differently. Intentional disregard for safety and gross negligence, in any sphere of the organisation, will of course be punished (though, such instances are very rare). However, accountability in the form of punishment is an unsound response to the vast majority of errors. Accountability is instead defined in terms of responsibility for finding solutions to the flaws in the system design, which allowed the mistakes to occur and cause harm.⁴³

If our conception of accountability changes to align with the system approach, our responses to harmful errors can too. Instead of meeting harm with hurt, as is the case with our current retributive justice construct, we can attempt to heal.

4.1. FROM RETRIBUTIVE TO RESTORATIVE JUSTICE

One way in which healing could be promoted, would be through initiatives grounded in restorative justice theory.⁴⁴ Although, the theory and concept originated, and has conventionally only been considered in the criminal justice victim-offender context, the

⁴² Leveson (2012) 431.

⁴³ Dekker (2007) 24.

⁴⁴ Todres "Toward healing and restoration for all: Reframing medical malpractice reform" *Conn L Rev* (2006) 39 667; Van Ness and Strong *Restoring justice: An introduction to restorative justice* (2014); Dekker and Breakey (2016) 85 *Safety science* 187.

underlying principles and values could arguably be well-suited to healthcare, if adapted and applied to the patient-provider relationship following harmful outcomes.⁴⁵

There is precedent for such an expanded application of restorative justice theory. Restorative approaches to conflict and wrongdoing are becoming more common in educational and business contexts.⁴⁶ Often referred to as ‘restorative practices’ when applied outside of the criminal domain, there is substantial overlap between the values, principles and methods involved in both restorative practices and restorative justice.

South Africa has a special relationship with restorative justice.⁴⁷ It played a key role during the dawn of our fragile new democracy in the Truth and Reconciliation Commission process. The chairman of the commission, Archbishop Desmond Tutu, explained the significance of the type of justice offered by the TRC:⁴⁸

‘One might go on to say that perhaps justice fails to be done only if the concept we entertain of justice is retributive justice, whose chief goal is to be punitive, so that the wronged party is really the state, something impersonal, which has little consideration for the real victims and almost none for the perpetrator.

We contend that there is another kind of justice, restorative justice, which was characteristic of traditional African jurisprudence. Here the central concern is not retribution or punishment. In the spirit of *ubuntu*, the central concern is the healing of breaches, the redressing of imbalances, the restoration of broken relationships, a seeking to rehabilitate both the victim and the perpetrator, who should be given the opportunity to be reintegrated into the community he has injured by his offense.

This is a far more personal approach, regarding the offense as something that has

⁴⁵ McNeil “Applying the Restorative Justice Model to Medical Malpractice” (2007); Braaten “Integrating Nursing Peer Review and a Restorative Just Culture for a Healthy Work Environment” (2017).

⁴⁶ Johnstone and Van Ness “Handbook of Restorative Justice” (2013) 325.

⁴⁷ Skelton and Frank “Conferencing in South Africa: Returning to our future” *Oxford: Hart Publishing* (2001) 104; Gade “Restorative Justice and the South African Truth and Reconciliation Process” *South African Journal of Philosophy* (2013) 32 10.

⁴⁸ Tutu *No future without forgiveness* (1999) 55.

happened to persons and whose consequence is a rupture in relationships. Thus we would claim that justice, restorative justice, is being served when efforts are being made to work for healing, for forgiving, and for reconciliation.’

4.2. A BRIEF OVERVIEW OF RESTORATIVE JUSTICE THEORY

4.2.1. INTRODUCTION

Howard Zehr is regarded as the father of restorative justice, being one of the first to articulate the theory in his book, *Changing Lenses*.⁴⁹ Critiquing our current view or ‘lens’ of criminal justice, which is focussed on lawbreaking with justice centred around blame and punishment, he advocated for a restorative view. Through this restorative justice lens, the focus would be on the violation of people and relationships, with justice viewed as an obligation to find reparative, reconciling, and reassuring resolutions. Martin Wright has also been influential, arguing that criminal justice should be restorative, rather than retributive, with greater participation by both victims and offenders through expanded compensation, restitution, and mediation processes.⁵⁰ Cragg engaged in more of a philosophical, conceptual discussion, he considers punishment with the sole aim to inflict suffering, rooted in retributivist theories, to be contrary to constructions of formal justice, and instead appeals for penal and sentencing reforms based on restorative justice.⁵¹ Theoretical frameworks, such as ‘reintegrative shaming’ have been explored as a way in which to theoretically analyse and evaluate restorative programmes.⁵² Several other authors have advanced the theoretical underpinnings and frameworks of restorative justice.⁵³

⁴⁹ Zehr *Changing lenses: A new focus for crime and justice* (1990).

⁵⁰ Wright “Justice for Victims and Offenders: a Restorative Approach to Crime” *M. Keynes: Open University Press. Alternatives to Judicial Responses Alenka Selih* (1991); Wright “Justice for Victims and Offenders” (1996) 224; Wright “Restorative Justice: The Basic Idea and Practice in the United Kingdom” *Victim policies and criminal justice on the road to restorative justice* (2001) 353.

⁵¹ Cragg “The practice of punishment” *Towards a Theory of Restorative Justice. New York* (1992); Cragg “The Practice of Punishment” (2003) 272.

⁵² Braithwaite *Crime, shame and reintegration* (1989); Moore “Shame, forgiveness, and juvenile justice” *Criminal Justice Ethics* (1993) 12 3.

⁵³ Johnstone and Van Ness (2013) 76.

Three restorative processes have been instrumental in the development of the broader restorative justice movement. Victim-offender mediation was launched in Canada in 1974, as a program to impact offenders by helping them understand how their victims were harmed by their actions.⁵⁴ Similar initiatives began to spread through North America and Europe. Conferencing was adopted by New Zealand in 1989, to deal with young offenders.⁵⁵ The community approach of family group conferencing had been influenced by the Maori culture and their conflict processes.⁵⁶ An Australian police officer saw the potential of the model and applied it to juvenile offenders.⁵⁷ It has since been adapted and is now used with adult offenders throughout the world. Circles, also has its roots in indigenous practices, those of the First Nations people of Canada.⁵⁸ The approach was first applied in a court of law during sentencing in a Yukon territory case in 1992. During this case, the judge rearranged 30 chairs to create a circle, in which an informal discussion could be held to seek solutions. The judge, lawyers, police, as well as the offender, his family, leadership of his Nation, the victim, and other members of the community were all part of the circle. The use of circles has expanded throughout North America.⁵⁹

Increasingly, restorative justice programmes and initiatives are being incorporated into criminal justice systems by governments around the world.⁶⁰ The federal government in Canada adopted sentencing reform legislation in 1995 that included restorative justice principles. The Youth Criminal Justice Act, that included even more substantial reforms, was also enacted. Legislation that promotes restorative practices for young offenders has now been adopted in New Zealand, Australia, Uganda, Costa Rica, England, Philippines and here at home in South Africa. The EU has also adopted legislation to encourage use of restorative justice by its members. In 2002, the United Nations Economic and Social Council (ECOSOC) endorsed a 'Declaration of Basic

⁵⁴ *Id.* 41.

⁵⁵ *Id.* 8.

⁵⁶ *Id.* 113.

⁵⁷ Van Ness and Strong (2014) 29.

⁵⁸ *Ibid.*

⁵⁹ *Id.* 30.

⁶⁰ *Ibid.*

Principles on the Use of Restorative Justice Programmes in Criminal Matters’.

Dissatisfaction with modern criminal justice and calls for reform have led to the emergence of restorative justice. This new approach, has over the past two decades, become a significant component of global criminal justice systems.

4.2.2. DEFINITION

Restorative justice is difficult to define, since it is such a contested concept.⁶¹ Therefore, it may be useful, as Zehr has done, to start with what it is not.⁶² Restorative justice is not primarily about forgiveness and reconciliation, although it provides a context where either or both might occur. Restorative justice is not mediation, as parties are not on a level playing field and one of the participants would as a precondition have to acknowledge his or her role and responsibility for the harm caused. Restorative justice is not a particular programme or blueprint, it is heavily dependent on culture and setting. As Zehr states: ‘Restorative justice is a compass, not a map’. Restorative justice is not exclusively intended for minor or first-time offences, in severe cases the need for restorative approaches may be particularly pertinent. And finally, restorative justice is neither a cure nor a replacement for the legal system.⁶³

What is it then? Johnstone and Van Ness have identified three basic conceptions of restorative justice.⁶⁴ The first of which, is the encounter conception. This has to do with the benefits that arise when the affected parties come together to discuss the harmful event and the matters surrounding it. The second is the reparative conception. Proponents of this conception argue that justice cannot be done by merely imposing proportionate suffering onto a wrongdoer, instead they contend that justice will only be attained when the harm is repaired through a process that involves both the wrongdoer and the victim. The third is the transformative conception. Such a conception envisions more wide-ranging societal changes. Here the focus is not necessarily on repairing the individual harm or particular relationship, but instead on repairing structural injustices.

⁶¹ Johnstone and Van Ness (2013) 6.

⁶² Zehr *The little book of restorative justice* (2002) 6.

⁶³ Zehr *The Little Book of Restorative Justice* (2015) 8.

⁶⁴ Johnstone and Van Ness (2013) 9.

The transformative conception sees restorative justice as a way of life, whereby in all cases of harm, without distinction, the victims are identified, their needs are assessed, and it is endeavoured to make things right. These three conceptions overlap and are related, they generally differ only as to where the emphasis on approach is placed, and consequently do not fall into distinct camps.

4.2.3. PRINCIPLES AND VALUES

Van Ness and Strong have suggested that three key principles underlie the implementation of restorative justice in processes and in systemic reform:⁶⁵ 1) Justice requires that we try to heal victims, offenders, and communities that have been harmed; 2) Victims, offenders, and communities should have the opportunity for active involvement in the justice process as early and as fully as they wish; and 3) To foster justice and safety, government should maintain a just order and the community should build a just peace.

The same authors have also identified, what they believe to be, the four cornerstone values that influence restorative justice programmes and processes:⁶⁶

- Inclusion: All affected parties should be encouraged to formulate and participate in restorative processes in response to the harmful act.
- Encounter: Affected parties are allowed the opportunity to come together in a sheltered setting to discuss the offense, harms, and the appropriate responses.
- Amends: Those who caused the harm should acknowledge their responsibility and remedy the damage to the extent possible.
- Reintegration: The affected parties are provided the means and opportunity to re-enter their communities as whole, contributing members without having to bear the burden or stigma of the harm and offense.

Zehr believes that restorative justice can essentially be reduced to the following set of guiding questions:

⁶⁵ Van Ness and Strong (2014) 45.

⁶⁶ *Id.* 50.

‘Who has been hurt? What are their needs? Whose obligations are these? Who has a stake in this situation? What is the appropriate process to involve stakeholders in an effort to put things right?’⁶⁷

4.3. REPARATIVE ACCOUNTABILITY

There are fundamental differences between the criminal justice and medical error domains. To begin with, the relationship, conduct and intent that gives rise to harm are entirely distinct. The motive behind criminal conduct, cannot be compared to the purpose behind medical interventions. After all, the principles of non-maleficence and beneficence are intrinsically linked to the latter, whereas criminal conduct is *mala fide* and might have a complete disregard for the wellbeing of another. The acts themselves are also incomparable, and although both might result in physical or psychological damage, the harm inflicted would necessarily be experienced differently. This would in part be due to the substantial difference in relationship between the affected parties. The healthcare provider-patient relationship plays a central role in medicine. It is often described as being a fiduciary one, deeply rooted in trust and generally concerned with the promotion of therapeutic objectives. This stands in stark contrast to any association there may be between victims and criminal offenders, where either no relationship existed prior to the crime, or what relationship there was degenerated into abuse and harm.

4.3.1. A RESTORATIVE APPROACH TO MEDICAL ERROR

However, rather than hinder, I would contend that the differences between criminal and iatrogenic harm advance the application of restorative justice principles to circumstances involving medical error. Owing to the fact that the injuries suffered had certainly not been intended, occurring in terms of an existing relationship predicated on trust and care, the harm may be more amenable to restorative processes. What there is to repair between the affected patient and healthcare worker might be a relative fracture, compared to the deep rift that would prevail between the victim of a (violent)

⁶⁷ Zehr (2002) 63.

crime and the perpetrator.⁶⁸

The concept of restorative justice is especially germane to the medical domain, since it has the potential to address many of the needs that patients and healthcare workers have after the occurrence of an adverse event. Restorative processes and approaches could also be beneficial to safety efforts, as it allows direct stakeholder involvement, by creating a safe environment within which to openly discuss systemic failures, the harm experienced and needs of the patient, remedial actions, and perhaps most importantly, preventative strategies to ensure that others are spared a similar outcome.

Interestingly, there are many similarities between what victims of crime want from the criminal justice system, and what patients expect and need after they have been injured by medical treatment. Furthermore, restorative justice processes are quite adept at addressing these expectations and needs in a constructive manner. Schiff has identified some of the immediate needs of victims and offenders, as follows:⁶⁹

- Information
- Acknowledgement and reassurance
- Apology
- Accountability
- Full participation
- Process must be fair, respectful and just
- Reparative agreement
- Support
- Restitution and compensation

After an event has taken place, the affected parties need to be provided with information. Both victims and offenders must be informed about the process, they should know exactly what will happen and when. Victims also need to know who harmed them and how they were harmed. They want acknowledgement that they did nothing wrong, see someone take responsibility for their harm and apologise for causing

⁶⁸ Todres (2006) *Conn L Rev* 39 667.

⁶⁹ Johnstone and Van Ness (2013) 228.

it. This may contribute to their own empowerment. Research suggests that a direct and meaningful apology may be just as, if not more important than restitution. Offenders on the other hand, have to take responsibility. They are held and hold themselves accountable, but are assured that they are not defined by their conduct and are not ostracised because of it. Offenders are given the opportunity to earn their redemption and way back into the community. They can achieve this, by thoroughly participating in the restorative process. Both victims and offenders want full participation and need to be heard. They want to participate in a fair, respectful and just process. Such a process will allow each one of the parties to have an impact on the reparative outcome. This reparative outcome could then be encapsulated in a reparative agreement, which may be crucial to the restorative process. Although, some have indicated that involvement in the process itself can be reparative. However, for some offenders, an agreement may provide substantive means by which to apologise, express regret, repair the harm and earn redemption. Throughout this entire process victims and offenders will require ongoing support. For victims, such support may encompass financial reparation or compensation.⁷⁰

This generally corresponds to what patients and healthcare providers may need after an adverse outcome.

4.3.2. RESTORING THE DOCTOR-PATIENT RELATIONSHIP

4.3.2.1. INFORMATION

The absence of adequate information is often cited as a reason why patients instigate legal proceedings. When information about the adverse event they suffered is not forthcoming, they resort to litigation as a way to uncover the details. Physicians that are advised to sever all ties with an injured patient, as a risk-management strategy, compound the problem. Open disclosure, is not only linked to less legal animosity, it is the ethical thing to do, and many doctors see it as a moral imperative. After all, the doctor-patient relationship does not simply cease to exist after an error has occurred, the fiduciary nature of the relationship, may still demand the compassionate exchange

⁷⁰ *Id.* 231.

of information and continued direct dialogue, that existed immediately before the accident.

4.3.2.2. ACKNOWLEDGEMENT AND REASSURANCE

Patients require and need the acknowledgment that they have been harmed, they need to know how it happened and the reassurance that their harm will be addressed. They also frequently want to be assured that similar incidents will not happen again. That steps will be taken to improve outcomes. Healthcare workers may share the same sentiments, wanting better results for their future patients.

One cannot underestimate the value that acknowledgement of their harm holds for the emotional reparation of patients. It plays a key role in the healing process.

4.3.2.3. APOLOGY

Another crucial part in healing process, is the apology. What may seem like a modest gesture of empathy, can have a significant impact in restoring the emotional suffering of patients. Unfortunately, healthcare workers have been hesitant to apologise. Although they probably want to, both for the patient's sake and because they genuinely are remorseful. However, most practitioners are apprehensive, either because they are ashamed, or since they are worried that their apology may be perceived as an admission of guilt. And their insurers may have also warned against it, for fear that it may expose them to liability if the patient should decide to institute a civil claim.

4.3.2.4. ACCOUNTABILITY

While, apologies can perhaps be seen as an admission of legal responsibility, oftentimes patients are more concerned with the fact that someone accepts responsibility for the harm done; that there is accountability and that changes will be made to prevent future accidents. It is not necessarily accountability in a legal sense. The accountability here, arises from the needs of the patient and has to do with the obligations those needs create. Those needs are met by the practitioner and the organisation, as they attempt to rebuild the relationship and trust that once existed. Accountability is how the needs are met. Accountability is how the harm is repaired and the suffering is healed. Accountability is how the system learns from the error and ensures that it will not happen again.

4.3.2.5. FULL PARTICIPATION

Such accountability can only be achieved when all stakeholders participate in the process. When everyone is allowed to give their account of what happened and tell their story. Patients want to be heard, as they have first-hand experience of the repercussions that a breakdown in the system's safeguards can cause. Practitioners want to participate, to explain why what they did made sense to them at the time. How they might have inherited organisational, operational or design problems, that resulted in the error. This can provide valuable insight into the adverse event, and the organisation can then participate by perhaps identifying the latent conditions or 'pathogens' in the system that contributed to the accident and take steps to address them.

4.3.2.6. PROCESS MUST BE FAIR, RESPECTFUL AND JUST

These open and frank accounts will of course only be possible if stakeholders are treated fairly and respectfully as part of a just process. Nothing constructive will come from a retributive process, where accountability is only thought of in terms of punishment. A retributive approach will see to it that things remain broken. Conversely, a restorative approach seeks to repair and heal. It could help repair the doctor-patient relationship. It may even allow us to strengthen the system, by revealing weaknesses that we can then confront.

4.3.2.7. REPARATIVE AGREEMENT

Such an approach may provide an opportunity to reach a reparative agreement between all the stakeholders, giving practitioners and the organisation a chance to express regret, remedy the harm and 'make things right' by implementing changes aimed at achieving safer care.

4.3.2.8. SUPPORT

Practitioners and healthcare organisations can also 'make things right' by providing ongoing support for patients and their families, and could even involve them in safety improvement processes. The organisation should also provide support for affected healthcare workers, who may be the forgotten 'second victims' of adverse events.

4.3.2.9. RESTITUTION AND COMPENSATION

Finally, patients who suffer harm may face significant future medical expenses, loss of income and other costs due to the injuries they have sustained. Compensation remains an important part of the restorative resolution. Unfortunately, compensation has often in the past only been provided after protracted and adversarial medico-legal negotiations. This can be immensely frustrating and damaging for patients and their families. In some jurisdictions, such as Sweden and New Zealand, compensation is provided on a no-fault basis, abolishing the need to invoke onerous legal proceedings. However, even without no-fault compensation schemes, much more can be done to assist injured patients.

Communication and resolution programmes (CRPs) that are founded on disclosure and transparency, encourage proactive efforts by healthcare providers, which could include early offers of compensation. CRPs have their roots partly in principles of just culture.⁷¹ CRPs could prove to be an ideal vehicle with which to introduce restorative justice principles into the healthcare context.⁷²

⁷¹ Gallagher et al. "Collaboration with Regulators to Support Quality and Accountability Following Medical Errors: The Communication and Resolution Program Certification Pilot." *Health Serv Res* (2016) 51 Suppl 3 2569.

⁷² Liang "A system of medical error disclosure." *Quality and Safety in Health Care* (2002) 11 64; Brennan and Mello "Patient safety and medical malpractice: a case study." *Ann Intern Med* (2003) 139 267; Duclos et al. "Patient perspectives of patient-provider communication after adverse events." *Int J Qual Health Care* (2005) 17 479; Scott "Doctors as Advocates, Lawyers as Healers" (2008); Robbennolt "Apologies and medical error." *Clin Orthop Relat Res* (2009) 467 376; Kachalia et al. "Liability claims and costs before and after implementation of a medical error disclosure program." *Ann Intern Med* (2010) 153 213; Adams et al. "Effect of a health system's medical error disclosure program on gastroenterology-related claims rates and costs." *Am J Gastroenterol* (2014) 109 460; Elwy et al. "Improving healthcare systems' disclosures of large-scale adverse events: a Department of Veterans Affairs leadership, policymaker, research and stakeholder partnership." *J Gen Intern Med* (2014) 29 Suppl 4 895; Mello et al. "Communication-and-resolution programs: the challenges and lessons learned from six early adopters." *Health Aff (Millwood)* (2014) 33 20; Mello et al. "Implementing hospital-based communication-and-resolution programs: lessons learned in New York City." *Health Aff (Millwood)* (2014) 33 30; Sage et al. "How policy makers can smooth the way for communication-and- resolution programs." *Health Aff (Millwood)* (2014) 33 11; Lipira and Gallagher "Disclosure of adverse events and errors in surgical care: challenges and strategies for improvement." *World J Surg* (2014) 38 1614; Mello et al. "The medical liability climate and prospects for reform." *JAMA* (2014b) 312 2146; Iedema et al., 'Risk and Clinical Incident Disclosure: Navigating between Morality and Liability' in (eds.), Springer, 2016, pp. 17-35; Gallagher et al. "Improving Communication and Resolution Following Adverse Events Using a Patient-Created Simulation Exercise." *Health Serv Res* (2016) 51

5. CONCLUSION

What happens after a line has been drawn, is just as, if not more important than where the line is drawn and by whom. If done correctly, it allows for the opportunity to move from retrospective to prospective accountability. Prospective accountability involves proactive measures that contribute to safer care, it is a collective form of accountability as everyone in the organisation is aligned toward improvement. This implies that administrators and managers are obligated to address latent conditions created at the organisational 'blunt end' and other system defects or weaknesses.

Unfortunately, due to the dynamic and complex nature of healthcare, even the most meticulous system defences and safeguards are bound to fail, leaving healthcare professionals at the 'sharp end' as the last line of defence. One way in which this last line of defence can be bolstered is by increasing the error wisdom and foresight of front-line practitioners. Reason has proposed a three-bucket model, to help practitioners avoid errors, enabling them to identify and assess high-risk situations. Equipped with 'error wisdom' or 'foresight', practitioners would then be able to act as 'harm-absorbers' between the system's weaknesses and the patient.

Macrae adapted Turner's 'incubation' model of man-made disasters to the healthcare context, to show another way in which harm can be avoided. Since the process of 'incubation' occurs incrementally and over a considerable period of time, it provides the opportunity for early detection and prevention. Organisations and regulators can make

Suppl 3 2537; Gallagher et al. (2016) 51 Suppl 3 *Health Serv Res* 2569; Lambert et al. "The "Seven Pillars" Response to Patient Safety Incidents: Effects on Medical Liability Processes and Outcomes." *Health Serv Res* (2016) 51 Suppl 3 2491; Mello et al. "Challenges of Implementing a Communication-and-Resolution Program Where Multiple Organizations Must Cooperate." *Health Serv Res* (2016) 51 Suppl 3 2550; Mello et al. "Case Outcomes in a Communication-and-Resolution Program in New York Hospitals." *Health Serv Res* (2016) 51 Suppl 3 2583; Ridgely et al. "Progress at the Intersection of Patient Safety and Medical Liability: Insights from the AHRQ Patient Safety and Medical Liability Demonstration Program." *Health Serv Res* (2016) 51 Suppl 3 2414; Moore et al. "Patients' experiences with communication-and-resolution programs after medical injury" *JAMA Internal Medicine* (2017); Resolution *Delivering fair resolution and learning from harm* (2017); Tingle "Reforming the approach to clinical negligence in the NHS." *Br J Nurs* (2017) 26 474; Mello et al. "Outcomes In Two Massachusetts Hospital Systems Give Reason For Optimism About Communication-And-Resolution Programs." *Health Aff (Millwood)* (2017) 36 1795.

the most of this opportunity if they actively look for warning signs of failure, define a set of specific failures they seek to avoid and establish an independent investigative body. This could foster a 'collective foresight', whereby managers and administrators of healthcare organisations, as part of a concerted effort involving the entire industry, actively anticipate accidents and put systems in place to support healthcare workers (exercising individual foresight as the last line of defence and inheritors of systemic defects) in their tasks and in uncovering latent conditions and error traps during the incubation phase. The existence of a just culture throughout the healthcare industry would be a prerequisite for 'collective foresight', or else the warning signs and relevant safety information will not come to light.

Much more can be done to promote healing after the occurrence of adverse events. The transition toward a just culture, and the type of accountability it entails, would allow us to move away from retributive responses to error, and instead permit us to explore restorative approaches. Trust is the basis of a just culture and it is also the basis of the doctor-patient relationship. Rather than meeting harm with hurt, we can attempt to heal. The principles and values of restorative justice theory could be well-suited to healthcare. Although there are substantial differences between the victim-offender and patient-doctor domains, these differences may strengthen the case for its application, since the motives, conduct and relationships are founded on beneficence and non-maleficence. It would be a much narrower gap to bridge.

Restorative processes also address many of the needs that parties may have after a harmful outcome, much more so than current retributive approaches. Unfortunately, compensation could generally only be obtained following protracted and adversarial medico-legal negotiations. However, alternative compensation avenues have emerged in recent years. Communication and resolution programmes are one such example and may hold promise.

CHAPTER 9. JUST CULTURE – PRACTICAL APPLICATION: LESSONS FROM AVIATION

1. INTRODUCTION

A just culture, allows a safety culture to exist.¹ Aviation has spent decades developing such a culture, by attempting to achieve an equilibrium between the system approach, that encourages the reporting of safety-related information and protects the collection thereof, and individual accountability.² Airlines have rules and procedures in place to

¹ Reason (1997) 266; Reason (1998b) 12 *Work & Stress* 293.

² See for example: Reason “Achieving a safe culture: theory and practice” *Work & Stress* (1998b) 12 293; Barach and Small “Reporting and preventing medical mishaps: lessons from non-medical near miss reporting systems” *BMJ: British medical journal* (2000) 320 759; Reason “Safety paradoxes and safety culture” *Injury Control and Safety Promotion* (2000b) 7 3; Leape “Foreword: Preventing medical accidents: Is systems analysis the answer” *Am. J.L. & Med.* (2001) 27 145; van der Schaaf “Medical applications of industrial safety science” (2002); Hudson “Achieving a safety culture for aviation” *Journal of Aviation Management* (2003) 2003 27; International “The need for a just culture in aviation safety management” *Eleventh Air Navigation Conference Montreal* (2003) 22 ; Kaplan “Benefiting from the” Gift of Failure”” *Journal of Legal Medicine* (2003) 24 29; Gill and Shergill “Perceptions of safety management and safety culture in the aviation industry in New Zealand” *Journal of Air Transport Management* (2004) 10 231; Waring “Beyond blame: cultural barriers to medical incident reporting” *Social science & medicine* (2005) 60 1927; Frankel et al. “Fair and just culture, team behavior, and leadership engagement: The tools to achieve high reliability” *Health services research* (2006) 41 1690; Ek et al. “Safety culture in Swedish air traffic control” *Safety Science* (2007) 45 791; Hudson “Implementing a safety culture in a major multi-national” *Safety Science* (2007) 45 697; Licu et al. “EUROCONTROL—Systemic Occurrence Analysis Methodology (SOAM)—A “Reason”-based organisational methodology for analysing incidents and accidents” *Reliability Engineering & System Safety* (2007) 92 1162; van Dam “Preserving Safety in Aviation: Just Culture” and the Administration of Justice” *The Air and Space Lawyer* (2009) 22 1; Learmount “Criminalization of Air Accidents: The Solutions May Be Forged in Europe” *Air & Space L.* (2010) 35 325; Patankar and Sabin “The safety culture perspective” *Human factors in aviation* (2010) 95; Toff “Human factors in anaesthesia: lessons from aviation” *British journal of anaesthesia* (2010) 105 21; McCune et al. “Safety culture in your safety management system” *Implementing safety management systems in aviation* (2011) 135; Paries “Lessons from the Hudson” *Resilience Engineering in Practice: A Guidebook* (2011) 9; Pasquini et al. “Requisites for successful incident reporting in resilient organisations” *Resilience engineering in practice: a guidebook. Farnham, Surrey, England* (2011); Wang “Safety Culture and Safety Management Systems—Enhancing the Heartware of Managing Aviation Safety” *Journal of Aviation Management 2011* (2011) 59 ; Bienefeld and Grote “Silence that may kill” *Aviation Psychology and Applied Human Factors* (2012); Patankar *Safety culture: Building and sustaining a cultural change in aviation and healthcare* (2012); Dekker and Leveson “The systems approach

govern and protect the collection, access and use of safety data.³ Assurances are provided that this information will not be used against staff for disciplinary or punitive purposes, unless there is evidence to suggest that their conduct was either grossly negligent or wilful. These protections prevail across the entire aviation industry.⁴

2. EUROPEAN UNION

2.1. REGULATION (EU) NO 996/2010 - INVESTIGATION AND PREVENTION OF ACCIDENTS AND INCIDENTS IN CIVIL AVIATION

The European Union (EU) has formally introduced the concept of just culture to EU law through the enactment of Regulation (EU) No 691/2010. Furthermore, Regulation (EU) No 996/2010 on the investigation and prevention of accidents and incidents in civil aviation, reinforced the EU commitment to establishing a just culture:

‘(23) An accident raises a number of different public interests such as the prevention of future accidents and the proper administration of justice. Those interests go beyond the individual interests of the parties involved and beyond the specific event. The right balance among all interests is necessary to guarantee the overall public interest.

(24) The civil aviation system should equally promote a non- punitive environment facilitating the spontaneous reporting of occurrences and thereby advancing the principle of ‘just culture’.

(25) The information provided by a person in the framework of a safety investigation should not be used against that person, in full respect of constitutional principles and national law.’

to medicine: controversy and misconceptions” *BMJ Qual Saf* (2014) bmjqs; Liao “Safety Culture in commercial aviation: Differences in perspective between Chinese and Western pilots” *Safety science* (2015) 79 193.

³ Reason (1995); Helmreich (2000) 320 *BMJ* 781; Reason (2000) 320 *BMJ* 768.

⁴ Müller et al. (2014) 213.

2.2. REGULATION (EU) NO 376/2014 - REPORTING, ANALYSIS AND FOLLOW-UP OF OCCURRENCES IN CIVIL AVIATION

On the 3rd of April 2014, the European Parliament and the Council adopted Regulation (EU) No 376/2014 on the reporting, analysis and follow up of occurrences in civil aviation.⁵ It came into effect on the 15th of November 2015. The new Occurrence Reporting Regulation is a major step toward even safer aviation, as it calls on the Union, its Member States, the European Aviation Safety Agency and organisations, to implement more proactive and evidence-based safety systems which focus on accident prevention based on the analysis of all relevant safety information, including information on civil aviation occurrences.

The objective of the Regulation is set out in Article 1 as follows:

‘1. This Regulation aims to improve aviation safety by ensuring that relevant safety information relating to civil aviation is reported, collected, stored, protected, exchanged, disseminated and analysed.

This Regulation ensures:

(a) that, where appropriate, safety action is taken in a timely manner based on analysis of the information collected;

(b) the continued availability of safety information by introducing rules on confidentiality and on the appropriate use of information and through the harmonised and enhanced protection of reporters and persons mentioned in occurrence reports; and

(c) that aviation safety risks are considered and dealt with at both Union level and national level.

2. The sole objective of occurrence reporting is the prevention of accidents and incidents and not to attribute blame or liability.’

⁵ “Regulation (EU) No 376/2014” (2014) 1.

It is evident from the preamble and the enacting terms in Article 15 and 16, that the European Parliament and Council has given significant recognition to the just culture approach. Since, this it is such a monumental legal development in the safety advancement domain, it seems pertinent to provide the applicable EU recitals here:

‘(33) The civil aviation safety system is established on the basis of feedback and lessons learned from accidents and incidents. Occurrence reporting and the use of occurrence information for the improvement of safety depend on a relationship of trust between the reporter and the entity in charge of the collection and assessment of the information. This requires strict application of rules on confidentiality. The purpose of protecting safety information from inappropriate use, and of limiting access to the European Central Repository solely to interested parties participating in the improvement of civil aviation safety, is to ensure the continuing availability of safety information so that appropriate and timely preventive action can be taken and aviation safety improved. In this context, sensitive safety information should be protected in an appropriate way and its collection should be ensured by guaranteeing its confidentiality, protecting its source and ensuring the confidence of staff working in civil aviation in occurrence reporting systems. Appropriate measures should be put in place to ensure that information collected through occurrence reporting schemes is kept confidential and that access to the European Central Repository is restricted. National rules on freedom of information should take into account the necessary confidentiality of such information. The information collected should be adequately protected from unauthorised use or disclosure. It should be used strictly for the purpose of maintaining or improving aviation safety and should not be used to attribute blame or liability.

(34) In order to ensure the confidence of employees or contracted personnel in the occurrence reporting system of the organisation, the information contained in occurrence reports should be protected appropriately and should not be used for purposes other than maintaining or improving aviation safety. The internal ‘just culture’ rules adopted by organisations pursuant to this Regulation should contribute in particular to the achievement of this objective. In addition, the

limitation of the transmission of personal details, or of information allowing the identification of the reporter or of the other persons mentioned in occurrence reports, by a clear separation between the departments handling occurrence reports and the rest of the organisation, may be an efficient way to achieve this objective.

(35) A reporter or a person mentioned in occurrence reports should be adequately protected. In this context, occurrence reports should be disidentified and details relating to the identity of the reporter and of the persons mentioned in occurrence reports should not be entered into databases.

(36) In addition, the civil aviation system should promote a 'safety culture' facilitating the spontaneous reporting of occurrences and thereby advancing the principle of a 'just culture'. 'Just culture' is an essential element of a broader 'safety culture', which forms the basis of a robust safety management system. An environment embracing 'safety culture' principles should not prevent action being taken where necessary to maintain or improve the level of aviation safety.

(37) A 'just culture' should encourage individuals to report safety-related information. It should not, however, absolve individuals of their normal responsibilities. In this context, employees and contracted personnel should not be subject to any prejudice on the basis of information provided pursuant to this Regulation, except in cases of wilful misconduct or where there has been manifest, severe and serious disregard with respect to an obvious risk and profound failure of professional responsibility to take such care as is evidently required in the circumstances, causing foreseeable damage to a person or to property, or seriously compromising the level of aviation safety.

(38) In order to encourage reporting of occurrences, it should be appropriate to protect not only reporters, but also persons mentioned in the occurrence reports concerned. However, such protection should not exonerate those persons from their reporting obligations under this Regulation. In particular, in a situation where a person is mentioned in an occurrence report and has himself or herself the obligation to report that same occurrence, and intentionally fails to report it, then

that person should lose his or her protection and face penalties in application of this Regulation.

(39) Without prejudice to national criminal law and the proper administration of justice, it is important to clearly demarcate the extent of the protection of the reporter and other persons mentioned in occurrence reports from prejudice or prosecution.

(40) In order to enhance the confidence of individuals in the system, the handling of occurrence reports should be organised in such a way as to appropriately safeguard the confidentiality of the identity of the reporter and other persons mentioned in occurrence reports with regard to fostering a 'just culture'. The aim, wherever possible, should be to enable an independent occurrence handling system to be established.

(41) Staff of organisations, of the competent authorities of the Member States and of the Agency who are involved in the evaluation, processing or analysis of occurrences have a significant role to play in the identification of safety hazards and safety deficiencies. Experience shows that when occurrences are analysed with the benefit of hindsight following an accident, the analysis leads to the identification of risks and deficiencies that might otherwise not have been identified. It is possible, therefore, that the persons involved in the evaluation, processing or analysis of occurrences may fear potential consequences in terms of prosecution before judicial authorities. Without prejudice to national criminal law and the proper administration of justice, Member States should not institute proceedings against persons who, in the competent authorities of the Member States, are involved in the evaluation, processing or analysis of occurrences in respect of decisions taken as part of their duties which subsequently, and with the benefit of hindsight, prove to have been erroneous or ineffective but which, when they were taken and on the basis of the information available at that time, were proportional and appropriate.

(42) Employees and contracted personnel should have the opportunity to report breaches of the principles delimiting their protection as established by this

Regulation, and should not be penalised for so doing. Member States should define the consequences for those who infringe the principles of protection of the reporter and of other persons mentioned in occurrence reports and should adopt remedies or impose penalties as appropriate.

(43) Individuals may be discouraged from reporting occurrences by the fear of self-incrimination and the potential consequences in terms of prosecution before judicial authorities. The objectives of this Regulation can be achieved without interfering unduly with the justice systems of the Member States. It is therefore appropriate to provide that unpremeditated or inadvertent infringements of the law that come to the attention of the authorities of the Member States solely through reporting pursuant to this Regulation should not be the subject of disciplinary, administrative or legal proceedings, unless where otherwise provided by applicable national criminal law. However, the rights of third parties to institute civil proceedings should not be covered by this prohibition and should be subject only to national law.

(44) Nevertheless, in the context of developing a 'just culture' environment, Member States should retain the option of extending the prohibition on using occurrence reports as evidence against reporters in administrative and disciplinary proceedings to civil or criminal proceedings.

(45) In addition, the cooperation between safety authorities and judicial authorities should be enhanced and formalised by means of advance arrangements between themselves which should respect the balance between the various public interests at stake and which should in particular cover, for example, access to and the use of occurrence reports contained in the national databases.'

3. THE INTERNATIONAL CIVIL AVIATION ORGANISATION (ICAO)

The collection, analysis and protection of information is a key element of proactive and evidence-based safety systems. The importance thereof is also reflected at the

international level. The International Civil Aviation Organisation (ICAO) has since 2001 gradually introduced safety management system (SMS) provisions. SMS is defined by the ICAO as: ‘A systematic approach to managing safety, including the necessary organizational structures, accountabilities, policies and procedures.’ Various SMS requirements could be found in ICAO Annexes 1, 6, 8, 11, 13 and 14.

3.1. ANNEX 19⁶

The ICAO High-level Safety Conference (HLSC) held in 2010 called for the development of a new Annex dedicated to Safety Management, that would also address the responsibilities states have under mandated State Safety Programs (SSP). This process led to the first new ICAO Annex in over thirty years, Annex 19. Phase 1 of its development involved the consolidation of the existing safety management provisions contained in the six annexes mentioned above. Annex 19 was adopted by the ICAO Council on the 25th of February 2013 and became applicable on the 14th of November 2013.

Resolutions A37-2 and A37-3 of the 37th General Assembly recognised the importance of establishing a just culture. These resolutions have been entrenched in Chapter 5 of Annex 19 and provides the necessary foundation for the collection, analysis and protection of safety data:

5.1 Safety data collection

Reporting systems

5.1.1 Each State shall establish a mandatory incident reporting system to facilitate collection of information on actual or potential safety deficiencies.

5.1.2 Each State shall establish a voluntary incident reporting system to facilitate collection of information on actual or potential safety deficiencies that may not be captured by the mandatory incident reporting system.

⁶ ICAO “ICAO AN 19 Annex 19 - Safety Management” (2013); “Annex 19 - Safety Management” (2016) 1; Council “Annex 19: Safety Management” (2016) 1.

5.1.3 Recommendation. — *Subject to Standard 5.3.1, State authorities responsible for the implementation of the SSP should have access to appropriate information available in the incident reporting systems referenced in 5.1.1 and 5.1.2 to support their safety responsibilities*

5.2 Safety data analysis

5.2.1 Each State shall establish and maintain a safety database to facilitate the effective analysis of information on actual or potential safety deficiencies obtained, including that from its incident reporting systems, and to determine any actions required for the enhancement of safety.

5.2.2 Recommendation. — *Each State should, following the identification of preventive actions required to address actual or potential safety deficiencies, implement these actions and establish a process to monitor implementation and effectiveness of the responses.*

5.2.3 Recommendation. — *The database systems should use standardized formats to facilitate data exchange*

5.3 Safety data protection

5.3.1 A voluntary incident reporting system shall be non-punitive and afford protection to the sources of the information.

Note 1.— A non-punitive environment is fundamental to voluntary reporting.

Note 2.— Each State is encouraged to facilitate and promote the voluntary reporting of events that could affect aviation safety by adjusting their applicable laws, regulations and policies, as necessary.

5.3.2 Recommendation. — *States should not make available or use safety data referenced in 5.1 or 5.2 for other than safety-related purposes, unless exceptionally, an appropriate authority determines in accordance with their national legislation, the value of its disclosure or use in any particular instance, outweighs the adverse impact such action may have on aviation safety.'*

Attachment B of Annex 19 aims to assist States by providing legal guidance for the

protection of safety information and data. It encourages States to enact national laws and regulations to protect information gathered from safety data collection and processing systems, while allowing for the proper administration of justice. The objective is to prevent the inappropriate use of information collected solely for improving aviation safety. Inappropriate use refers to 'the use of safety information for purposes different from the purposes for which it was collected, namely, use of the information for disciplinary, civil, administrative and criminal proceedings against operational personnel, and/or disclosure of the information to the public'. If safety information is to be used in disciplinary, civil, administrative and criminal proceedings it should be afforded suitable safeguards, as provided by national law.

Exceptions to the protection of safety information should only be granted by national laws and regulations when:

- 'a) there is evidence that the occurrence was caused by an act considered, in accordance with the law, to be conduct with intent to cause damage, or conduct with knowledge that damage would probably result, equivalent to reckless conduct, gross negligence or wilful misconduct;
- b) an appropriate authority considers that circumstances reasonably indicate that the occurrence may have been caused by conduct with intent to cause damage, or conduct with knowledge that damage would probably result, equivalent to reckless conduct, gross negligence or wilful misconduct; or
- c) review by an appropriate authority determines that the release of the safety information is necessary for the proper administration of justice, and that its release outweighs the adverse domestic and international impact such release may have on the future availability of safety information.'

The first amendment of Annex 19 is expected to include upgraded SSP provisions, enhancement of the SMS provisions and amendments that enhance legal safeguards and further strengthen the provisions that deal with the protection of safety data, safety

information and related sources.⁷

4. SOUTH AFRICA - CIVIL AVIATION ACT

South Africa is a member of ICAO, having ratified the Chicago Convention of 1944.⁸ As such, SA is obliged to incorporate certain commitments into national legislation. This includes the prescribed standards and recommended practices (SARPS) contained in the Annexes to the Convention. To ensure that States implement the critical elements of SARPS, the ICAO established the Universal Safety Oversight Audit Programme (USOAP). This Programme has evolved and now follows a Continuous Monitoring Approach (CMA), which allows for systematic, proactive monitoring of activities, as well as the analysis of safety risk factors. In recent years, it has played a key role in supporting State's efforts in implementing SSP.

To ensure compliance with the ICAO prescripts, SA enacted the Civil Aviation Act, which came into operation on 31 March 2010.⁹ The Act provides for the establishment of the South African Civil Aviation Authority (SACAA), with wide-ranging regulatory, safety oversight and international compliance functions.

4.1. CIVIL AVIATION REGULATIONS AND CIVIL AVIATION TECHNICAL STANDARDS

An amendment of the Civil Aviation Regulations 2011, in line with ICAO Annex 19 on 28 October 2016, obliges stakeholders in the South African aviation industry to establish a Safety Management System (SMS) as prescribed in South African Civil Aviation Technical Standards (SA-CATS) 140.¹⁰ The requirements for such a SMS are set out in CAR 140.01.3 and include:

(a) safety policy and objectives:

⁷ ICAO (2013) Amendment 1 will become applicable on 7 November 2019.

⁸ Organization "Convention on International Civil Aviation" (1944) 131.

⁹ Civil Aviation Act 13 of 2009. Replacing the South African Civil Aviation Authority Act of 1998.

¹⁰ "SA-CATS 140" (2017) 1. Civil Aviation Regulations and Technical Standards can be obtained from: <http://www.caa.co.za/Pages/Acts%20and%20Regulations/Notices.aspx>.

- (i) management commitment and responsibility;
 - (ii) safety accountabilities;
 - (iii) appointment of key safety personnel;
 - (iv) coordination of emergency response planning;
 - (v) SMS documentation.
- (b) safety risk management:
- (i) hazard identification;
 - (ii) safety risk assessment and mitigation.
- (c) safety assurance:
- (i) safety performance monitoring and measurement;
 - (ii) management of change;
 - (iii) continuous improvement of the SMS.
- (d) safety promotion:
- (i) training and education;
 - (ii) safety communication.’

Provision is also made for the establishment of safety data collection systems, safety data protection, analysis and information exchange:

‘140.02.1 Safety data collection systems

(1) The Director and each of the entities referred to in regulation 140.01.1 shall establish-

(a) a mandatory incident reporting system to facilitate the collection of information on actual or potential safety deficiencies;

(b) a voluntary reporting system to facilitate the collection of information on actual or potential safety deficiencies that may not be captured by the mandatory incident reporting system; and

(c) a confidential reporting system to facilitate the collection of information on

actual or potential safety deficiencies that may not be captured by mandatory or voluntary reporting systems.

(2) With approval of the Director, a small and less complex entity may put in place a simplified mechanism for the collection, evaluation, processing, analysis and storage of details of occurrences. The entity may share those tasks with other entities of the same nature, while complying with the rules on confidentiality and protection pursuant to this Regulation.

(3) No information obtained under the voluntary reporting system shall be used against a person reporting in any disciplinary, legal or proceedings relating to the capacity or competence of such person.

140.02.3 Safety data protection

(1) The handling of safety data collected through safety data collection and processing systems shall be done with a view to preventing the use of information for purposes other than safety, and shall appropriately safeguard the confidentiality of the identity of the person making the report and of the persons mentioned in occurrence reports, with a view to promoting a 'just culture'.

(2) The Director and an entity referred to in regulation 140.01.1 shall take the necessary measures to ensure appropriate confidentiality of data collected through reporting systems referred to in regulation 140.02.1 (1)(b) and (c).

(3) The Director and an entity referred to in regulation 140.01.1 shall process personal data only to the extent necessary for the purposes of this Regulation and in compliance with national legislation dealing with the protection of personal information.

(4) Data collected through safety data collection and processing systems referred to in regulation 140.02.1 shall be used only for the purpose for which it has been collected.

(5) The Director, any entity or any other person shall not make available or use information on occurrences in order to attribute blame or liability or for any purpose

other than the maintenance or improvement of aviation safety.

(6) The Director shall not be prevented from taking any action necessary for maintaining or improving aviation safety.

140.02.4 Safety data analysis

(1) The Director shall establish and maintain a safety data collection and processing system to facilitate analysis of information on actual or potential safety deficiencies obtained, including that from its occurrence reporting systems or databases, and to determine any actions required for the enhancement of safety.

(2) An entity referred to in regulation 140.01.1 shall establish and maintain a safety database to facilitate analysis of information on actual or potential safety deficiencies obtained, including that from its occurrence reporting systems/databases, and to determine any actions required for the enhancement of safety.

(3) An entity referred to in regulation 140.01.1 shall submit aviation safety performance indicators and targets to the Director, in which an acceptable level of safety shall be commensurate with the size, scope and complexity and shall be acceptable to the Director.

(4) The Director and any entity referred to in regulation 140.01.1 shall establish a process for-

(a) identifying hazards and occurrences to aviation safety and for evaluating and managing the associated risks;

(b) internal reporting and analysing of hazards and occurrences for developing remedial action plans for the timely resolution of all identified safety hazards and incidents;

(c) early alerting of the persons responsible for operations or maintenance about known or suspected hazards and occurrences that would require immediate safety resolution action to be taken through the operational or maintenance control

systems.

140.02.5 Safety information exchange

(1) The Director shall establish a safety information sharing network among all role players within aviation industry and shall facilitate the free exchange of information covering actual and potential safety deficiencies.

(2) An entity referred to in regulation 140.01.1 shall establish a safety information sharing network among employees and service providers within its operations and shall facilitate free exchange of information covering actual and potential safety deficiencies.’

The promulgation of the amended regulations, has for the first time in our law, given express recognition to the concept of just culture. It is defined in the Regulations as: ‘a culture in which persons are not punished for actions, omissions or decisions taken by them that are commensurate with their duties, experience and training, but in which gross negligence, wilful violations and destructive acts are not tolerated’ [emphasis added]

4.1.1. SAFETY MANAGEMENT SYSTEM

SA-CATS 140, mentioned above, prescribes the components and elements of a SMS in more detail and elaborates the essentials of a just culture, as a prerequisite for establishing a broader safety culture. The document notes that a SMS must include:

‘Safety policy that outlines the principles, processes and methods of entity's SMS to achieve the desired safety outcomes. The policy establishes senior management's commitment to incorporate and continually improve safety in all aspects of its activities.’

The document further states that the policy should: ‘include safety reporting procedures’ and ‘clearly indicate which types of behaviours are unacceptable related to the entity's aviation activities and include the circumstances under which disciplinary action would not apply’. A similar provision is found under the heading of ‘safety assurance’:

‘The safety reporting procedures relating to safety performance and monitoring shall clearly indicate which types of operational behaviours that are acceptable or unacceptable, and include the conditions under which immunity from disciplinary action would be considered. A non-punitive policy is required to enhance the reporting culture. Immunity from disciplinary action may not be granted in instances of violation and gross negligence.’

The reasoning behind this is, that it allows for an environment in which safety information is readily available for purposes of implementing ‘safety risk management’ based on a combination of reactive, proactive and predictive methods. As the document explains:

‘Reactive methods approved by an entity or operator refers to methods of identifying hazards and or incidents that are based on the investigation of occurrences. Proactive methods aim to use any other information within the entity for the identification of potential hazards and or incidents. Predictive methods rely on data that is collected within the entity that could be used effectively to predict the existence of hazards and or incidents, usually done by trend analysis.’

4.1.2. AVIATION SAFETY INVESTIGATION BOARD

Chapter 4 of the Act establishes an Aviation Safety Investigation Board. However, a number of essential provisions have not yet come into force. This has led to the adoption of an interim measure whereby the SACAA investigates incidents and accidents on behalf of the Department of Transport, in accordance with a memorandum of understanding regarding the independence of the investigation function. Investigations should preferably be conducted by a specialised independent aviation accident investigation body, so as to not create a conflict of interest. The legislator is in the process of addressing this issue. For purposes of the discussion and to show the contrast between the immediate approach that aviation and medicine has with regard to incidents and accidents, the provisions, that set out the objects of the Aviation Safety Investigation Board are presented here:

‘11. *Objects of Aviation Safety Investigation Board.* (1) The objects of the Aviation Safety Investigation Board are to advance aviation transportation safety by:

(a) conducting independent investigations, including, when necessary, public inquiries into selected aircraft accidents and aircraft incidents in order to make findings as to their causes and contributing factors;

(b) identifying safety deficiencies as evidenced by aircraft accidents and aircraft incidents;

(c) making recommendations designed to eliminate or reduce any such safety deficiencies;

(d) reporting publicly on its investigations and on the findings in relation thereto;

(e) promoting compliance with the provisions and procedures of Annexure 13 to the Convention;

(f) investigating aircraft accidents and aircraft incidents in compliance with the provisions and procedures of Annexure 13 to the Convention; and

(g) discharging all other functions and obligations in compliance with the provisions and procedures of Annexure 13 to the Convention.

(2) The Aviation Safety Investigation Board must not apportion blame or liability in any report following the investigation of any aircraft accident or aircraft incident, and the sole objective of the investigation is accident prevention.

(3) In making its findings as to the causes and contributing factors of an aircraft accident and an aircraft incident, it is not the function of the Aviation Safety Investigation Board to assign fault or determine civil or criminal liability, but the Board must not refrain from fully reporting on the causes and contributing factors merely because fault or liability might be inferred from the Aviation Safety Investigation Board's findings.

(4) No finding of the Aviation Safety Investigation Board must be construed as assigning fault or determining civil or criminal liability.

(5) The findings of or the evidence before the Aviation Safety Investigation Board are not binding on the parties to any legal, disciplinary or any other proceedings

and may not be used in any civil, criminal or disciplinary proceedings against persons giving such evidence.’

5. CONCLUSION

In the weeks following perhaps, the most successful ditching in aviation history, Captain Sullenberger, who glided US Airways Flight 1549 safely into the Hudson River, contacted his local library to ask for an extension and waiver of overdue fees. A book Sullenberger had checked out, was left behind in the cockpit and had sustained quite a bit of water damage. Luckily, the late fees were waived and along with the Key to the city of New York, Mayor Bloomberg, presented Captain Sully with a new (dry) copy of the book he had lost – ‘Just Culture: Balancing Safety and Accountability’ by Sidney Dekker.

.....

Safety management in healthcare is often unfavourably compared to that of aviation. Commercial aviation has a remarkable safety record, whereas the same cannot be said for healthcare. Healthcare organisations have in recent years endeavoured to emulate many of the aspects that contribute to the successes and low error rates observed in HROs. Some promising lessons and interventions aimed at achieving ‘high-reliability’ have come from aviation.¹¹

Many of these interventions translocated from aviation have targeted human factors (i.e. team management and training, cognitive aids, human fatigue, work environment interfaces). For instance, checklists, which are compulsory and widely used in aviation, form an integral part of the WHO Safe Surgery campaign and are slowly being adopted to improve surgical outcomes.

Perhaps, the most consequential lesson to be learnt from aviation (and other HROs), is the importance of a culture of safety, and the critical role that a just culture plays in

¹¹ There are of course important differences between healthcare and aviation and some interventions may not translate well or would require nuanced implementation.

realising and advancing safety efforts.

Aviation has introduced a regulatory framework that supports safety improvement and the establishment of a just culture. Healthcare could very well benefit from the implementation of similar provisions.

Several countries have replicated aviation's approach to incident reporting and accreditation. The UK has recently gone a step further and replicated aviation's approach to safety and incident investigations. The Healthcare Safety Investigation Branch (HSIB), modelled on independent air safety investigation entities, began its operations on 1 April 2017.

The HSIB consists of a team of experienced safety experts, with backgrounds in the NHS, aviation and military investigations, human factors specialists and other investigator expertise. While the HSIB is funded by the Department of Health and hosted by NHS Improvement, it operates independently of them and organisations such as the Care Quality Commission (CQC) and NHS.

The HSIB will investigate up to 30 safety incidents each year in order to provide meaningful safety recommendations and share what they learn across the whole of the healthcare system 'for the benefit of everyone who is cared for by it and works in it'.

South Africa seems to be taking steps in the right direction (having established the Office of Health Standards Compliance and developed a Patient Safety Incident Reporting and Learning guideline). However, more can be done to encourage a culture conducive to safety improvement. The Civil Aviation Act and Regulations, show how it could be done and serve as legislative precedent.

One possible barrier to the establishment of a just culture, the medical malpractice system, is discussed in the following chapter. The functioning and efficacy of the system will be considered, with specific reference to the impact of its deterrence effect on quality and safety of care.

CHAPTER 10. THE FUNCTIONING AND EFFICACY OF THE MEDICAL MALPRACTICE SYSTEM

1. INTRODUCTION

Healthcare, taking a cue from other safety-critical industries, has in recent years slowly transitioned from a traditional approach to medical error, whereby the most proximate individuals were blamed for their inevitable mistakes and lapses, towards an approach that strives to identify and address the systemic flaws that precipitate incidents.¹ This system approach to medical error contends that flawed systems, rather than flawed individuals, are responsible for adverse events and patient harm.² Some have raised concerns that this shift in blame, may lead to a deterioration in accountability.³ As indicated in the previous chapter, such a view conflates accountability and blame.⁴ Blame is the enemy of safety, whereas accountability is a crucial component thereof.

The adoption of a system approach allows us to change our understanding of the concept. Instead of being a retroactive retributive construct, and therefore detrimental to safety, accountability can take on a prospective collective form, thereby advancing safety efforts.⁵

Nevertheless, situations will arise where an inevitable line would have to be drawn to

¹ Leape (1994) 272 *JAMA* 1851; Leape et al. (1995) 274 *JAMA* 35; Leape (2001) 27 *Am. J.L. & Med.* 145.

² Reason (2000) 320 *BMJ* 768.

³ Leape and Fromson (2006) 144 *Annals of Internal Medicine* 107; Wachter and Pronovost (2009) 361 *N Engl J Med* 1401; Dekker and Hugh (2010) 362 *N Engl J Med* 275; author reply 275; Wachter "Personal accountability in healthcare: searching for the right balance" *BMJ Qual Saf* (2013) 22 176; Driver et al. (2014) 9 *Journal of hospital medicine* 99; McTiernan et al. (2015) 24 *BMJ Qual Saf* 162; Moriates and Wachter, *Accountability in Patient Safety* (2016).

⁴ Sharpe (2004); Dekker and Leveson (2014) *BMJ Qual Saf* bmjqs.

⁵ Reason *The human contribution: unsafe acts, accidents and heroic recoveries* (2008).

balance the ‘no blame’ system approach with individual accountability.⁶ The just culture notion has been advanced as a possible solution.⁷ It seeks to promote an environment in which errors can be reported, allowing the organisation to learn from its mistakes, but clearly stipulates that certain conduct is unacceptable and will result in disciplinary action. This is tremendously important, as a just culture lies at the heart of a broader safety culture, which is again fundamental to patient safety.⁸

There is a seemingly irreconcilable tension between the objectives and initiatives of the medical malpractice system and the patient safety movement, which has found recognition and acceptance among those involved in healthcare.⁹ This tension reflects two very disparate and conflicting cultures of injury prevention and safety improvement.¹⁰ Where medicine has in the past two decades moved away from the traditional ‘person approach’ to medical error, the legal system still subscribes thereto and thus blames injuries on the inattentiveness, carelessness and incompetence of individual practitioners. To complicate matters further, the system also fulfils a compensatory function.¹¹ A determination of fault triggers a pecuniary award. Proponents believe that the threat of litigation and the financial incentive involved deters errors and therefore impels safer practice. This (outdated, ineffectual) philosophy is, of course, antithetical to the one effectuated in high-hazard industries and propounded by safety experts.¹²

This chapter will consider functioning and efficacy of the malpractice system with particular emphasis on its two core objectives – compensation and deterrence. The

⁶ Wachter and Pronovost (2009) 361 *N Engl J Med* 1401; Dekker and Hugh (2010) 362 *N Engl J Med* 275; author reply 275; Hickson and Moore... “Balancing systems and individual accountability in a safety culture” ... *Front Office to ...* (2012).

⁷ Reason (1990) 302; Reason (1998b) 12 *Work & Stress* 293; Marx (2001) *Trustees of Columbia University*; Dekker (2012a).

⁸ Reason (1998b) 12 *Work & Stress* 293.

⁹ Studdert et al. (2004) 350 *N Engl J Med* 283.

¹⁰ Bovbjerg et al. “Paths to reducing medical injury: professional liability and discipline vs. patient safety--and the need for a third way.” *J Law Med Ethics* (2001) 29 369.

¹¹ Wachter (2007) 200.

¹² Reason (2000) 320 *BMJ* 768.

latter objective is considered as it relates to quality and safety of care. The system may also contribute to a number of additional problems; some of these are also highlighted.

2. THE MALPRACTICE LITIGATION STUDIES – UNCOVERING THE UNDERLYING PATIENT SAFETY PROBLEM

2.1. THE MEDICAL INSURANCE FEASIBILITY STUDY (CALIFORNIA)

Malpractice litigation is an inextricable part of the patient safety story.¹³ Indeed, as noted in Chapter 3, concern about professional liability costs led to the studies that shed light on the underlying problem of patient harm. The first of which was a study commissioned by the California Medical Association and California Hospital Association in the mid-1970s.¹⁴ The Medical Insurance Feasibility Study was conducted at the height of California's tort-liability, indemnity 'crisis' to determine the cost of medical injuries. A random sample of 20 864 medical records from 23 representative hospitals were reviewed.

The results stunned the sponsors of the study. Investigators identified 970 injuries caused by health care management, 4.65% of the entire sample. This meant that around 1 in 20 patients admitted to hospital would suffer iatrogenic harm. Extrapolating from the findings, Danzon estimated that 140 000 iatrogenic injuries occurred in California during 1974.¹⁵ Investigators also wanted to determine how many of the adverse events would lead to verdicts in favour of the plaintiff if malpractice lawsuits were filed. They found that 17% of the injured cases could be classified as negligent and warrant compensation. Thus, 1 in 126 admitted patients suffered harm as a result of negligent care. Yet, Danzon estimated that at most, 1 in 10 negligently injured

¹³ Vincent (2011) 23.

¹⁴ Association (1977).

¹⁵ Danzon *Medical Malpractice* (1985) 20.

patients filed a claim and only 40% of those received payment.¹⁶ In other words, just 1 in 25 patients injured due to negligence receive compensation through the malpractice system.¹⁷

Considering that the study was conducted to bolster arguments for tort reform, so as to decrease the ‘perceived’ prevalence of malpractice litigation, the findings were quite unpalatable. Whilst, the Associations may have hoped that the study would help perpetuate or propagate, what Baker refers to as, the ‘medical malpractice myth’, it ultimately revealed the opposite: ‘their own research showed that the real problem was too much medical malpractice, not too much litigation.’¹⁸ Negligent care injured a great many patients, yet despite the rhetoric very few actually sued, and even fewer received compensation.

Unsurprisingly, the study was consequently suppressed. It received very little publicity and the results were scarcely published.¹⁹ Only a technical summary was ever made somewhat widely available, wherein the significance of the findings was mostly downplayed and obfuscated.²⁰ However, the technical summary only surfaced a few years after restrictive tort reform had been enacted in California.²¹

2.2. THE HARVARD MEDICAL PRACTICE STUDY (NEW YORK)

The California study was mostly buried and forgotten, until another group of researchers undertook similar investigations more than a decade later. The Harvard Medical Practice Study, which was modelled after the earlier California study, set out to determine more current and reliable estimates of the incidence of adverse events and negligence in hospitalised patients.²² A random sample of 30 121 medical records from 51 acute care hospitals in New York State were reviewed. The records were screened

¹⁶ *Id.* 23.

¹⁷ *Id.* 24.

¹⁸ Baker *The Medical Malpractice Myth* (2007) 2.

¹⁹ Mello and Brennan “Deterrence of medical errors: theory and evidence for malpractice reform” *Tex L Rev* (2001) 1599.

²⁰ Mills “Medical insurance feasibility study. A technical summary.” *West J Med* (1978) 128 360.

²¹ Baker (2007) 2.

²² Brennan et al. (1991) 324 *N Engl J Med* 370.

by trained nurses and medical-record analysts, who found 7817 records that met the screening criteria. Of these records, screened as positive, 7743 were independently reviewed by two physicians for evidence of adverse events and negligence.

Physicians identified 1133 adverse events and 280 negligent ones in the 1984 admissions. This allowed the researchers to estimate the state-wide incidence rates of adverse events and adverse events due to negligence. Adverse events occurred in 3.7% of the hospitalisations and 1% of all adverse events had been caused by negligence. In other words, 1 in 27 patients suffered harm because of health care management (slightly less than the 1 in 20 found by the California investigators), but negligence injured 1 in 4 of those patients (a much higher proportion than the 1 in 6 reported by the California study).²³

The Harvard study also found that a staggering number of patients were being harmed by adverse events, more than half of these adverse events were caused by management error and could therefore be potentially preventable. Among the 58% of adverse events caused by management error, nearly half were attributable to negligence.²⁴ The investigators were for the first time able to provide population estimates for adverse events and adverse events caused by negligence. The burden of iatrogenic injury was large. They estimated that there were 98 609 adverse events among patients admitted to hospital in 1984, 13 451 of which led to death. Even more distressing was the number adverse events caused by negligence. The investigators estimated that 27 179 injuries, including 6895 deaths and 877 cases of permanent and total disability, resulted from negligent care in New York in 1984.²⁵

By matching the random sample of clinical records with state-wide data on medical malpractice claims, the investigators were able to determine the fraction of adverse events due to negligent medical care that led to malpractice claims. Astoundingly, they found that less than 2% of injuries caused by medical negligence led to claims being

²³ Weiler *Medical malpractice on trial* (1991) 12.

²⁴ Leape et al. "The nature of adverse events in hospitalized patients. Results of the Harvard Medical Practice Study II." *N Engl J Med* (1991) 324 377.

²⁵ Brennan et al. (1991) 324 *N Engl J Med* 370.

filed. In other words, 98% of all adverse events due to negligence did not result in malpractice claims. The investigators also estimated the state-wide ratio of adverse events caused by negligence (27 179) to malpractice claims (3 570) was 7.6 to 1, although they do note that this relative frequency overstates the chances.²⁶

Clearly, despite all the anecdotal evidence, the Harvard study found that the vast majority of patients who are harmed by medical negligence do not sue. Malpractice litigation therefore only infrequently compensates those injured and very rarely identifies, and holds providers accountable for substandard care.

2.3. UTAH/COLORADO STUDY

A validation study was undertaken by a subgroup of the Harvard investigators in Utah and Colorado.²⁷ The investigators used similar methods to estimate the incidence and types of adverse events and negligent adverse events that occurred in 1992 from a representative random sample of 15 000 records. The incidence and types of events corresponded to those found in the California and New York studies. Overall, the investigators reported that adverse events occurred in 2.9% of hospitalisations. In Utah, 32.6% of these adverse events were due to negligence; in Colorado, 27.4%.

As the authors noted, almost a decade after the Harvard study, iatrogenic injury was still a significant public health problem. The medical injury data obtained during the first part of the study were again individually matched with medical malpractice claims data to determine how frequently negligent management of patients led to malpractice claims.

The problematic relationship between negligent adverse events and subsequent claims, was also found in the validation study. Of all the patients who suffered harm due to negligent care, only 3% filed claims; 97% of those who suffered negligent injuries did not sue. Although, the incidence of malpractice far exceeded malpractice claims, the researchers, anomalously found that there was a high probability that those providers

²⁶ Localio et al. "Relation between malpractice claims and adverse events due to negligence. Results of the Harvard Medical Practice Study III." *N Engl J Med* (1991) 325 245.

²⁷ Thomas et al. (2000) 38 *Medical Care* 261.

who were eventually sued will have rendered non-negligent care.²⁸

2.4. FROM NEGLIGENCE TO PREVENTABILITY

The Utah/Colorado study, was preceded by the publication of the Quality in Australian Health Care study, which reported that 16.6% of admissions in the same year as the Utah/Colorado study were associated with adverse events.²⁹ Both studies used ostensibly similar methods and sample sizes but had surprisingly different results.³⁰

The large disparity between the rates of adverse events, observed in the US and Australia prompted investigators of both studies to compare methods, characteristics and differences. They found that five methodological discrepancies accounted for some of the disparity between the two studies. However, when the Australian data were analysed using the Utah/Colorado methods, the comparative rates were 10.6% and 3.2%, respectively; still a three-fold difference. The authors of the studies suggest that the difference could be explained by the divergent objectives of the studies. The Australian study sought to measure the impact of iatrogenic harm on their health care system by estimating the prevalence of medical injury and the repercussions that adverse events have on admissions and costs. In addition, they wanted to obtain information to support quality improvement and error prevention efforts.

In contrast, the US study was undertaken to examine the feasibility of a 'no-fault' insurance scheme. In pursuit of sweeping tort-reform, it was necessary for the investigators to measure the annual incidence of adverse events and more specifically, the number of adverse events caused by negligence that may be eligible for compensation. Seeing that the Australian study was more interested in quality improvement, there may have been an incentive to detect as many adverse events as possible, whereas the US study may have been less inclined to detect events, to bolster

²⁸ Studdert et al. "Negligent care and malpractice claiming behavior in Utah and Colorado." *Med Care* (2000) 38 250.

²⁹ Wilson et al. (1995) 163 *Med J Aust* 458.

³⁰ Runciman et al. (2000) 12 *International Journal for Quality in Health Care* 379; Thomas et al. (2000) 12 *Int J Qual Health Care* 371.

the affordability-arguments for ‘no-fault’ insurance.³¹

Studies into the incidence of adverse events that have been conducted since, have all followed the rationale of the Australian study, and have predominantly been concerned with patient safety and quality improvement. For that reason, preventability has instead been adopted as a measure in subsequent studies, thereby replacing determinations of negligence. This enables studies to be conducted from a positive and constructive position, rather than a negative and potentially hostile one.

2.5. THE MALPRACTICE LITIGATION ‘LOTTERY’³²

The Harvard Medical Practice Study and the Colorado/Utah validation study were initially intended to determine the relationship between substandard care and claiming behaviour, with reference to the underlying rate of negligently caused medical injuries, in order to help bring about tort reform. However, the foremost contribution of these two studies has been the revelation that patients face an immense burden of iatrogenic harm. The data obtained in the studies played a key part in the Institute of Medicine report.³³ By extrapolating the data and estimates of deaths to the entire US population, the IOM managed to gain widespread attention and galvanised political and professional will at the highest levels of the US government. The release of the IOM report is generally regarded as the single most important development in the field of patient safety. Since its publication, numerous other governments and professional organisations have released similar reports and bulletins on patient safety.³⁴ Many countries have now conducted their own adverse event studies and the available evidence suggests that iatrogenic injuries represent a major source of morbidity and mortality globally.³⁵

³¹ Studdert et al. “Can the United States Afford a “No-Fault” System of Compensation for Medical Injury” *Law and Contemporary Problems* (1997) 60 1; Thomas et al. (1999) 36 *Inquiry* 255; Gawande et al. “The incidence and nature of surgical adverse events in Colorado and Utah in 1992.” *Surgery* (1999) 126 66.

³² Lytton et al. “Tort as a litigation lottery: A misconceived metaphor” *BCL Rev.* (2011) 52 267.

³³ Kohn et al. (2000).

³⁴ See the discussion in Chapter 2.

³⁵ Jha et al. (2013) 22 *BMJ Qual Saf* 809.

3. FUNCTIONING AND EFFICACY OF THE MALPRACTICE SYSTEM

In addition to uncovering staggering numbers of adverse events (for which they have become renowned) the Harvard and Utah/Colorado studies raised some serious questions about the functioning of the medical malpractice system.³⁶ Rather concerning, these questions relate to the system's two core objectives:³⁷

- i) its capacity to compensate injured patients
- ii) its ability to identify and deter substandard care

First, however, it is important to note that almost all of the empirical evidence we have regarding the functioning of a tort-based medical malpractice system comes from the United States and although there are similarities between our malpractice system, the surrounding context and theirs, there are also important differences.³⁸ The generalisability of research findings must be understood in that light. In fact, as I have argued elsewhere, the absence of empirical evidence and reliable information surrounding the (in)effectiveness of the South African system constitutes a major impediment to proper policy considerations and informed discussion.³⁹

For purposes of this discussion, and as it relates to patient safety, a general high-level overview of malpractice systems and their functioning will suffice. The available fragments of research will be presented to hopefully, form a broader mosaic on which

³⁶ Weiler (1991); Localio et al. (1991) 325 *N Engl J Med* 245; Thomas et al. (2000) 38 *Medical Care* 261.

³⁷ Posner "The concept of corrective justice in recent theories of tort law" *The Journal of Legal Studies* (1981) 10 187; Coleman "Tort law and the demands of corrective justice" *Ind. LJ* (1991) 67 349; Wright "Substantive Corrective Justice" *Iowa L. Rev.* (1991) 77 625; Schwartz "Mixed theories of tort law: affirming both deterrence and corrective justice" *Tex. L. Rev.* (1996) 75 1801; Zipursky "Civil recourse, not corrective justice" *Geo. LJ* (2002) 91 695; Brennan "Medical malpractice" *The New England Journal of Medicine* (2004) 350 283; Joint "Health care at the crossroads: strategies for improving the medical liability system and preventing patient injury" *Oakbrook Terrace, IL: Joint Commission* (2005); Gardner "What is tort law for? Part 1. The place of corrective justice" *Law and Philosophy* (2011) 30 1. Corrective justice is often cited as a third objective. The argument for restorative justice is made in Chapter 8. Paragraph 4.

³⁸ OECD "Policy Issues in Insurance Medical Malpractice Prevention, Insurance and Coverage Options" (2006) 10.

³⁹ Oosthuizen and Carstens "Medical malpractice: The extent, consequences and causes of the problem" (2015).

to base further arguments.

Unfit for Purpose:

3.1. CAPACITY TO COMPENSATE INJURED PATIENTS

3.1.1. TOO MANY CLAIMS?

One of the most persistent myths about the medical malpractice system, is that there are too many malpractice claims.⁴⁰ However, the available evidence suggests that the overwhelming majority of patients who suffer injuries due to negligent care do not institute claims.⁴¹ In fact, the studies have found that less than 4% of negligently injured patients sue. Negligent adverse event to claims ratios of 10:1, 7:1 and 5:1 have been reported. Clearly, only a fraction of eligible claims ever reach the legal system.

As much as 70% of all claims that do reach the system are closed without payment.⁴² Nearly 60% of claims go unresolved, neither settled nor adjudicated. Instead, the majority of claims are abandoned by plaintiffs either because they uncover information during the course of litigation that dampens their initial assessment regarding the value of the claim or the likelihood of success.⁴³ Patients also abandon claims because of the lengthy period between filing suit and resolution, malpractice cases often take years to be resolved and can be traumatic and frustrating for the litigants involved. In one study the average dropped claim had been pending for nearly 3 years.⁴⁴

Recent studies have further indicated that rates of malpractice claims paid on behalf of physicians in the United States have declined substantially.⁴⁵ One report found an

⁴⁰ Baker (2007); Sloan and Chepke *Medical Malpractice* (2008) 17.

⁴¹ Localio et al. (1991) 325 *N Engl J Med* 245; Thomas et al. (2000) 38 *Medical Care* 261.

⁴² Studdert et al. (2004) 350 *N Engl J Med* 283.

⁴³ Golann "Dropped medical malpractice claims: their surprising frequency, apparent causes, and potential remedies." *Health Aff (Millwood)* (2011) 30 1343.

⁴⁴ *Ibid.*

⁴⁵ Bishop et al. "Paid malpractice claims for adverse events in inpatient and outpatient settings." *JAMA* (2011) 305 2427; Paik et al. "The Receding Tide of Medical Malpractice Litigation: Part 2-Effect of Damage Caps: The Receding Tide of Medical Malpractice Litigation: Part 2" *Journal of Empirical Legal Studies* (2013) 10 639; Paik et al. "The Receding Tide of Medical Malpractice Litigation: Part 1-National Trends: The Receding Tide of Medical

average annual decrease of nearly 7% between 1994 and 2013.⁴⁶ Another study conducted by Schaffer *et al.* found that the rate of claims paid on behalf of all physicians declined by 55.7% from 1992 to 2014.⁴⁷ The authors observed that the decrease occurred across all specialties, and although there was substantial variation in extent between specialties, all but one showed a significant decline.⁴⁸

3.1.2. TOO MANY FRIVOLOUS CLAIMS?

Since, this does not support the ‘malpractice myth’ proponents of traditional tort-reform point to (and often misrepresent), the weaker aspects of the Malpractice Studies, particularly the findings regarding the validity of claims, to support contentions that claims are often frivolous and without merit.

Baker, has disputed this interpretation and showed how it conflicts with all the other research.⁴⁹ He, specifically, cites the Farber and White study to refute assertions of frivolous claims.⁵⁰ Farber and White found the quality of medical care to be an extremely important determinant of medical malpractice liability and noted that claims are often filed by poorly informed plaintiffs in order to gather more information regarding the standard of care they received. Cases were likely to be dropped if negligence was found to be unlikely.

Peters, reviewing the available evidence regarding malpractice settlements, comes to the same conclusion. He certainly shows how the odds of a settlement and the likely

Malpractice Litigation: Part 1” *Journal of Empirical Legal Studies* (2013) 10 612; Saber Tehrani et al. “25-Year summary of US malpractice claims for diagnostic errors 1986-2010: an analysis from the National Practitioner Data Bank.” *BMJ Qual Saf* (2013) 22 672; Mello et al. (2014b) 312 *JAMA* 2146; Schaffer et al. “Rates and Characteristics of Paid Malpractice Claims Among US Physicians by Specialty, 1992-2014.” *JAMA Intern Med* (2017) 177 710.

⁴⁶ Mello et al. (2014b) 312 *JAMA* 2146.

⁴⁷ Schaffer et al. (2017) 177 *JAMA Intern Med* 710.

⁴⁸ Despite the downturn in paid malpractice claims, the mean payment did, however, increase by 23.3% over the same period.

⁴⁹ Baker (2005) 33 *J Law Med Ethics* 77; Baker (2007).

⁵⁰ Farber and White “Medical malpractice: an empirical examination of the litigation process.” *Rand J Econ* (1991) 22 199.

size of any settlement are both closely related to the merits of the plaintiff's claim.⁵¹ Thus, quality of care drives settlement outcomes. There may be a few outliers, where the outcomes of settlements depart from the merits, but for the most part in such cases the settlement data actually favours defendant physicians. Malpractice defendants possess several advantages than can be employed to gain favourable settlements. As Peters notes:

‘Defendants have superior resources, more experienced lawyers, and the benefit of other sources of bargaining power, such as a repeat-player's risk neutrality and incentive for hard bargaining. As a result, plaintiffs have more reason to complain about the system's imperfections than defendants do.’⁵²

The most recent, and probably the best, study on the merits of claims and fairness of malpractice outcomes was published in 2006.

Studdert *et al.* investigated the merits and outcomes of malpractice litigation using structured retrospective reviews of 1452 closed claims, to measure the prevalence, costs, outcomes, and distinguishing characteristics of claims that did not involve identifiable error.⁵³ Their findings correspond to those of Farber and White, underscoring how difficult it is for plaintiffs and their attorneys to find out what occurred before the initiation of a claim. (Golan made the same observation in relation to dropped claims) The litigation process triggers investigations, consultation with experts, and the sharing of information. This includes information that a claimant would not have possessed before filing a claim and would not have acquired without resorting to litigation. That perhaps explains why they found that one third of all claims did not involve error. Regardless, most of these ‘meritless’ claims went unpaid.

Despite, what traditional tort-reform proponents would contend, where care is not

⁵¹ Peters Jr “What we know about malpractice settlements” *Iowa L Rev* (2006) 1832.

⁵² *Id.* 1833.

⁵³ Studdert et al. “Claims, errors, and compensation payments in medical malpractice litigation.” *N Engl J Med* (2006) 354 2024.

actually substandard, claimant patients very seldom receive compensation.⁵⁴ In actuality, non-payment of claims with merit are significantly more common than payment of claims that are not associated with errors or injuries.⁵⁵ The authors explicitly stated that the non-error claims that they observed did ‘not square with the notion of opportunistic trial lawyers pursuing questionable lawsuits’ and concluded that ‘portraits of a malpractice system that is stricken with frivolous litigation are overblown.’⁵⁶ If claims that did not involve errors were eliminated it would have decreased costs by no more than 13-16%.⁵⁷ Clearly, the vast majority of expenditures go toward litigation over actual errors and payment of them. The authors thus found that the malpractice system was able to adequately separate claims without merit from those with merit and compensate the latter.

However, the study raised some major concerns about the performance of the malpractice system. One of these concerns, as mentioned, relates to the number of plaintiffs that go uncompensated, despite there being evidence that they had been negligently injured. In their study, one in six claims involved errors and received no compensation. These patients are then left to shoulder the immense economic and non-economic burden of their preventable injuries. Another major concern, is the inefficiency and cost of the malpractice system. The authors noted that the average time between injury and resolution among the claims they examined was five years, and that one in three claims took six years or more to resolve. The system’s overhead costs are also exorbitant. The authors found that for every dollar spent on compensation, 54 cents went to administrative expenses.⁵⁸

The authors conducted their study during a period in which medical malpractice and possible reforms were eliciting serious debate and policy discussions. Not much has

⁵⁴ Taragin et al. “The influence of standard of care and severity of injury on the resolution of medical malpractice claims.” *Ann Intern Med* (1992) 117 780; Sloan *Suing for medical malpractice* (1993); Studdert et al. (2006) 354 *N Engl J Med* 2024.

⁵⁵ Studdert et al. (2006) 354 *N Engl J Med* 2024.

⁵⁶ *Id.* 2031.

⁵⁷ *Ibid.*

⁵⁸ *Ibid.*

changed, tort reform is seemingly always on the agenda (and South Africa is no exception). Advocates of tort reform regularly blame the supposed prevalence of ‘frivolous’ attorneys and claims, as drivers of wasted expenditure and substantial health care cost increases. Traditional reforms, such as shortening statutes of limitation, caps on damages, limits on attorneys’ fees and pre-trial screening panels, are subsequently advanced as panaceas, to help constrain these meritless or ‘frivolous’ lawsuits. However, since, frivolous lawsuits are relatively rare, these reforms would have very little of an impact on either efficiency or costs of litigation. Instead, it will only make it harder for injured patients to access the legal system, ensuring that even fewer negligently harmed patients, who are eligible and should receive compensation, file claims. Thus, increasing the, already immense, disparity between malpractice and malpractice claims.

On this point, Studdert *et al.* concluded their discussion as follows:

‘Our findings suggest that moves to curb frivolous litigation, if successful, will have a relatively limited effect on the caseload and costs of litigation. The vast majority of resources go toward resolving and paying claims that involve errors. A higher-value target for reform than discouraging claims that do not belong in the system would be streamlining the processing of claims that do belong.’⁵⁹

3.1.3. FAIRNESS OF MALPRACTICE OUTCOMES

If one considers the evidence accumulated over the past two decades regarding the outcomes of malpractice claims, the predominant assumption that the malpractice system regularly yields unfair or unfounded outcomes, is definitely refuted by the data.⁶⁰ The wide range of studies conducted over this period, have all produced consistent findings, indicating that the outcomes of malpractice litigation are remarkably well-correlated to the quality of care provided, as judged by other practitioners.⁶¹

⁵⁹ *Id.* 2032.

⁶⁰ Peters “Twenty years of evidence on the outcomes of malpractice claims.” *Clin Orthop Relat Res* (2009) 467 352.

⁶¹ Sloan and Hsieh “Variability in medical malpractice payments: is the compensation fair” *Law and Society Review* (1990) 997; Taragin et al. (1992) 117 *Ann Intern Med* 780; Sloan (1993); Localio et al. “Identifying adverse events

Settlements and their size, are similarly related to the merits of the underlying malpractice claim.⁶² The evidence also suggests that defendants are at a substantial advantage during settlement proceedings, which has the effect of decreasing the amounts paid relative to the fair expected value of claims. Insurers, after all, have an economic incentive to accurately evaluate the merits and potential value of cases.⁶³ They therefore, rely heavily on a form of peer review, whereby they gather multiple expert evaluations and act in accordance with the appraisals about the prospects of claims.⁶⁴ The malpractice system has many faults, but bias against practitioners is not one of them.⁶⁵ In fact, the evidence shows that the opposite may be true, that physicians actually have the benefit of more favourable outcomes.⁶⁶ In addition, even with strong evidence of negligence, malpractice claims are still considered to be notoriously hard to win at trial.⁶⁷

3.2. ABILITY TO IDENTIFY AND DETER SUBSTANDARD CARE

Despite malpractice litigation constituting a persistent threat to medical professionals over the past few decades, harmful medical errors have continued to be an alarmingly prevalent aspect of modern healthcare.⁶⁸ This has raised questions about the

caused by medical care: degree of physician agreement in a retrospective chart review” *Annals of internal medicine* (1996) 125 457; Spurr and Howze “The effect of care quality on medical malpractice litigation” *The Quarterly Review of Economics and Finance* (2001) 41 491; Peters (2009) 467 *Clin Orthop Relat Res* 352.}

⁶² Vidmar *Medical malpractice and the American jury: Confronting the myths about jury incompetence, deep pockets, and outrageous damage awards* (1997); Sloan and Chepke (2008) 172.

⁶³ Baker (2005) 33 *J Law Med Ethics* 508; Baker (2007) 77.

⁶⁴ Peters (2009) 467 *Clin Orthop Relat Res* 352.

⁶⁵ Vidmar “Medical Malpractice Lawsuits: An Essay on Patient Interests, the Contingency Fee System, Juries, and Social Policy” *Loy. LAL Rev.* (2004) 38 1217; Vidmar “Juries and medical malpractice claims: empirical facts versus myths” *Clinical orthopaedics and related research* (2009) 467 367.

⁶⁶ Baker (2007) 73.

⁶⁷ Baker (2005) 33 *J Law Med Ethics* 509; Boehm “Debunking medical malpractice myths: unraveling the false premises behind tort reform” *Yale J. Health Pol’y L. & Ethics* (2005) 5 357; Salvi “Why medical malpractice caps are wrong” *N. Ill. UL Rev.* (2005) 26 553; Peters Jr (2006) *Iowa L Rev* 1787; Baker (2007) 90.

⁶⁸ Kohn et al. (2000); Classen et al. (2011) 30 *Health Aff (Millwood)* 581; James (2013) 9 *J Patient Saf* 122; Makary and Daniel (2016) 353 *BMJ* i2139.

malpractice system's ability to identify and deter substandard care.⁶⁹ Its general role, as it relates to the promotion of patient safety, has also been widely discussed and disputed.⁷⁰

3.2.1. DOES THE THREAT OF MALPRACTICE LIABILITY DETER INJURIES AND IMPROVE QUALITY OF CARE?

As Sloan and Hsieh note, this is fundamentally an empirical question and therefore, cannot be established on the basis of theoretical arguments and causal observations alone.⁷¹ Two approaches have been employed to try and empirically analyse the deterrence effect of malpractice liability. The first, examines healthcare providers in a certain government jurisdiction to determine whether injury rates and practice patterns are positively influenced in areas within the jurisdiction where the malpractice liability threat is higher. The second approach, investigates the influence of changes in tort law which alter the probability of being sued and examines whether such changes affect the incidence of adverse outcomes.⁷²

The First Approach

3.2.1.1. WEILER ET AL.

The Harvard Medical Practice Study, an example of the first approach, provided the data, for perhaps, the first thorough attempt at determining whether the threat of

⁶⁹ Schwartz and Komesar "Doctors, damages and deterrence. An economic view of medical malpractice." *N Engl J Med* (1978) 298 1282.

⁷⁰ Leape (1994) 272 *JAMA* 1851; Kachalia et al. "Physician responses to the malpractice crisis: from defense to offense." *J Law Med Ethics* (2005) 33 416; Mello et al. "'Health courts' and accountability for patient safety." *Milbank Q* (2006) 84 459; Barringer et al. "Administrative compensation of medical injuries: a hardy perennial blooms again." *J Health Polit Policy Law* (2008) 33 725; Kachalia et al. "Beyond negligence: avoidability and medical injury compensation." *Soc Sci Med* (2008) 66 387; Mello and Kachalia "Evaluation of options for medical malpractice system reform" *Medicare Payment Advisory Commission* (2010); Kachalia and Mello "New directions in medical liability reform." *N Engl J Med* (2011) 364 1564; Mello et al. "Administrative compensation for medical injuries: lessons from three foreign systems." *Issue Brief (Commonw Fund)* (2011a) 14 1; Kachalia "Improving patient safety through transparency." *N Engl J Med* (2013) 369 1677; Kachalia et al. "Legal and Policy Interventions to Improve Patient Safety." *Circulation* (2016) 133 661.

⁷¹ Sloan and Hsieh *Health economics* (2017) 289.

⁷² *Id.* 291.

malpractice liability indeed deters injuries.⁷³ Weiler *et al.* conducted an econometric analysis of the data, using a two-equation model.⁷⁴ One equation measured the influence of the litigation threat on the hospital's injury rate. The relationship between the litigation threat and specific threat-altering characteristics of the areas in which the hospitals were situated, formed part of the second equation. The authors described their findings, as follows:

'Our econometric analysis provides some evidence, though not scientific demonstration, that the higher the number of malpractice claims, the lower the number of negligent injuries experienced by the patient population as a whole (patient population at the hospital). That result emerged from our data even though the host of constraints on the data set combined to reduce rather than enhance the likelihood that such a causal connection would manifest itself.'⁷⁵

The results of their analysis, however, failed to achieve statistical significance. Weiler and colleagues, in the end had to conclude their analysis accordingly:

'Although we did observe the hypothesized relationship in our sample-the more tort claims, the fewer negligent injuries-we cannot exclude the possibility that this relationship was coincidental rather than causal.'⁷⁶

3.2.1.2. MELLO AND BRENNAN

Mello and Brennan, re-analysed the data, and provided an expansive discussion of the immense difficulties faced whilst seeking to establish a deterrence link.⁷⁷ The authors rather amusingly described their attempts as a 'multi-pronged assault on the elusive deterrence phenomenon, which could be lauded as a careful sensitivity analysis or derided as a statistical fishing expedition'.⁷⁸ The studies that have followed the first

⁷³ Localio *et al.* (1991) 325 *N Engl J Med* 245.

⁷⁴ Weiler *A measure of malpractice: medical injury, malpractice litigation, and patient compensation* (1993a).

⁷⁵ *Id.* 132.

⁷⁶ *Id.* 133.

⁷⁷ Mello and Brennan (2001) *Tex L Rev* 80 1595.

⁷⁸ *Id.* 1611.

approach have been inconsistent and open to methodological criticism.⁷⁹ They have shown that, there is at most, limited empirical evidence that the threat of medical malpractice litigation improves quality of care.

The Second Approach

Almost all the earlier studies that have followed the second approach, have only tangentially considered the extent to which the malpractice environment deters substandard care or improves healthcare quality.⁸⁰ Instead, these studies have primarily focussed on the relationship between litigation forces, healthcare costs and unnecessary resource utilisation. Furthermore, where the link between malpractice liability and deterrence has been explored, it has been with reference to broad aggregate measures, which may not necessarily be good indicators of quality, such as overall mortality.⁸¹

Two notable studies (using a difference-in-difference methodology) have empirically examined the potential deterrence link as part of their more meticulous investigations into defensive medicine. In theory, tort reforms that reduce the threat of malpractice claims, weaken the deterrence signal, and consequently result in increased rates of adverse outcomes. In other words, liability-limiting reforms may undermine tort deterrence, thus reducing the incentive to provide better quality care.⁸²

3.2.1.3. KESSLER AND MCCLENNAN

The first study by Kessler and McClennan, widely-cited on the topic of defensive medicine, analysed the effects of malpractice liability reforms using data on all elderly Medicare beneficiaries treated for serious heart disease in 1984, 1987, and 1990.⁸³ Although, their study set out to determine whether the fear of liability drove healthcare

⁷⁹ Danzon “Liability for medical malpractice” *Handbook of health economics* (2000) 1 1339.

⁸⁰ Sloan and Hsieh (2017) 293.

⁸¹ Avraham and Schanzenbach (2015) *SSRN Journal*; Frakes and Jena (2016) 143 *J Public Econ* 142.

⁸² Sloan and Chepke (2008) 189; Mello and Kachalia (2010) *Medicare Payment Advisory Commission*.

⁸³ Kessler and McClellan “Do Doctors Practice Defensive Medicine?” *The Quarterly Journal of Economics* (1996) 111 353.

providers to administer unnecessary treatments that were mainly intended to reduce their risk of being sued. It could, to some extent provide information about the deterrent effect of malpractice litigation. The authors found that malpractice reforms did exert an influence on defensive practices, as a decrease in liability pressure led to a decrease in medical expenditure. Reforms that directly limit provider liability, such as damage caps, reduced Medicare spending for in-hospital care of cardiac patients by 5–9%. However, their finding that the cost of care decreased without a commensurate effect on adverse outcomes, did nothing to bolster the deterrence argument.⁸⁴

3.2.1.4. SLOAN AND SHADDLE

The second study, was conducted by Sloan and Shaddle, who set out to reassess the previous findings regarding defensive medicine.⁸⁵ Their study included four primary diagnoses, compared to the Kessler and McClennan study, which only examined cardiovascular diagnoses. The authors, contrary to the earlier study, concluded that neither direct, nor indirect reforms had any significant effect on clinical decisions or health outcomes. Their results did, however, support the inference from the Kessler and McClennan study regarding deterrence. Their findings also suggested that the threat of liability did not deter medical injuries. Relaxing the threat of lawsuits did not lead to more adverse outcomes. On this point the authors note:

‘In one respect, our results are troubling. A primary goal of tort is to deter iatrogenic injuries. However, there is no empirical support in the literature that the threat of medical malpractice lawsuits achieves a deterrent function. If the threat of tort does deter iatrogenic injuries, one would expect that implementing public policies that reduce the threat of tort would lead to poorer patient outcomes. In reality, with one exception, reducing the threat of tort has no effect on patient outcomes in our

⁸⁴ Kessler and McClellan (1996) 111 *The Quarterly Journal of Economics* 353; Kessler and McClellan “How liability law affects medical productivity.” *J Health Econ* (2002) 21 931.

⁸⁵ Sloan and Shadle “Is there empirical evidence for “Defensive Medicine”? A reassessment.” *J Health Econ* (2009) 28 481.

analysis. This study's results represent an addition to a body of literature that suggests that imposition of liability does not deter medical injuries.⁸⁶

3.2.1.5. KLINK AND STRATMANN

Klick and Stratmann evaluated the effect of different tort-reforms on physician supply, in order to gauge whether the threat of liability influenced the location decisions of physicians in high-risk specialties.⁸⁷ Their results suggest that only noneconomic damage caps are effective in increasing the per capita number of doctors in the highest-risk specialties. However, the authors also wanted to determine whether this increase in supply will generate improvements in public health. They note that there may be a trade-off between increased access and harm that might result from the decreased incentive to provide optimal care. To determine whether that is the case, they investigated the effect of tort-reform on infant mortality rates (a particularly appropriate metric, considering that obstetricians are often the target of reforms). However, in the end Klick and Stratmann also failed to identify a statistically significant relationship between reforms and infant mortality, leaving the deterrence question unanswered.

3.2.1.6. CURRIE AND MACLEOD

Currie and MacLeod used data from national vital statistics natality files on millions of individual births from 1989 to 2001, to investigate whether specific tort reforms affect the types of procedures that are performed and the health outcomes of mothers and their infants.⁸⁸ This study employed more proximal measures of care, in comparison to those discussed above (which is preferable).

The authors developed a model that analysed the incentives created by specific tort reforms and explored the effect of tort reform on both the level of care and procedure use during child birth. They found that 'contrary to popular belief, reducing the threat of

⁸⁶ *Id.* 490.

⁸⁷ Klick and Stratmann "Medical Malpractice Reform and Physicians in High-Risk Specialties" *The Journal of Legal Studies* (2007) 36 S121.

⁸⁸ Currie and MacLeod "First Do No Harm? Tort Reform and Birth Outcomes" *Quarterly Journal of Economics* (2008) 123 795.

malpractice can increase the use of procedures, such as C-sections, and may reduce the effort made by doctors in realistic scenarios.’ The strongest finding from the study was, that joint-and-several liability reforms reduced C-sections and complications associated with birth. The authors noted the potential benefits of this reform:

‘By aligning malpractice risk more closely with the physician’s own actions, JSL reform causes physicians to take more care and avoid unnecessary and potentially harmful procedures. In addition, JSL reform may cause hospitals to undertake systematic reforms that are beneficial to patients generally in order to avoid being held responsible for a large share of the damages in medical malpractice cases.’⁸⁹

In contrast to joint-and-several liability reform, the authors observed that caps on non-economic damages actually increased the incidence of unnecessary C-section procedures and led to increased preventable labour and delivery complications. Tort reform that reduced malpractice risk appeared to increase procedure use, with potentially harmful outcomes. Currie and MacLeod posit that physicians may perform certain ‘procedures in marginal cases not because of fear of liability but because the procedures are more profitable and less time-consuming than the alternatives’.⁹⁰ Furthermore, doctors may be more likely to do so where the threat of liability is reduced. This accords with the deterrence theory. However, it is tempered in that they also found that there is ‘little evidence that increases in procedure use induced by damage caps affect infant health, suggesting that the marginal procedures induced or discouraged by tort reform have little impact on infant health.’⁹¹ The authors conclude by noting the intricacies of the incentives created by the malpractice system, in addition to this complexity, interactions with other incentives facing physicians may make predictions regarding the outcomes of tort reforms difficult.

⁸⁹ *Id.* 826.

⁹⁰ *Id.* 797.

⁹¹ *Ibid.*

3.2.1.7. YANG ET AL.

Yang *et al.* also studied the effects of tort law on birth outcomes, more specifically, whether reducing liability pressure adversely impacts public health.⁹² To do so, the authors examined the impact of malpractice premiums and tort reforms on rates of four widely used indicators of adverse birth outcomes: birth injury, low Apgar score, low birthweight, and preterm birth. Their analysis employed a longitudinal research design, which considered millions of individual births in 51 jurisdictions over 12 years.

Previous research has linked liability pressures to changes in obstetrical practice. The authors undertook this study to determine if those changes result in improved birth outcomes. They found that 'birth outcomes are no better in states where obstetricians face high liability pressure than in states where liability pressures are lower.'⁹³ It did not matter whether the measure of pressure used was insurance premiums or liability-limiting tort reforms. Their findings concerning birth outcomes were essentially consistent with those of Currie and MacLeod. Both studies found that tort reforms were not significantly associated with lower Apgar scores.

In their conclusion, Yang *et al.*, set out their findings in relation to the deterrence theory as follows:

'In sum, the results of this analysis are inconsistent with the view that liability pressure reduces risks of adverse birth outcomes. Evidence of a deterrent effect, insofar as such an effect exerts itself on actual outcomes of care, is lacking. At one level, this result must raise fundamental questions about the performance of the malpractice system. Another inference is that adopting liability-limiting reforms, at least in the area of obstetrics, appears unlikely to adversely affect health outcomes, as some opponents of tort reform have claimed (American Trial Lawyers Association).'⁹⁴

⁹² Yang et al. "Does Tort Law Improve the Health of Newborns, or Miscarry? A Longitudinal Analysis of the Effect of Liability Pressure on Birth Outcomes" *Journal of Empirical Legal Studies* (2012) 9 217.

⁹³ *Id.* 237.

⁹⁴ *Ibid.*

3.2.1.8. IIZUKA

Iizuka examined the relationship between malpractice pressure and health outcomes by using a series of patient safety indicators (as proposed by the Agency for Healthcare Research and Quality).⁹⁵ These indicators are specifically intended to identify potentially preventable medical errors or adverse events. The author focussed on four specific indicators and the in-hospital mortality rates associated with obstetrics and gynaecology. Unlike previous studies that looked at the influence of tort reform on mortality, Iizuka found some evidence for deterrence. He found that liability pressure was positively associated with decreased preventable medical complications. Furthermore, the effects varied depending on the reforms implemented. Thus, joint-and-several liability reform (which increases doctor accountability) decreased preventable medical complications, and collateral source rule reforms as well as punitive damage caps increased labour and delivery complications. However, the author found no relationship between non-economic damages caps and adverse outcomes, which is strange considering that such reform usually has the largest impact on liability pressure among the four reforms examined.⁹⁶ Nonetheless, this study suggests that concerns regarding the detrimental effect of tort reforms on patient safety may be legitimate (similar to the findings of Currie and MacLeod).

3.2.1.9. FRAKES AND JENA

Frakes and Jena conducted, what is perhaps, the most extensive study of the relationship between the deterrence function of the medical malpractice system and patient outcomes. The authors used data from the National Hospital Discharge Surveys (1979-2005) and the Behavioral Risk Factor Surveillance System (1987-2008) to examine the effect of medical malpractice liability on several comprehensive healthcare quality metrics. The indicators they analysed, encompassed almost all of the quality domains targeted by both the OECD's Health Care Quality Indicator's project, as well as the domains of quality promulgated by the Agency for Health Care Research and Quality.

⁹⁵ Iizuka "Does higher malpractice pressure deter medical errors?" *The Journal of Law and Economics* (2013) 56 161.

⁹⁶ Frakes and Jena (2016) 143 *J Public Econ* 146.

To identify the influence of liability pressures on health care quality, Frakes and Jena employed two approaches: The first approach relies on a difference-in-difference methodology, similar to previous studies, to evaluate the impact of traditional reforms. This includes damage-caps and related reforms, that essentially preserve the basic structure of the medical malpractice system, but with lessened liability pressure and consequences. In contrast, the second, novel approach, eschews these traditional remedy-orientated reforms and instead studies the impact of more substantive reforms, which directly alter the standards of care against which physicians are judged in cases of alleged medical malpractice. They specifically analysed the changes that occurred when amended state-wide laws meant that physicians were no longer appraised in accordance with customary local practices, but rather judged in relation to national standards of care. The reasoning being that, such a refinement of the expected standard (in other words, raising the benchmark) would potentially have a much more direct and persuasive influence on clinical practices.

With regard to the first approach, which analysed remedy-focused/traditional reforms, Frakes and Jena find that higher malpractice pressure within the existing liability system ‘can at most lead to a modest level of deterrence, inconsistent with the idea that the current medical liability system can be used to substantially improve health care quality through deterrent forces.’⁹⁷ Their results suggest that the system brings about little to no benefits in healthcare quality. They contend that this, almost inconsequential effect of malpractice liability may be due to the structural nature of the existing liability system, which largely holds physicians to standards determined according to professional customs. Standards of care are essentially enforced in a largely self-regulatory manner. Furthermore, industry customs may not necessarily be aligned with evidenced-based best practice. This is problematic, seeing that adherence would be measured in accordance with the legal standard, which is almost entirely informed by the industry espoused customary standard, as attested to by expert witnesses (generally practicing in the same field and jurisdiction as the defendant).

⁹⁷ *Id.* 157.

The second part of the authors' empirical analysis was more encouraging in regard to the potential positive influence of medical liability. Where the malpractice system was more substantively reformed, by raising the legally-expected standard of care through locality rule abdications, quality improvements followed. What is more, the authors indicate that 'this relationship between health care quality and changes in clinical malpractice standards works in an expansionary direction only'.⁹⁸ Meaning that, physicians provide better quality care in order to meet legally-expected higher standards of care, and once they do they continue to deliver those quality-levels even when expectations are lowered at a later stage. Malpractice pressures may thus, be helpful in 'elevating the quality floor'.⁹⁹

Frakes and Jena offer a possible explanation:

'By retreating from a liability system based on custom that only reinforced those informational deficiencies and by instead imposing a new liability system that sets liability standards optimally, physicians may update their priors regarding the benefits of precaution taking, given the saliency of information that may flow through liability channels. Such updating alone may cause an increase in delivered quality.'¹⁰⁰

Accordingly, the law could still play a valuable role in shaping clinical practices and health care quality, but we would have to better understand the liability structure that would be conducive thereto. The fear of liability in a system riddled with imperfect information may only bring modest improvements, if any, whereas liability contingent upon the imposition of evidence-based standards and better-informed science may advance quality of care and patient safety.¹⁰¹

⁹⁸ *Id.* 158.

⁹⁹ *Ibid.*

¹⁰⁰ Frakes and Jena "Does Medical Malpractice Law Improve Health Care Quality" (2014); Frakes (2015) *The University of Chicago Law Review* 379.

¹⁰¹ Frakes (2015) *The University of Chicago Law Review* 379.

3.2.1.10. ZABINSKI AND BLACK

Zabinski and Black examined whether the adoption of caps on non-economic damages in five states (Texas, Florida, Georgia, Illinois, and South Carolina), which reduces the liability risk for providers, influenced hospital patient safety.¹⁰² The authors also focussed on more direct measures of quality and safety, and employed a difference-in-difference research design to compare the rates of hospital adverse events in the chosen five states to rates in control states, which did not adopt damage caps during the sample period. Patient Safety Indicators developed by the AHRQ were used as measures of health outcomes. Although Frakes and Jena, also used PSIs as in-hospital quality measures, this investigation measured the effect of medical malpractice risk on a significant set of indicators that have not previously been studied, using a much larger sample size.

Zabinski and Black found a gradual increase in rates for most PSIs after reform, which they believe to be consistent with ‘a gradual relaxation of care, or failure to reinforce care standards over time.’¹⁰³ Furthermore, they report that the observed decline in safety is widespread, applying to instances of care that often result in malpractice claims (e.g., PSI-5; foreign body left in during surgery), as well as aspects of care that do not usually result in suits (e.g., PSI-7; central-line associated bloodstream infection). The authors indicate that this broad slackening of care suggests that malpractice liability creates ‘general deterrence’, which can be thought of as an incentive to be careful in general, in addition to any ‘specific deterrence’ impact it may have on particular clinical practices.¹⁰⁴

As mentioned above, Frakes and Jena found evidence to support the notion of ‘specific deterrence’ in the context of maternal safety following a shift to national rather than local standards of care (their PSI subsets focussed on mortality and maternal trauma).

¹⁰² Zabinski and Black “The Deterrent Effect of Tort Law: Evidence from Medical Malpractice Reform” (2015).

¹⁰³ *Id.* 23.

¹⁰⁴ *Ibid.*

However, in contrast to this study, traditional reforms such as caps, had no significant impact on patient outcomes.

Most previous studies had not found any evidence for deterrence. This study's finding which suggests that patient safety gradually declined after the reforms, is indicative of a deterrence effect. In fact, this study is the first, either for medical malpractice or indeed, in any area of personal injury liability, to find strong evidence consistent with classic tort law deterrence theory – reduced risk of malpractice litigation, led to higher rates of preventable adverse events in hospitals.

On the potential implications that the seemingly contradictory findings on the topic have, Zabinski and Black state:

'One combined message is that standards of care affect the behavior of healthcare providers. Higher standards can lead to higher healthcare quality; reduced liability pressure can lead to lower quality. This suggests that we should look for ways to strengthen care standards. Med mal liability is one avenue, but not the only one. Public reporting of quality information, financial incentives, and liability could all play complementary roles. At the same time, our results suggest that one should be cautious about relaxing tort liability without providing a substitute source of incentives.'¹⁰⁵

3.2.1.11. BILIMORIA ET AL.

Bilimoria *et al.* moved beyond general representative proxies of quality and safety, such as PSIs, and instead focussed on the relationship between the state-level malpractice environment and the post-operative outcomes of a particular procedure (i.e. colorectal surgery).¹⁰⁶ The authors analysed the administrative claims data of 116 977 Medicare fee-for-service beneficiaries from 3641 hospitals who underwent colorectal surgery. State-level malpractice risk was determined by using mean general surgery malpractice insurance premiums, paid claims per surgeon, state tort reforms, and a composite

¹⁰⁵ *Id.* 25.

¹⁰⁶ Bilimoria et al. (2016) 263 *Ann Surg* 1126.

measure.¹⁰⁷ They analysed the data in order to test the deterrence hypothesis, i.e. that patients receiving care in states with the highest malpractice risk would have better outcomes than patients who underwent surgery in states with less risk of liability. To examine the outcomes and analyse the associations they used measures such as: thirty-day postoperative mortality, associated complications, readmission, and 30-day post discharge episode-of-care.

The authors found no evidence to indicate that patient outcomes were superior in high-risk malpractice environments. Instead, their investigation adds to the existing body of literature that failed to detect a deterrence effect and suggests that the malpractice system may not necessarily contribute to better patient care. Interestingly, they found that patients treated in high-risk malpractice states actually had an increased risk of sustaining postoperative adverse events compared to patients treated in low-risk malpractice states. The authors note that this could be due to defensive medicine practices that result in patient harm.

The authors conclude by questioning the merits of the existing malpractice liability structure:

‘This study finds no evidence suggesting that liability is effective in deterring negligent medical practice or in promoting better outcomes. In addition, the costs of the overall medical malpractice system, estimated to be more than \$55 billion annually, could be decreased and reallocated to quality improvement initiatives which may actually result in better patient outcomes.’

3.2.1.12. BLACK ET AL.

Black *et al.* studied the relationship between hospital adverse events and malpractice claim rates in Florida and Texas.¹⁰⁸ They employed Patient Safety Indicators (PSIs), to measure the rates for 17 types of adverse events. The authors found a strong positive

¹⁰⁷ *Id.* 1131.

¹⁰⁸ Black et al. “The Association between Patient Safety Indicators and Medical Malpractice Risk: Evidence from Florida and Texas” *American Journal of Health Economics* (2017) 3 109.

association (which is likely to be causal) in Florida (at hospital-level) between adverse in-hospital patient safety events and the number of medical malpractice claims paid by these hospitals. A similar association holds for Texas, at a county-level.

The results suggest that hospitals that invest in patient safety can significantly reduce malpractice claims, in addition to the direct benefits for patient outcomes. Furthermore, slight increases in patient safety (as measured by PSIs) led to significant decreases in malpractice claims: ‘a one standard deviation reduction in PSI rates predicts a 16.2% fall in paid malpractice claims.’¹⁰⁹ The authors also report a substantial variation in PSI rates at the hospital level (ranging from 55 to 390 per 10,000 discharges). They note that this wide variation implies that much lower PSI rates are achievable at reasonable cost, since some hospitals are achieving them.¹¹⁰ Taken together, this strengthens the business-case for safety, since hospitals can invest in safety at a reasonable cost, which not only reduces the patient-injury burden, but also their malpractice liability risk.¹¹¹ However, the incentives for safety may have to be substantially bolstered. As other studies have shown that increased malpractice risk, does not necessarily lead to better patient outcomes. In other words: Safer care leads to less malpractice liability, but more malpractice liability does not lead to safer care.¹¹² This investigation is also, to a certain extent, related to previous studies that evaluated the relationship between filed medical malpractice claims and actual negligence. It adds to the substantial body of evidence, which suggests that most claims are related to adverse events and, therefore, not ‘frivolous’.

¹⁰⁹ *Id.* 128.

¹¹⁰ *Id.* 111.

¹¹¹ Greenberg et al. “Is better patient safety associated with less malpractice activity?: Evidence from California” *Rand health ...* (2011); Pettker et al. “A comprehensive obstetric patient safety program reduces liability claims and payments.” *Am J Obstet Gynecol* (2014) 211 319.

¹¹² Mello et al. “Who Pays for Medical Errors? An Analysis of Adverse Event Costs, the Medical Liability System, and Incentives for Patient Safety Improvement: Who Pays for Medical Errors” *Journal of Empirical Legal Studies* (2007) 4 835; Krupka et al. “The impact on hospitals of reducing surgical complications suggests many will need shared savings programs with payers.” *Health Aff (Millwood)* (2012) 31 2571.

3.2.1.13. BILIMORIA ET AL.

In one of the most recent studies on the malpractice system's ability to deter negligent practices and incentivise better quality and safer care, Bilimoria and colleagues expand on their previous work by examining the impact that differences in malpractice environment have on measures of hospital quality.¹¹³ They examined a wide range of indicators, including: processes of care, imaging utilisation, 30-day mortality and readmission, PSIs, and patient experience.

Similar, to their previous study, the authors found no consistent association between malpractice environment and their selected hospital process-of-care measures.¹¹⁴ However, some evidence was found that malpractice risk may incentivise the practice of defensive medicine. Bilimoria *et al.* note some of the possible factors that may interfere with the identification of a deterrent effect: 'These include the possibility that the low rate of malpractice claiming relative to the incidence of negligence provides little incentive for behavior change, and the possibility that physicians' behavioral alterations do not produce measurable improvements in patient outcomes.'¹¹⁵ This study casts yet more doubt on the notion that increased liability pressure improves quality of care and patient safety. The findings strengthen the position of those who argue that, the excessive expenditure involved with the malpractice system could perhaps 'be reinvested in alternative, evidence-based strategies that are more effective in improving patient outcomes.'¹¹⁶

3.2.1.14. MINAMI ET AL.

Minami and a number of researchers who were originally involved in the colorectal surgery study¹¹⁷, conducted another observational study of Medicare fee-for-service beneficiaries in order to determine whether the malpractice environment affects health

¹¹³ Bilimoria et al. (2016) 263 *Ann Surg* 1126.

¹¹⁴ Bilimoria et al. "Relationship Between State Malpractice Environment and Quality of Health Care in the United States." *Jt Comm J Qual Patient Saf* (2017) 43 241.

¹¹⁵ *Id.* 248.

¹¹⁶ *Id.* 249.

¹¹⁷ Bilimoria et al. (2016) 263 *Ann Surg* 1126.

care quality and safety.¹¹⁸ The authors, however, extended their investigation to include patients who had undergone several additional types of operations in 2010: colorectal, lung, oesophageal, or pancreatic resection, total knee arthroplasty, craniotomy, gastric bypass, abdominal aortic aneurysm repair, coronary artery bypass grafting, or cystectomy. The outcomes they measured included 30-day readmission, prolonged length of stay, mortality, and postoperative complications (e.g. sepsis, myocardial infarction, pneumonia).

This study, which consisted of a much wider range of surgical procedures, also failed to find an association between select measures of malpractice environment and surgical complications. High-risk malpractice environments were not consistently associated with a lower likely incidence of postoperative complications. In fact, some higher liability environments were actually associated with an increased likelihood of certain 30-day postoperative complications. As the authors note: ‘the finding does raise questions regarding the ability of the tort system to improve patient care.’¹¹⁹

Overall, their results suggest that ‘the severity of the state medical malpractice system may fail to effectively promote higher quality surgical care.’¹²⁰ The poor correlation between negligent injuries and filed claims, is once more offered as a possible explanation as to why malpractice environments do not result in improved care. The authors state that: ‘As a consequence, providers perceive that malpractice claiming is haphazard and does not help derive risk-reduction information from the outcomes of tort litigation.’¹²¹ Furthermore, because claims arise so infrequently ‘improvements in rates of negligent injury are not likely to lead to reductions in claims rates for the individual physician.’¹²²

¹¹⁸ Minami et al. “Association Between State Medical Malpractice Environment and Postoperative Outcomes in the United States.” *J Am Coll Surg* (2017) 224 310.

¹¹⁹ *Id.* 316.

¹²⁰ *Ibid.*

¹²¹ *Ibid.*

¹²² *Ibid.*

Minami *et al.* conclude as follows:

‘The lack of a consistent association between malpractice environment and improved surgical outcomes not only questions the efficacy of our current medical malpractice system as an effective vehicle for deterrence, but also suggests a possible unintentional potential to increase harm to patients.’¹²³

3.3. ADDITIONAL PROBLEMS WITH THE MALPRACTICE SYSTEM

The discussion has thus far focussed on the two principal objectives of a fault-based malpractice liability system. The available evidence suggests that such a system's effectiveness, measured in terms of its ability to adequately compensate injured patients and incentivise improved patient outcomes through the deterrence of unsafe care, can at best be described as dysfunctional.¹²⁴ Moreover, aside from the system's poor performance as a compensation and deterrence mechanism, it suffers from a number of additional drawbacks. Some of which will briefly be touched on here.

The system is not only ineffective in discharging its two principal objectives, it does so in a way which is highly inefficient and unsatisfactory for almost all involved. Claims often take years to be resolved, one study found the average time between injury and resolution was five years.¹²⁵ These protracted disputes, which may be subject to appeal, are bad for both plaintiffs and defendants. Injured patients, are forced to put up with financial uncertainty, their traumatic experience, and the anxious wait for clarity regarding their, likely, much-needed compensation. Healthcare workers, are deprived of time which could be spent caring for patients and endure the stresses, acrimony and unpleasantness associated with burdensome legal proceedings.¹²⁶ Furthermore, the financial costs involved in administering the system are exorbitant. A sizable portion of all expenditure is consumed by administrative expenses. Estimates suggest the total cost of litigating claims may be equal to more or less half of the compensation eventually

¹²³ *Ibid.*

¹²⁴ Mello et al. “Fostering rational regulation of patient safety.” *J Health Polit Policy Law* (2005) 30 389; Mello et al. (2014b) 312 *JAMA* 2146.

¹²⁵ Studdert et al. (2006) 354 *N Engl J Med* 2024.

¹²⁶ Seabury et al. “On average, physicians spend nearly 11 percent of their 40-year careers with an open, unresolved malpractice claim.” *Health Aff (Millwood)* (2013) 32 111.

paid out. Approximately 60 cents of every dollar expended on the system is absorbed by administrative costs (predominantly legal fees).¹²⁷ South African litigants likely face many similar frustrations.

3.3.1. THE COSTS OF THE MEDICAL LIABILITY SYSTEM

Liability reform is frequently touted as a solution to increasing health expenditure, proponents argue that reform would address two drivers of health care costs: rising indemnity insurance premiums, the cost of which is passed on to patients in the form of higher prices and defensive medicine, the costs incurred through the unnecessary utilisation of health resources for the primary purpose of reducing liability risk. Notwithstanding, all the interest in liability reform as a way to rein in spending, thorough estimates regarding the cost of the medical liability system have been hard to come by.

Mello *et al.* estimated the cost of the US medical liability system in order to better understand its relation to overall health spending.¹²⁸ The authors broke down the various components of liability system costs and used the best available data to generate national annual estimates for each component. The major categories of costs are: indemnity payments (claims paid, usually through liability insurers, to plaintiff patients); administrative expenses (attorneys' fees, legal costs and insurer overhead); defensive medicine costs; and other costs which are difficult to quantify (lost clinician work time, healthcare prices, and reputational and emotional toll).

According to their estimates, the cost of the medical liability system represents a small fraction of total health care spending. The total annual cost is estimated to be \$55.6 billion in 2008 dollars. Although the amount is not trivial, it is only equivalent to approximately 2.4% of total national health care spending in the US. The limitations in the supporting data, should be noted. Particularly surrounding defensive medicine costs, which accounts for a substantial proportion of the total estimate (\$45.6 billion). The authors explicitly note that national extrapolations from Kessler and McClellan's study on defensive medicine should be interpreted with considerable caution, since later

¹²⁷ Studdert et al. (2004) 350 *N Engl J Med* 283.

¹²⁸ Mello et al. "National costs of the medical liability system." *Health Aff (Millwood)* (2010a) 29 1569.

studies could not replicate their findings.

The authors doubt that reforms would have much of an effect on healthcare expenditure overall, and indicate that cost savings would be better achieved through other measures more directly associated with the healthcare delivery system:

‘Reforms that offer the prospect of reducing these costs have modest potential to exert downward pressure on overall health spending. Reforms to the health care delivery system, such as alterations to the fee-for-service reimbursement system and the incentives it provides for overuse, probably provide greater opportunities for savings.’¹²⁹

The authors suggest that health insurance could rather be extended to cover the uninsured, since better coverage would reduce their need to file malpractice claims in order to recover malpractice-injury induced medical expenses. Such a financing reform coupled with collateral-source offsets and a move to universal coverage would be a much preferable liability cost-reduction solution.¹³⁰

3.2.2. AFFORDABILITY AND AVAILABILITY OF INSURANCE

One of the major concerns raised by physicians, professional associations and mutual insurers, related to the medical liability system, is the issue of indemnity insurance. South Africa is currently experiencing a hard insurance market. High-risk specialities have seen substantial increases in premiums over the past few years.¹³¹ Although, it has not yet become an availability crisis, many physicians, particularly obstetricians, neurosurgeons and paediatricians doing neonatal work, contend that they are facing an affordability crisis.¹³²

¹²⁹ *Id.* 1575.

¹³⁰ *Ibid.*

¹³¹ Pepper and Slabbert (2011) 6 *South African Journal of Bioethics and Law* 60.

¹³² Howarth “The threat of litigation : private obstetric care - quo vadis?” *South African Journal of Bioethics and Law* (2011) 4 85; Howarth “The rising cost of litigation; a threat to private obstetric care?: review” *Obstetrics and Gynaecology Forum* (2013) 23 33; Howarth “Obstetric risk avoidance: will anyone be offering obstetrics in private practice by the end of the decade” *S Afr Med J* (2013) 103 513; Howarth et al. “The importance of comprehensive protection in today’s healthcare environment.” *S Afr Med J* (2013) 103 453; Howarth et al. “Public somnambulism:

Several countries have faced, and are facing, similar difficulties related to their respective insurance markets.¹³³ In most countries, these markets are financed through diverse sources and initiatives. Aside from traditional insurance underwriting companies, the specific characteristics of the malpractice insurance market, as well as certain historical and cultural factors, has meant that these markets are usually dominated by one or more non-profit associations of physicians or medical defence organisations, which provide legal assistance and coverage for their members. These structures are often reinsured through insurance captives or reinsurers.¹³⁴ In South Africa, the Medical Protection Society provides a range of medico-legal services and coverage for more than 30 000 practitioners in the private sector.¹³⁵ Practitioners in the public sector, as employees in state facilities, are indemnified by the state.

There are reports that it has become exceedingly difficult to afford indemnity cover, especially for obstetricians and other high-risk specialities.

Stakeholders differ vehemently on what the drivers of the problem are. Practitioners and insurers place the blame solely on the increase in severity and frequency of claims, as well as the lawyers that are opportunistically fanning the flames. Attorneys and consumer groups, point to inadequate standards of care, widespread unsafe practices and natural fluctuations in the insurance cycle. Since the stakeholders disagree on the causes of the problem, they strongly disagree on the solutions. The debates are often greatly influenced by personal agendas and vested interests. Proposals are almost exclusively aimed at limiting liability as a way to save costs (although, this has proven to be less effective than many would suppose).

3.3.3. PATIENTS PAY THE PRICE

As explained elsewhere, patients stand to lose the most. They are the ones who have to contend with the direct effects of malpractice and may ultimately, in a cruel twist, end

A general lack of awareness of the consequences of increasing medical negligence litigation" *S Afr Med J* (2014) 104 752.

¹³³ OECD (2006) 16.

¹³⁴ *Id.* 10; Sloan and Hsieh (2017) 285.

¹³⁵ "MPS – South Africa" Medical Protection Society <http://www.medicalprotection.org/southafrica/home>.

up having to face the indirect consequences as well.¹³⁶ Healthcare costs may increase and there may be a diminution in their access to care.¹³⁷ This is in addition to the difficulties injured patients already face when they attempt to obtain redress through the existing compensation and liability system. Furthermore, the existing system disincentivises the open and transparent disclosure of errors, which could hinder safety efforts and mar the doctor-patient relationship.

Although, the direct costs of the malpractice liability system, which includes insurance, may be relatively minor when compared to total health spending, it could have a major impact on access to care and may contribute to undesirable, unsafe practices and defensive behaviours.

3.3.4. DEFENSIVE MEDICINE

The direct costs of the medical liability system (insurance premiums, pay-outs, and litigation expenses) seem to account for a small fraction of total health spending. In fact, Mello *et al.* estimate that the direct costs make up just 0.4% thereof.¹³⁸ A reduction in direct costs therefore, has limited potential to make health care more affordable.¹³⁹ Focus has thus shifted to addressing the indirect costs induced by the system. As defensive medicine is supposedly responsible for most of the costs associated with the medical liability system, it is often raised to justify traditional liability-limiting reforms. Defensive medicine also has the potential to directly affect the care that patients receive, and as such it merits further discussion.

Defensive medicine has been defined as a deviation from sound medical practice, induced primarily by a threat of liability.¹⁴⁰ Practitioners seek to minimize the threat by engaging in either *assurance* or *avoidance* behaviour.

¹³⁶ Oosthuizen and Carstens (2015).

¹³⁷ Seggie (2013) 103 *S Afr Med J* 433.

¹³⁸ Mello et al. "National costs of the medical liability system." *Health Aff (Millwood)* (2010b) 29 1569.

¹³⁹ Paik et al. "Will tort reform bend the cost curve? Evidence from Texas" *Journal of Empirical ...* (2012) 9 173.

¹⁴⁰ Hershey "The defensive practice of medicine: myth or reality" *The Milbank Memorial Fund Quarterly* (1972) 50 69; Studdert et al. "Defensive medicine among high-risk specialist physicians in a volatile malpractice environment." *JAMA* (2005) 293 2609.

Assurance behaviour (or 'positive' defensive medicine), refers to practices that are primarily undertaken to deter patients from filing malpractice suits, or to pre-emptively persuade the legal system that the reasonable standard of care was met. It consists of additional services that hold marginal or no medical value. Such practices may include: over-ordering of diagnostic tests, unnecessarily referring patients to specialists, prescribing more medications than medically indicated and suggesting unwarranted invasive procedures. Apart from being wasteful and expensive, assurance behaviour could either reduce or improve quality, depending on the circumstances. Additional care may have some benefits; however, it could also expose patients to significant risk of harm.¹⁴¹

Avoidance behaviour (or 'negative' defensive medicine), refers to decisions practitioners take to isolate or distance themselves from sources of legal risk. It has an undesirable effect on patient care, as high-risk patients and interventions are avoided by physicians either restricting or ceasing their practice altogether. Such behaviour reduces access to care.

It has been particularly difficult to determine the exact extent of defensive medicine.¹⁴² Practitioners consistently contend that they alter their practices to mitigate against the risk of malpractice liability.¹⁴³ South African physicians report similar changes in practice.¹⁴⁴ A survey of private GPs conducted by the Medical Protection Society (an indemnity insurer) in 2012 found that nearly 60% of responding doctors changed the way they practiced out of fear for what they perceived as a higher risk malpractice environment. Some of the changes can be classified as assurance behaviour: 86% of practitioners reported that they now keep more detailed medical records; 65% acknowledged that they conduct more investigations; and 67% indicated that they now refer more patients for a second opinion as a result of increased litigation risks.

¹⁴¹ Tancredi and Barondess "The problem of defensive medicine" *Science* (1978) 200 879.

¹⁴² Studdert et al. "Defensive medicine and tort reform: a wide view." *J Gen Intern Med* (2010) 25 380.

¹⁴³ Studdert et al. (2005) 293 *JAMA* 2609; Bishop and Federman... "Physicians' views on defensive medicine: a national survey" *Archives of Internal ...* (2010) 170 1081. 93% of physicians surveyed reported practicing defensive medicine.

¹⁴⁴ Whitehouse *Practice Matters* (2013) 9.

Avoidance behaviour was also reported: 61% of the surveyed practitioners indicated that they had chosen to stop treating certain conditions or performing certain procedures; and 29% said they had a lower threshold for removing patients from the practice list.

Roytowski *et al.* conducted an online survey, to establish the impact of the malpractice liability environment on the behaviours and perceptions of South African neurosurgeons.¹⁴⁵ Neurosurgery is considered a 'super high-risk' field, in terms of malpractice claims and insurance coverage. Over half (53.8%) of the respondent neurosurgeons have been sued, and 31.8% reported that they had faced a claim in the past 3 years. 84% of respondents agreed that there was a medicolegal crisis in their specialty. The majority of the neurosurgeons (58.5%) indicated that they would have chosen a different speciality had the current medical liability situation existed when they decided to train in the specialty. Almost all the respondents reported changing their practice patterns as a response to the perceived liability risk: 89% reported that they ordered imaging studies (not medically warranted) solely to minimise risk, 76% reported having referred patients for defensive reasons; 64% ordered extra laboratory tests; and 39% had prescribed medication that was not clinically indicated. A quarter of the respondents had undertaken procedures almost entirely for defensive purposes. In addition to these assurance behaviours, 31% of the neurosurgeons had engaged in avoidance behaviour, having discontinued the provision of what they considered to be high-risk procedures, due to their supposed liability-threat.

A more recent online survey, compared the defensive practices of neurosurgeons from Canada, South Africa and the United States.¹⁴⁶ Neurosurgeons from the low-risk US states and South Africa reported similar rates of defensive practices and were much more likely to practice defensively compared to practitioners in Canada. A substantial proportion (84.8%) of South African neurosurgeons, reported that they engaged in defensive practices, and 57.6% indicated that they generally viewed their patients as

¹⁴⁵ Roytowski et al. "Impressions of defensive medical practice and medical litigation among South African neurosurgeons" *S Afr Med J* (2014) 104 736.

¹⁴⁶ Yan et al. "International Defensive Medicine in Neurosurgery: Comparison of Canada, South Africa, and the United States." *World Neurosurg* (2016) 95 53.

potential lawsuits. South African perceptions regarding the malpractice environment seem to be particularly severe, despite paying less for insurance, generally having faced less claims in the past 3 years and having less lifetime settlements, compared to neurosurgeons from the other countries. This is reflected once more, in that no Canadian respondent reported thinking about retirement due to liability risk, whereas 38.2% of neurosurgeons from low-risk US states and 38.8% from high-risk US states did. As for South African neurosurgeons – 50% reported that liability pressure made them consider early retirement. The implication of defensive medicine in the South African healthcare context is clear. As a result, thereof healthcare may become more expensive, health-resources would unnecessarily be expended, and access to care would be diminished.

Fears about increasing litigation and its effects on medical practice are not new, even among South African physicians. An article in the *South African Medical Journal* from 1976, makes for interesting reading and could almost certainly be republished (with few minor changes) today—four decades later.¹⁴⁷ In a recent national survey conducted in the US, 91.0% of respondents reported that they believed physicians order more tests and procedures than necessary to protect themselves from malpractice suits.¹⁴⁸ An overwhelming majority (90.7%) of physicians surveyed also agreed that ‘protections against unwarranted malpractice suits are needed to decrease the unnecessary use of diagnostic tests.’ Physicians, argue that liability-limiting malpractice reforms could substantially curb healthcare expenditure by reducing their litigation-compelled defensive proclivity.¹⁴⁹

However, survey results should be interpreted with caution.¹⁵⁰ Self-reports of defensive practices may be biased. The prevalence of defensive medicine may be strategically exaggerated for political expediency.¹⁵¹ Most practitioners are dissatisfied with the

¹⁴⁷ Wienand “[Malpractice and claims].” *S Afr Med J* (1976) 50 1768.

¹⁴⁸ Bishop and Federman... (2010) *Archives of Internal ...* 1081.

¹⁴⁹ Paik et al. (2012) *Journal of Empirical ...* 9 173; Paik et al. “Damage caps and defensive medicine, revisited.” *J Health Econ* (2017) 51 84.

¹⁵⁰ Baicker et al. “Reevaluating Reports of Defensive Medicine.” *J Health Polit Policy Law* (2015) 40 1157.

¹⁵¹ Avraham and Schanzenbach (2015) *SSRN Journal*.

existing malpractice system and would welcome liability-limiting reforms.¹⁵² Concerns about malpractice risk may be used to justify over-utilisation, as there may be a financial incentive to conduct more tests or perform more procedures – so-called ‘offensive medicine’.¹⁵³

It could also merely be that the perception of the legal threat is much greater than the actual risk of being sued and that physicians overestimate the risk.¹⁵⁴ As mentioned, relative to the number of negligent, potentially compensable injuries, claims are actually very uncommon. Most physicians are also fully insured against the direct financial impact of damage awards. Whilst, the monetary impact can be limited through indemnity arrangements, the possible reputational damage, emotional impact and lost time involved with litigation cannot.¹⁵⁵ This could certainly explain why practitioners would be risk averse, even if the perceived threat is remote. The evidence suggesting that physicians in high-risk specialities will likely face at least one claim during their career and that on average, physicians spend nearly 11% of their careers with an open, unresolved claim, will not allay fears (notwithstanding the fact that only a fraction will lead to payment).¹⁵⁶

It may also be that physicians genuinely believe that they face a deluge of claims, from an onslaught of greedy attorneys with frivolous suits. Such an outlook of the malpractice

¹⁵² Baicker et al. (2015) 40 *J Health Polit Policy Law* 1157.

¹⁵³ Avraham and Schanzenbach (2015) *SSRN Journal*.

¹⁵⁴ Lawthers et al. “Physicians’ perceptions of the risk of being sued” *Journal of Health ...* (1992) 17 463; Carrier et al. “Physicians’ fears of malpractice lawsuits are not assuaged by tort reforms.” *Health Aff (Millwood)* (2010) 29 1585.

¹⁵⁵ Charles and Franke “Sued and Nonsued Physicians’ Self-Reported Reactions” *Am J Psychiatry* (1985); Shapiro “A Survey of Sued and Nonsued Physicians and Suing Patients” *Arch Intern Med* (1989) 149 2190; Rowe “Doctors’ responses to medical errors.” *Crit Rev Oncol Hematol* (2004) 52 147; West et al. “Association of perceived medical errors with resident distress and empathy: a prospective longitudinal study.” *JAMA* (2006) 296 1071; Baicker et al. “Malpractice liability costs and the practice of medicine in the Medicare program” *Health Affairs* (2007) 26 841; Saberi et al. “A survey of sued physicians’ self-reported reactions to malpractice litigation in Iran.” *J Forensic Leg Med* (2009) 16 301; Dranove et al. “Delivering Bad News: Market Responses to Negligence” *The Journal of Law and Economics* (2012) 55 1; Shurtz “The impact of medical errors on physician behavior: evidence from malpractice litigation.” *J Health Econ* (2013) 32 331.

¹⁵⁶ Jena et al. “Malpractice risk according to physician specialty.” *N Engl J Med* (2011) 365 629; Seabury et al. (2013) 32 *Health Aff (Millwood)* 111.

environment could be driven by misinformation. Advocacy efforts by medical professional societies and other stakeholders (insurers or the government, that have a financial interest in liability reform) may contribute to a crisis-narrative.¹⁵⁷ It could well be that it is in just our human nature to overestimate the risk of rare or unfamiliar events.¹⁵⁸

Advocacy efforts (similar to those seen locally) have succeeded in certain US states and have led to the introduction of liability-limiting tort reforms. As such, it could provide some insight into what effect, if any, liability reform has on the practice and costs of defensive medicine. In other words, it could allow us to better understand the responsiveness of defensive medicine to tort reform. These reforms could also shed some light on other aspects, such as: physician-supply, health care spending, insurance premiums, claiming rates and pay-outs.¹⁵⁹

3.3.5. PROFESSIONAL AND EMOTIONAL IMPACT ON THE PRACTITIONER

The threat of medical malpractice litigation affects practitioners both professionally and personally.¹⁶⁰ Practitioners who have faced litigation are more likely to report emotional symptoms, many indicating that they suffer from depressed moods, inner tension, anger, and frustration.¹⁶¹ Some groups of symptoms reported correspond with depressive disorders and stress syndromes.¹⁶² The emotional well-being of practitioners is especially affected if they were more personally involved with the patient prior to the malpractice claim.¹⁶³ It is common for practitioners to feel personally

¹⁵⁷ Kachalia et al. (2005) 33 *J Law Med Ethics* 416.

¹⁵⁸ Slovic "The perception of risk" (2016).

¹⁵⁹ See discussion in the final chapter, Paragraph 7.2.

¹⁶⁰ Charles and Franke (1985) *Am J Psychiatry* ; Forster et al. "Reducing legal risk by practicing patient-centered medicine." *Arch Intern Med* (2002) 162 1217; Aasland and Førde "Impact of feeling responsible for adverse events on doctors' personal and professional lives: the importance of being open to criticism from colleagues." *Qual Saf Health Care* (2005) 14 13.

¹⁶¹ Charles and Franke (1985) *Am J Psychiatry* 438.

¹⁶² *Id.* 439.

¹⁶³ Shapiro (1989) 149 *Arch Intern Med* 2190.

attacked in the event of litigation.¹⁶⁴ Especially, if they feel that they have performed in the patient's best interest and in accordance with the medically indicated standard of care.¹⁶⁵ Many practitioners may consider early retirement and discourage others from entering medicine, which may impact on the availability of healthcare.¹⁶⁶

3.3.6. RELUCTANCE TO DISCLOSE ERRORS

The fear of litigation may also negatively impact on the reporting of errors. Practitioners will not be forthcoming with information if it could result in an expensive and arduous civil claim.¹⁶⁷ However, if errors and adverse events are not reported, nothing can be done to prevent their reoccurrence.¹⁶⁸

Medical errors are an unfortunate but inescapable reality, which is why expectations should be properly managed at the start of any treatment. Informed consent plays a vital role in this regard, as patients should be made aware of the risks involved. The actions taken once an adverse event has occurred are just as important.¹⁶⁹ The absence of adequate communication could lead to and reinforce a decision to litigate.¹⁷⁰ The doctor-patient relationship is one of trust and that relationship suffers when doctors view their patients as nothing more than potential lawsuits, or if patients view their practitioners as unsympathetic, indifferent commercialised health service providers. There is evidence to suggest that a breakdown in this compassion-centred relationship

¹⁶⁴ Bark et al. "Impact of litigation on senior clinicians: implications for risk management." *Qual Health Care* (1997) 6 7.

¹⁶⁵ Merenstein "A piece of my mind. Winners and losers." *JAMA* (2004) 291 15.

¹⁶⁶ Charles and Franke (1985) *Am J Psychiatry* 440.

¹⁶⁷ Gallagher et al. (2003) 289 *JAMA* 1001.

¹⁶⁸ Kohn et al. (2000) 86.

¹⁶⁹ Kachalia et al. (2010) 153 *Ann Intern Med* 213. The University of Michigan Health System implemented a program of full disclosure of medical errors with offers of compensation and saw a decrease in the number of lawsuits; lower liability costs; and shorter resolution times.

¹⁷⁰ Beckman "The Doctor-Patient Relationship and Malpractice: Lessons From Plaintiff Depositions" *Arch Intern Med* (1994) 154 1365.

and associated communication, can contribute to the filing of malpractice claims.¹⁷¹ When it comes to the patient's decision to litigate, what happened during the preceding and subsequent consultations in the doctor's office may be just as important as what happened during treatment.¹⁷²

Disclosing errors in a sympathetic and honest manner may not only be beneficial to the safety of the health system as a whole. It may even result in a less adversarial, more trusting doctor-patient relationship and consequently, less litigation.¹⁷³ The complex nature of the healthcare environment needs to be considered when approaching the problem; a number of organisational and systemic factors could contribute to an error, the focus often unfairly falls upon the individual, as he or she is merely the most identifiable cog in an intricate system.¹⁷⁴

4. CONCLUSION

The virtues and failings of the medical malpractice system have for decades been the subject of vigorous debate. Physicians, insurers, lawyers, patients and politicians have all vehemently contested the system's merits and faults – in line with their respective interests, of course. Most of the earlier disputes were centred around the financial aspects of the system. In fact, concerns about the cost of claims and their relation to injuries drove the studies that uncovered the true burden of iatrogenic injury. The California, New York and Utah/Colorado studies, which would later form an integral part of the IOM report, that ultimately launched the patient safety movement. Regardless of where one stands in the debate surrounding the malpractice system, it must be credited for the role it played in revealing the overlooked scourge of patient harm. For that

¹⁷¹ Levinson et al. "Physician-patient communication. The relationship with malpractice claims among primary care physicians and surgeons." *JAMA* (1997) 277 553.

¹⁷² *Id.* 557.

¹⁷³ Vincent et al. (1994) 343 *Lancet* 1609; Kraman and Hamm "Risk management: extreme honesty may be the best policy." *Ann Intern Med* (1999) 131 963; Vincent (2003) 348 *N Engl J Med* 1051.

¹⁷⁴ Kohn et al. (2000) 43.

reason, it forms an inextricable part of the patient safety story.

The existing malpractice liability system essentially has two core social objectives: It endeavours to identify and deter substandard care and it aims to compensate those patients who were injured through negligence. The deterrence function thereof is particularly relevant to patient safety. In theory, practitioners would avoid unsafe practices due to the threat of litigation and the consequent emotional and financial costs that would be incurred during a civil trial. Attorneys function as gatekeepers in the system, as they consider the merits of potential claims, along with other factors, when advising their clients to institute claims or not. If a claim succeeds, indemnity insurance ensures that practitioners are not bankrupted and that patients receive compensation. Theoretically, the existing system is adequate and efficient. However, in reality, there are a number of problems.

In addition to uncovering disquieting numbers of adverse events, the early malpractice studies raised some serious questions about the functioning and efficacy of the malpractice system—especially, regarding its two core objectives.

A severe disconnect exists between patients who suffer harm due to negligent care and those who actually file claims. Only a fraction of eligible claims ever reach the legal system and even fewer result in compensation. Some have suggested that this implies that many frivolous claims are filed. However, the evidence suggests otherwise. The malpractice system actually does an adequate job of distinguishing between legitimate and meritless claims. Unfortunately, it does so in a highly inefficient and costly manner. Claims generally take years to be resolved and the overhead costs of the system are exorbitant, with more than half of the expenditure going towards the administration thereof.

The inefficiency of the malpractice system as a compensatory mechanism is just one of the major indictments against it. The other, perhaps more important indictment, from a patient safety standpoint, is its influence on the standard of care provided. More specifically, does the malpractice system identify and deter substandard care, and does this deterrence function result in improved quality and outcomes? This is fundamentally an empirical question and various studies have attempted to analyse the supposed

deterrence effect of the malpractice system, with mixed findings. The evidence suggests that, if higher malpractice pressure does produce a deterrence effect, it can at best be described as modest. The intricacies and incentives surrounding the provision of optimal care and the malpractice system cannot be underestimated or disregarded. The limited effect of malpractice liability could perhaps be attributed to the structural nature of the existing system, whereby standards are set in accordance with professional custom and by those same professionals whom the system is meant to oversee. The system is also plagued by important informational deficiencies. Furthermore, low rates of claiming relative to the incidence of negligent injuries probably negate any potential incentive for behavioural change.

This is not to say that the law has no role to play in shaping clinical practices and healthcare quality. One study suggests that a more substantive reform of the system, in which the expected standard is set at a higher, optimal evidenced-based level, may induce better quality of care and improved safety. This would entail an understanding and development of a particular liability structure that would be more conducive to positive outcomes. Medical malpractice liability is one way to strengthen care standards, but not the only way (and perhaps not even the best way). Public reporting of quality information, financial incentives, and malpractice liability could all play complementary roles in this respect. Investment in quality and safety improvement initiatives could also be part of the overall strategy and may pay greater dividends. There is already evidence to suggest that hospitals that invest in patient safety can significantly reduce malpractice claims, in addition to the direct benefits in patient outcomes. These improvements could be achieved at reasonable cost, which strengthens the business case for safety. It certainly raises the question, whether, the exorbitant costs taken up by the administration of the inefficient malpractice system, could not be 'reinvested in alternative, evidence-based strategies that are more effective in improving patient outcomes'.

The case for alternative strategies and reform become even more pertinent, considering the fact that, the malpractice system's poor performance as a compensation and deterrence mechanism, is compounded by a number of additional problems. The costs involved with the system, although a relatively small proportion of total health spending,

are certainly not trivial. However, traditional reforms that exclusively target the costs of the system would likely have a negligible impact on total healthcare expenditure. Direct changes to the healthcare delivery system would probably achieve greater costs savings, with added health coverage benefits. This is not to say that the money currently expended through the malpractice system, cannot be directed to a more efficient compensation scheme or towards a structure that aids in the achievement of enhanced quality and safer care. Unfortunately, the reforms that inevitably receive the most political attention and which have been enacted, restrict liability, making it more difficult for patients to institute claims or obtain compensation. These traditional reforms seek to address the financial consequences of the malpractice system, to the exclusion of other problems (including those that relate to the two core functions of the system). The availability and affordability of indemnity insurance, as well as the prevalence of defensive medicine, are often raised as justification. Proponents of tort-reform contend that access to healthcare and the cost of care is detrimentally affected by these factors. If this is driven by altruistic concern for their patients or self-interest, is up for debate. Nevertheless, the system is dysfunctional and the processes involved therewith are miserable and slow for both doctors and patients. Medical malpractice litigation is unpleasant for all involved. The threat thereof, can also discourage the disclosure of errors and harm the compassion-centred nature of the doctor-patient relationship.

Notwithstanding, patients have the most reason to be unsatisfied with the malpractice system. They have to contend with the direct physical and emotional effects of malpractice and may ultimately, in a cruel twist, end up having to face the direct and indirect consequences of a flawed malpractice system as well. Patients must surmount significant obstacles if they are to obtain much-needed compensation and if they manage to do so too successfully, they are confronted with passed-on higher healthcare costs and reduced access to care.

Yet, aside from all the major flaws of the system and the dissatisfaction, from all involved, with its functioning, its greatest's fault, rather ironically, might be that it is fault-based. The preceding chapters have hopefully clarified how the malpractice system's traditional individualistic, retributive justice approach to error, stands in stark contrast to what we now know about human error, prospective accountability and effective safety

management. The medical malpractice system may hamper the establishment of a just culture, making it a potential barrier to safer care.

A number of reforms have been proposed (and adopted) to address some of the flaws of the malpractice system. These can be divided into conventional and more fundamental reforms. Conventional reforms are almost always directly aimed at the financial implications of malpractice litigation and would merely alter the existing malpractice system. Fundamental reforms are more wide-ranging and include alternative approaches that would make healthcare safer, while also compensating injured patients. These reforms and their effects, particularly as they relate to patient safety, will be examined elsewhere.

The focus of the discussion will now turn to the South African context. The next few chapters will focus on the healthcare system and consider the steps that have been taken from a policy and legal standpoint, to try and improve the quality and safety of care provided.

I. HEALTHCARE AND MEDICAL MALPRACTICE SYSTEMS - HEALING THE DIVIDE

The Medical Malpractice System should not be considered in isolation. It fundamentally affects and is affected by the Healthcare system. The systems cannot simply be reduced to a dichotomy, they are substantially interrelated. Their interrelated nature gives rise to inevitable tension, often coming to a head, in that both systems influence the functioning of the other, dictated by finite resources. Despite the differences and divergent purposes, the Healthcare and Medical Malpractice system have one vitally important thing in common – the patient. The patient and their interests are central to both these systems. And there is perhaps, nothing patients value more highly than their safety. This foremost concern for safety now permeates most modern healthcare systems. Indeed, non-maleficence (derived from the Latin phrase, *primum non nocere*) is a principal precept of bioethics and has been a fundamental principle since the advent of Western medicine. The Malpractice system also revolves around the patient. It seeks to ensure that injured patients are recompensed and aims to deter future substandard care. These are essentially the system's two main objectives – compensation and deterrence. Some may reasonably conflate the latter objective, as being consistent with patient safety efforts, assuming that effective deterrence would incentivise safer care and prevent iatrogenic harm.

If one accepts that the patient, and particularly their safety, underlies or should underlie both these systems, one recognises that the Healthcare system and the Medical Malpractice system have another thing in common – weaknesses. Some of these weaknesses have been discussed in the preceding chapters. Paradoxically, both systems, which are meant to serve the best interest of patients, have failed to do so. The healthcare system heals, but also all too frequently harms. The malpractice system aims to compensate and deter substandard care, but it rarely does and instead it creates a punitive environment at variance with a just culture (and a broader safety culture, which underlies the systems-approach and supports effective safety improvement).

II. THE SOUTH AFRICAN HEALTHCARE SYSTEM

The focus now turns to the South African context. The following chapters will consider the progression of the quality and patient safety framework in the healthcare system, from a legal and policy perspective.¹⁷⁵ Some of the most notable developments will be discussed. The first chapter provides an overview of the changes that took place between 1994 and 2011. In the early years of democracy, expansion in the access to care was prioritised, attention gradually transitioned to the elusive provision of quality care. Fragmented interventions and the absence of leadership, proper management, regulatory oversight and enforcement severely hampered efforts. The introduction of national quality standards in 2008 was, however, encouraging and indicative of a renewed commitment to improved care. The second chapter discusses the post-2011 period, which commenced with the introduction of an ambitious plan for health reform. The discussion will focus on the entity tasked with transforming the quality landscape with an eye towards the establishment of National Health Insurance – the Office of Health Standards Compliance. The third chapter on the South African health system, will look at the Ideal Clinic initiative and the strategies recently put in place by the government that specifically address patient safety.

¹⁷⁵ The discussion is focused on national legislation and policies. It should however, be noted that health services are a concurrent functional area in terms of Schedule 4 Part A of the Constitution. Various provinces have enacted their own health acts and implemented policies that impact on matters related to quality and safety. For instance: The Kwa-Zulu Natal Health Act makes provision for an ombud, quality assurance, the monitoring of norms and standards, inspection and accreditation of healthcare establishments. The Western Cape has an act that establishes an independent health complaints committee. (Western Cape Independent Health Complaints Committee Act no. 2 of 2014) The Gauteng District Health Services Act empowers the MEC to prescribe regulations on norms and standards for primary health care services. (Gauteng District Health Services Act no. 8 of 2000 not commenced) The Free State Health Act makes provision for an ombudsperson and an inspectorate for health establishments. (Provincial Health Act No. 3 of 2009). One of the objectives of the Eastern Cape Provincial Health Act is to determine and provide for the implementation of provincial health policy, norms and standards. This includes the development and implementation of management, accreditation, evaluation and monitoring standards and regulatory procedures for all public health care establishments within the Province. (Eastern Cape Provincial Health Act no. 10 of 1999).

CHAPTER 11. THE SOUTH AFRICAN HEALTHCARE SYSTEM – QUALITY AND SAFETY ON THE POLICY AGENDA

1. INTRODUCTION

Studies and reports have revealed the extent of the problem in healthcare systems around the world. Globally, best estimates suggest that around 1 in 10 hospitalised patients experience harm. More than half of these injuries are preventable.¹ The limited evidence available seems to indicate that the burden of unsafe care is much worse in low- and middle-income countries.² This is likely due to a combination of compounding factors such as understaffing, poor infrastructure, overcrowding, drug and medical supply shortages, a lack of basic equipment, and inadequate hygiene and sanitation.³ Inept leadership, careless management and a weak quality and safety culture further exacerbate the problem.⁴ This bleak situation is reflected in the WHO's estimate which suggests that approximately two-thirds of all adverse events occur in these nations.⁵

South Africa, as a middle-income country, faces many of these same challenges, especially in the public sector where the majority of patients receive their care. Unfortunately, there is no publically available information on the local incidence of adverse events. As is the case with most developing countries, the lack of accurate data in of itself presents an immense challenge.

A retrospective review of randomly selected medical records of patients in hospital in a convenience sample of 26 hospitals from eight developing and transitional countries,

¹ Organization *Healthier, fairer, safer: the global health journey, 2007–2017* (2017).

² Organization *Global priorities for patient safety research* (2009a).

³ Allegranzi et al. (2011) 377 *Lancet* 228.

⁴ Organization "Patient safety in developing and transitional countries: new insights from Africa and the Eastern Mediterranean" *Geneva: World Health Organization* (2011) 57 203.

⁵ Jha et al. (2013) 22 *BMJ Qual Saf* 809.

marked the first attempt to fill this knowledge gap and provides some insight into the extent of the problem.⁶ Of the 15 548 records reviewed, 8.2% showed at least one adverse event (ranging between 2.5% to 18.4% per country). This reported rate probably represents an underestimate of the true rate. A very high proportion of these events (83%) were judged to be highly preventable. In addition, the percentage of adverse events associated with deaths (30%) was also much higher than the 4-15% reported in developed countries.

This would mean that nearly 2% of patients, across the eight countries studied, suffered an adverse event that was associated with their death. About 34% adverse events were from therapeutic errors in relatively non-complex clinical situations (compared to 7% in Western countries). Inadequate training and supervision of clinical staff or the failure to follow policies or protocols contributed to most events. South African hospitals participated in the study, but due to sampling limitations, country-specific findings were not disclosed. The study's conclusion is, however, clear: patient safety is a major public health concern in low- and middle-income countries, it requires significant attention from policymakers, further research and remedial action.

Developed countries have started to address the burden of unsafe patient care, and progress is being made (albeit slowly). Some of the more significant developments in this patient safety journey have already been discussed elsewhere. The rest of the chapter will focus on the South African context.

2. QUALITY AND SAFETY IN SOUTH AFRICA

THE CONSTITUTION

As the supreme law of the Republic, the Constitution pervades and informs all areas and aspects of law and policy.⁷ Carstens and Pearmain offer a superlative elucidation

⁶ Wilson et al. (2012) 344 *BMJ* e832.

⁷ The Constitution of the Republic of South Africa, 1996.

of the Constitution's influence on the provision of health care services.⁸ The authors demonstrate and note that the impact of the Constitution is 'far-reaching and profound'.⁹ Indeed, the Constitutional imperatives enshrined in the Bill of Rights form the foundation of the entire health care system. Section 27 guarantees everyone the right to have access to health care services.¹⁰ It also requires the state to 'take reasonable legislative and other measures, within its available resources, to achieve the progressive realisation' of this right.¹¹ Many of the developments discussed below and in the following two chapters, emanate from this constitutional obligation. Legislation and policies have also endeavoured to reify the related rights contained in Chapter 2, which are inextricably interlinked with the delivery of health care.

Viewed together these rights, as a collective, may become greater than the sum of their parts. It could for instance be argued that the right to human dignity¹², life¹³, bodily and psychological integrity¹⁴, an environment that is not harmful to health or wellbeing¹⁵ and those rights encapsulated in section 27, combined – constitute a right to health (satisfying the World Health Organisation's definition thereof).

All of these rights are certainly relevant to patient safety. Particularly, the right to an environment that is not harmful to health or wellbeing.¹⁶ This right would most likely extend to infection prevention and control measures, sharps and waste management, and the safe administration of medicine. However, an expansive interpretation of the right (taking the importance of the other impacted rights, and the consequences of their infringement, into account)¹⁷ could bolster the argument for the implementation of

⁸ See Chapter 2 of Carstens and Pearmain *Foundational principles of South African medical law* (2007).

⁹ *Id.* 227.

¹⁰ S 27(1)(a).

¹¹ S 27(2).

¹² S 10.

¹³ S 11.

¹⁴ S 12(2).

¹⁵ S 24(a).

¹⁶ S 24(a).

¹⁷ S 10,11, 12(2), 14, 22, 32 and 34.

incident reporting systems, computerised physician order entry, human factors engineering approaches, independent safety investigations, adequate staffing, efforts to prevent clinician fatigue, etc.

When a patient suffers an injury due to unsafe care, several of the mentioned rights might be adversely impacted (life, dignity, bodily and psychological integrity). Injured patients may find themselves in a severely distressing and vulnerable situation. A situation which may be exacerbated if their rights continue to be infringed (impairment brought on by the injury) or if additional rights are undermined. For instance, the healthcare provider, fearing liability, might be hesitant to disclose and explain the true nature of the adverse event. Not only will the patient be emotionally affected by the absence of an explanation, but by infringing the right to access information, the patient may be deprived of the opportunity to exercise or protect his or her other rights, i.e. informed decisions regarding future remedial treatment or possible legal options.¹⁸ Section 34 becomes all the more important to patients who have suffered harm, as the courts may very well be their only recourse to obtain some semblance of closure, redress and financial support.¹⁹

Furthermore, section 39(1)(b) of the Constitution expressly requires that international law must be considered in interpreting the Bill of Rights.²⁰ Section 39(1)(c) also states that foreign law may be considered in interpreting the Bill of Rights.²¹

INTRODUCTION

The South African government has only recently begun to put patient safety firmly on the healthcare agenda. However, the notion of safer patient care is not entirely unfamiliar to local policymakers. The African National Congress' Health Plan of 1994 and the Department of Health's 1997 White Paper, aside from noting the importance of

¹⁸ S 32(1).

¹⁹ S 34.

²⁰ S 39(1)(b).

²¹ S 39(1)(c).

quality care, both included passing references to infection control, drug and maternal safety.²²

Although, the rest of the discussion is mainly focussed on governmental and public-sector interventions, the Council for Health Services Accreditation of Southern Africa (COHSASA) merits mention.²³ COHSASA was registered as a non-profit organisation in October 1995 and started operations in 1996.²⁴ It has developed accreditation programmes for hospitals, subacute care facilities, psychiatric facilities and primary health care clinics.²⁵ COHSASA has long been the only national accrediting body for health care facilities in South Africa and has assisted hospitals, in both the public and private health sectors, to work towards compliance with professional organisational standards.²⁶ COHSASA has also collaborated with the state in the development of national quality improvement strategies and policies.²⁷

²² Congress *A national health plan for South Africa* (1994); South and Department *White paper for the transformation of the health system in South Africa* (1997). This chapter will focus on public sector and governmental interventions.

²³ "COHSASA - Improving health care through standards & accreditation" Council for Health Services Accreditation of Southern Africa <http://www.cohsasa.co.za>; Whittaker et al. "Quality standards for healthcare establishments in South Africa" *South African Health ...* (2011) 1 59.

²⁴ Whittaker et al. "Status of a health care quality review programme in South Africa." *Int J Qual Health Care* (2000) 12 247; Organization "Quality and accreditation in health care services: a global review" (2003) 191.

²⁵ Salmon et al. "The impact of accreditation on the quality of hospital care: KwaZulu-Natal province Republic of South Africa." (2003); Linegar et al. "Academic hospital accreditation strengthens postgraduate training programmes: Case study from Universitas Academic Hospital" *SAMJ: South African Medical Journal* (2012) 102 147.

²⁶ Purvis et al. "International Health Care Accreditation Models and Country Experiences: Introductory Report on Options for The Republic of South Africa" (2010); Shaw et al. "Profiling health-care accreditation organizations: an international survey." *Int J Qual Health Care* (2013) 25 222. The recently established, Office of Health Standards Compliance, will monitor and enforce compliance with national norms and standards. Facilities will be inspected and will have to comply with certain prescribed standards to obtain certification. The OHSC has been legislatively enacted, however, all of its governing provisions have not yet commenced. The OHSC is discussed in a later chapter.

²⁷ Whittaker et al. "Introducing quality assurance to health service delivery--some approaches from South Africa, Ghana and Kenya." *Int J Qual Health Care* (1998) 10 263.

COHSASA was to play a prominent role in the development of the government's Office of Health Standards Compliance (OHSC), however, the OHSC turned to the United Kingdom's Care Quality Commission and its audit tools and processes instead.²⁸ Various concerns have been raised regarding this development, with some experts suggesting that the Department of Health was 'reinventing the wheel' or that external pressures and time-constraints may have compromised the initiative.²⁹ Despite the rocky start, Prof Whittaker, the founder and previous director of COHSASA, was appointed to serve on the OHSC's board for a period of three years.³⁰

The focus now turns to mainly governmental and public-sector patient safety-related interventions and initiatives.

2.1. CONFIDENTIAL ENQUIRY SYSTEM

Efforts to record and analyse maternal mortality started around the same time as the White Paper's release, with the Confidential Enquiry system, modelled on the UK process, coming into operation in October 1997. The first comprehensive report into maternal deaths was published two years later in 1999.³¹ The Confidential Enquiry into Maternal Deaths has now been operational for nearly 20 years.³² Similar audit reports on perinatal care, infant and child health have also been produced. Saving Babies, a report from users of the Perinatal Problem Identification Programme, has been published since 2000.³³ And Saving Children, which surveys infant and child healthcare,

²⁸ Bateman "Coming soon: nowhere to hide for hospital managers" *SAMJ: South African Medical Journal* (2011b) 101 294.

²⁹ Bateman (2010) 100 *SAMJ: South African Medical Journal* 620.

³⁰ Bateman "Honing healthcare leaders' competence and attitudes equals facility-level delivery." *S Afr Med J* (2015) 105 85. "Whittaker appointed to OHSC Board" Council for Health Service Accreditation of Southern Africa (2014-02-26) <http://www.cohsasa.co.za/articles/whittaker-appointed-ohsc-board>.

³¹ South et al. *First interim report on confidential enquiries into maternal deaths in South Africa* (1998).

³² Moodley et al. "The Confidential Enquiry into Maternal Deaths in South Africa: a case study." *BJOG* (2014) 121 Suppl 4 53. The sixth report was published in 2016.

³³ South et al. *Saving babies : a perinatal care survey of South Africa, 2000* (2000); Rhoda et al. "Experiences with perinatal death reviews in South Africa—the Perinatal Problem Identification Programme: scaling up from programme to province to country" *BJOG: An International Journal of Obstetrics & Gynaecology* (2014) 121 160. <https://www.ppip.co.za/saving-babies/>.

has been published since 2004.³⁴ These audit reports have reviewed countless avoidable deaths and identified many possible improvements.

In 2008 the authors of these three mortality reports came together to present strategies and actions that could help save the lives of South Africa's mothers, babies and children.³⁵ They singled out gaps in quality and equity, the need for consistent leadership and accountability, and implored that audits are only as powerful as the interventions that follow.³⁶

In addition to the frequent audits, most of the health data collected and used to track and evaluate health outcomes, which is used to inform health budgets, policy and programmes, comes from the District Health Management Information System. This system, first introduced in 1996, has since 2001 been operational throughout the entire country.³⁷ Unfortunately, the data and health indicator information obtained (weaknesses in the data, notwithstanding), have rarely been converted into interventions that actually improve quality and safety.³⁸

2.2. THE 10-POINT PLAN

In response to the evidence of poor quality care³⁹ the Department of Health outlined their plan to shift focus from not merely ensuring that underserved communities had access to care, but to ensuring that quality health services were being delivered.⁴⁰ A ten-point plan to strengthen implementation of efficient, effective and high-quality health services was proposed. In order to improve the quality of care provided, ten key

³⁴ Krug et al. *Saving children 2004 : a survey of child healthcare in South Africa* (2004); Chopra et al. (2009) 374 *The Lancet* 835.

³⁵ Bradshaw et al. *Every death counts : saving the lives of mothers, babies and children in South Africa* (2008)

³⁶ South (2008) 371 *The Lancet* 1294.

³⁷ Garrib et al. "An evaluation of the District Health Information System in rural South Africa." *S Afr Med J* (2008) 98 549.

³⁸ Trust "District Health Barometer" (2016) 1. A new district health management information system policy has recently been adopted.

³⁹ Segall et al. *Review of public health service delivery : "the bottle is half full" : policy oriented overview of the main findings* (1999); South and Department *South Africa Demographic and Health Survey 1998 : full report* (1999).

⁴⁰ Department *Health sector strategic framework, 1999-2004* (1999).

objectives were identified, which included: strengthening the Batho Pele programme; developing a National Policy on Quality; launching the Patients Charter; establishing a complaints mechanism in all health facilities; implementing clinical management guidelines; introducing peer review and clinical audits at all health facilities; listening to patients' views and expectations; and training health personnel in quality improvement strategies.

As an aside, if one reads through the entire ten-point plan, one recognises many of the same ideas which underlie the National Health Insurance and one can only wonder why so little progress has been made and what will be done differently this time around to achieve the long-standing objectives.

2.3. BATHO PELE PRINCIPLES

The White Paper on Transforming Public Service Delivery, or the Batho Pele White Paper as it is more commonly known, is one of the country's most important policy documents.⁴¹ It provides a policy framework and practical implementation strategy for the transformation of Public Service Delivery (including the delivery of public healthcare services). Batho Pele (meaning 'People First') is based on eight national principles referred to as the Batho Pele Principles. For instance, one of the principles is Redress: 'If the promised standard of service is not delivered, citizens should be offered an apology, a full explanation and a speedy and effective remedy; and when complaints are made, citizens should receive a sympathetic, positive response.'

A lack of planning and poor leadership has meant that this principle and the other seven (consultation, service standards, access, courtesy, information, openness and transparency, value for money) have often not been upheld in the public sector, to the detriment of quality and safety.

2.4. PATIENTS' RIGHTS CHARTER

⁴¹ South and Department *Batho pele, "people first": white paper on transforming public service delivery* (1997); Khoza and Du Toit "The Batho Pele Principles in the health services" *Professional Nursing Today* (2011) 15 8. (GN1459 in GG 18340 of 1 October 1997).

To effectuate the Batho Pele policy, the Patients' Rights Charter was launched in November 1999 as a common standard for achieving the realisation of the right to access to health care services as enshrined in the Constitution.⁴² The Charter starts by declaring that: 'Everyone has the right to a healthy and safe environment that will ensure their physical and mental health or well-being'.

Patients are also afforded the right to complain about health services and to have those complaints investigated: 'Everyone has the right to complain about health care services and to have such complaints investigated and to receive a full response on such investigation.'⁴³

The Patients' Right Charter now also forms part of the Health Professions Council's ethical guidelines, requiring all practitioners to adhere thereto.⁴⁴

2.5. THE PRIMARY HEALTH CARE PACKAGE FOR SOUTH AFRICA – A SET OF NORMS AND STANDARDS

The draft Health Bill required the production of norms and standards that could be used by provinces in order to provide health services at acceptable levels. The newly established Directorate for Quality Assurance was tasked with the drafting thereof.⁴⁵ Their efforts resulted in a document, released in 2001, entitled, 'The Primary Health Care Package for South Africa – a set of norms and standards'.⁴⁶

The document described the norms and standards that were to be made available in the essential package of primary care services. Its introduction meant that, patients could for the first time see the quality of primary care services they could expect to

⁴² Health "National Patients' Rights Charter" (1999) 1.

⁴³ Other rights to which patients are entitled to include: Access to healthcare, participation in decision-making, confidentiality and privacy, informed consent, continuity of care etc.

⁴⁴ Africa "Guidelines for Good Practice in the Health Care Professions – National Patients' Rights Charter" (2008).

⁴⁵ South et al. *National Health Bill*. (2003).

⁴⁶ South et al. *The primary health care package for South Africa - : a set of norms and standards* (2001).

receive. It also provided guidance to provincial and district health authorities on how to provide these services. Both the Patients' Rights Charter and the Batho Pele Principles formed part of this document.

2.6. POLICY ON QUALITY IN HEALTH CARE FOR SOUTH AFRICA

The 'Policy on Quality in Health Care for South Africa', was adopted in 2001 (an abbreviated version was published in April 2007).⁴⁷ It provided a broad strategic direction for health facilities and officials to follow in order to ensure that quality health care was being provided and that continuous improvement would take place. The policy aimed to improve quality in both the public and private sector by identifying a number of 'national aims for improvement', which included: addressing access to health care; increasing patients' participation and the dignity afforded to them; reducing underlying causes of illness, injury, and disability through preventive and health promotion activities; expanding research on evidence of effectiveness; ensuring the appropriate use of health care services; and reducing health care errors (adverse events).

This policy document is significant, as it marked the first time that the government acknowledged the existence of substantial levels of medical error. The need to reduce errors and improve patient safety, was vaguely described, as follows:

'Significant levels of error occur with health care, which often result in injury to patients. Health care and health status can be improved by way of improving patient safety and reducing the level of error in health care delivery. Systems can be designed and health professionals trained in methods to improve patient safety by reducing hazards in health care, and to make the consequences of errors less serious when they do occur.'⁴⁸

⁴⁷ Health A policy on quality in health care for South Africa (2007).

⁴⁸ *Id.* 6.

Quality assurance interventions would be directed at four main targets: health professionals; patients; the community; and the health service delivery system. With this last target, the government essentially prescribed the system approach:

‘Perhaps the most important innovation in quality improvement has been the increased focus on problems with systems.’⁴⁹

‘By identifying weaknesses in systems that cause errors in processes or outcomes, the systems can be redesigned to avoid these errors and improve the quality of health care delivery. The results of changes to systems can be monitored and evaluated and further adjustments made where necessary. This is an ongoing process of assessment, redesign and monitoring and evaluation that ensures that systems are constantly evaluated and, where necessary, modernised to improve quality.’

This policy is based on a two-pronged approach to quality improvement: creating an environment in which quality health care will flourish; and building capacity to improve quality.

One of the ways in which the policy drafters wanted to create an environment in which quality health care would flourish, was by ‘reducing errors and increasing safety in health care’. To this end, it was proposed that an ‘adverse event reporting system will help to reduce errors and increase safety’. A national incident reporting system was to be developed:

‘Identifying and reducing errors and focusing on systems changes, can substantially reduce injuries and adverse events. Therefore, an adverse events (incidents) reporting system will be developed for the National Health System to identify errors and prevent their recurrence’⁵⁰

⁴⁹ *Id.* 8.

⁵⁰ *Id.* 12.

According to the policy, building capacity to improve quality will be done by: fostering evidence-based practice and innovation; adapting organisations for change; engaging the health care workforce; providing appropriate training; and investing in information systems that measure quality improvement.

The policy document, in broad terms, expanded on the listed five points: Fostering evidence-based practice required the building-up of expertise in research on effectiveness issues, technology assessments and dissemination processes; Being able to adapt organisations for change required skilled managers with a commitment to creating learning organisations seeking excellence, focused on users and working with clinicians; Health professionals needed to be closely involved in working out ways to improve the way they work; Providing quality care to patients required training skilled health workers and establishing a culture that values lifelong learning and recognises its important role in improving quality; National standards for private and public information systems are required to measure quality improvements across the National Health System.

A section of the policy document was directed expressly at the public sector and called for action at all levels. The policy implored staff to adopt a 'Quality Assurance culture and approach to the delivery of health care'.⁵¹ The District Health System had a particular important role to play in ensuring that national standards and guidelines were reflected in the delivery of services.

The monitoring of standards was also prioritised in the policy document.⁵² There was to be ongoing Quality Monitoring process (to assess compliance with standards) throughout the National Health System, to determine whether patients were receiving the quality of care they had a right to expect. Accordingly, patient input was to be an important component of the quality monitoring process. The policy required that a

⁵¹ *Id.* 17.

⁵² *Id.* 19.

national complaints procedure be established and upheld by all health establishments. It further stated that patients were entitled ‘to obtain a full explanation and a speedy and effective remedy for a professional or other fault from a public, private or non-governmental health establishment, its governing body, its directors, or employees or a health care provider.’⁵³ The policy also called for the use of national patient surveys to gather the views and experiences of patients, as a measure of performance of the health system.⁵⁴

Quality would also be monitored through governance structures.⁵⁵ The Office of Standards Compliance was a key component of the policy, and would to be established in order to measure a standard set of health indicators and provide an annual assessment report on quality to the Minister or National Health Council. An Inspectorate would measure standards compliance in all health establishments. Compliance was to be rewarded through a system of accreditation, licensure and certification. Hospital Boards and Clinic Committees, made up of members from the community and management, would also deal with matters affecting quality of care, by ensuring that patients’ rights are upheld, monitoring adherence to the Batho Pele principles and seeing to complaints.

The policy also expected health care providers to monitor quality.⁵⁶ Staff satisfaction surveys were to be conducted to identify aspects that could negatively impact on quality. Clinical audits would also play an important role, as it would bring together professionals from all divisions of health care to improve quality. All health professionals at all levels of care were expected to participate in clinical audit. The policy assured that a managerial model would be developed to prevent the clinical audit and peer review process from developing into a search for individual error only, so as to guard against denigration and condemnation. Peer review would also be open for public scrutiny, accountable for nationally set professional standards and the actions taken to maintain

⁵³ *Ibid.*

⁵⁴ *Id.* 20.

⁵⁵ *Ibid.*

⁵⁶ *Id.* 21.

these standards. Professional bodies would continue to monitor standards of professional conduct.⁵⁷ Facility Based Quality Teams (Service Improvement Teams) would monitor the quality of the services provided by analysing collected data

2.7. THE NATIONAL HEALTH ACT

The National Health Act 2003 (assented to on 14 July 2004, commenced in part on 2 May 2005) provides the overarching legislative framework for a structured and uniform healthcare system.⁵⁸ The objectives of the Act include, amongst others: providing in an equitable manner the best possible health services that available resources can afford; setting out the rights and duties of health care providers, health workers, health establishments and users; and protecting, respecting, promoting and fulfilling the right to an environment that is not harmful to health or well-being.⁵⁹

The Act gave formal legal recognition to a number of aspects addressed in the Policy on Health Care document. Provision was made for a complaints procedure.⁶⁰ The National Department of Health was expected to facilitate and co-ordinate the establishment, implementation and maintenance of a comprehensive national health information system.⁶¹ Furthermore, all health establishments were to comply with the quality requirements and standards prescribed by the Minister after consultation with the National Health Council.⁶² Safety was explicitly referenced as a matter that could be addressed by the contemplated quality requirements and standards:

‘The quality requirements and standards contemplated in subsection (1) may relate to human resources, health technology, equipment, hygiene, premises, the delivery of health services, business practices, safety and the manner in which users are accommodated and treated.’⁶³

⁵⁷ *Id.* 22.

⁵⁸ National Health Act 61 of 2003.

⁵⁹ S 2 National Health Act.

⁶⁰ S 18.

⁶¹ S 74.

⁶² S 47.

⁶³ S 47(2).

However, this would mean little, since Chapter 10, the most important quality-related component of the Act, never came into effect. This crucial Chapter sought to establish an Inspectorate for Health Establishments and an Office for Standards Compliance. Together, they were meant to monitor and enforce compliance with prescribed standards.⁶⁴ Essentially, centralising the regulation of quality and ensuring consistent application of standards across all healthcare facilities throughout the country. I would argue that many of the quality and safety breakdowns in our health system, particularly in the public sector, can be traced back to the lack of accountability brought on by the failure to promulgate Chapter 10.

2.8. THE HEALTH PROFESSIONS AMENDMENT ACT 29 OF 2007

The Amendment Act was assented to 11 January 2008 and commenced on the 1st of August 2008.⁶⁵ It amended Section 56 of the Act, which dealt with deaths of persons under anaesthesia and broadened it to provide for the handling of cases relating to the death of a person undergoing a procedure of a therapeutic, diagnostic or palliative nature. Essentially, it seeks to regulate the mandatory reporting of procedure-related deaths. Classifying these deaths as ‘unnatural’ for purposes of the Inquest Act and Births and Deaths Registration Act.⁶⁶

‘56. Death of person undergoing procedure of therapeutic, diagnostic or palliative nature.—The death of a person undergoing, or as a result of, a procedure of a therapeutic, diagnostic or palliative nature, or of which any aspect of such a

⁶⁴ S 47(3) and S 77-89.

⁶⁵ Health Professions Amendment Act 29 of 2007.

⁶⁶ Carstens and Pearmain “The Regulatory Framework of the South African Health System” *Med. & L.* (2009) 28 91; Madiba et al. “The amended legislation on procedure-related deaths: an advance in patient care” *SAMJ: South African Medical Journal* (2011) 101 234; Rout and Farina (2012) 18 *Southern African Journal of Anaesthesia and Analgesia*; du Toit-Prinsloo and Saayman “Performance of autopsies in South Africa: Selected legal and ethical perspectives” *Continuing Medical Education; Vol 30, No 2 (2012): Anatomical Pathology* (2012); Jansen van Vuuren “Acts and procedures concerning procedure-related deaths in South Africa” *African Journal of Primary Health Care & Family Medicine* (2013) 5 5. The mentioned authors have highlighted some of the contentious aspects of the provision.

procedure has been a contributory cause, shall not be deemed to be a death from natural causes as contemplated in the Inquest Act, 1959 (Act No. 58 of 1959), or the Births and Deaths Registration Act, 1992 (Act No. 51 of 1992).⁶⁷

3. RENEWED FOCUS ON QUALITY

Despite the absence of a central regulatory entity, quality improvement interventions continued.⁶⁸ However, these improvement efforts were often fragmented or inconsistent. The complexity and uncertainty brought on by a multiplicity of policies and strategies, haphazardly applied throughout the health system, made effective implementation and benchmarking extremely difficult. Consequently, the Department of Health, identified the need for a common set of national standards that would be used to inform and measure quality.

3.1. THE CORE STANDARDS

Launched in April 2008, the 'Core Standards' provided a framework for the assessment of health establishments.⁶⁹ Existing policies, guidelines and plans were used to formulate the core standards, so as to ensure that establishments would be measured against legitimate expectations. The standards express the expected level of care or performance. The main objectives of the initiative were:

‘to develop core national standards, criteria and indicators and the tools for their assessment in health establishments; to establish a baseline in an initial set of hospitals and Community Health Centres to inform the development of Facility

⁶⁷ S 56 Health Professions Amendment Act.

⁶⁸ South and Department *National Department of Health strategic plan 2010/11-2012/13* (2010). The Department of Health has published a 10 Point Plan to improve the health sector. One of the objectives is improving the quality of health services, through improved patient care and accreditation of health facilities. South and Department *Negotiated Service Delivery Agreement 2010- 2014* (2010). The introduction of the Negotiated Service Delivery Agreement has also reaffirmed the importance of improving quality and the government's commitment thereto.

⁶⁹ South and Department *Core standards for health facilities in South Africa* (2008). S 21(2)(b) and S 47(1) National Health Act.

Improvement Plans; to review and evaluate the process and methodology for further developing the national core standards and mechanisms for their assessment; and to build on the lessons learned and expand the process to the next set of hospitals.’

The Core Standards were to be piloted in an initial group of 28 hospitals and 4 Community Health Centres, at varying levels of care in different provinces. Appraisals would be conducted, focussing on seven core ‘domains’ (safety, clinical care, governance, patient experience of care, access to care, infrastructure and environment, and public health). Safety was the first domain: ‘Patient safety includes initiatives to identify, report, analyse and prevent any unintended or unexpected incidents that could harm health care users.’ The intent of the domain was described as: ‘To minimise risk and improve patients’ safety through reporting, analysis and prevention of medical errors and adverse events.’ Four action areas were outlined, each with their own set of organisational standards and criteria. For instance, the ‘patient safety systems (reporting and information)’ action area, required ongoing assessment and management of risks, as well as the active monitoring and handling of adverse events.

The Core Standards were revised and further piloted in 2010. This revision entailed benchmarking the standards against other accreditation programmes and aligning them with the National Department of Health’s strategies and policy directives.⁷⁰

3.2. A HOSPITAL CLINICAL ADVERSE EVENT PREVENTION PROGRAMME IN THE FREE STATE

During this same period, an unrelated pilot study conducted across 31 hospitals in the Free State, heralded the first serious attempt to assess and address the scale of adverse events in the South African public sector.⁷¹ Early data from the study showed ‘three times as many high-risk clinical management incidents compared with the developed world.’ This joint project by the Free State health department and the Council

⁷⁰ Whittaker et al. (2011) *South African Health ...* 1 59.

⁷¹ Bateman “Adverse events--at last a scientific way forward” *S Afr Med J* (2008) 98 74.

for Health Service Accreditation of Southern Africa (COHSASA), utilised the Advanced Incident Management System (AIMS), to measure the effect of a related quality improvement programme known as AMCu (AIMS, Management and Culture interventions). The evaluation of this hospital clinical adverse event prevention programme, is discussed in detail in Dr Kabane's (the previous Head of the Department of Health in the Free State) thesis.⁷² The results of this study are encouraging. Furthermore, the research led to the development of a hospital-based patient-safety risk-reduction model for the Free State, which could be developed and adopted by other health departments.

3.3. NATIONAL CORE STANDARDS FOR HEALTH ESTABLISHMENTS IN SOUTH AFRICA

In 2011, following three years of stakeholder engagement and development, the 'National Core Standards for Health Establishments in South Africa' (NCS) were published.⁷³ In the foreword, the Minister of Health, Dr Aaron Motsoaledi, noted the significance of the adopted NCS and their ultimate purpose:

'The importance of providing quality health services is non-negotiable. Better quality of care is fundamental in improving South Africa's current poor health outcomes and in restoring patient and staff confidence in the public and private health care system. If quality is defined as "getting the best possible results within available resources", then these National Core Standards set out how best to achieve this.'

The Minister also acknowledged the pervasive problems that precipitated the NCS intervention:

'The factors that contributed to the current situation must also be taken into account: poor management, a lack of accountability, a culture of mediocrity rather

⁷² Kabane "An evaluation of the effectiveness of a hospital clinical adverse event prevention programme" *repository.up.ac.za* (2014) PhD.

⁷³ South and Department *National core standards for health establishments in South Africa: abridged version* (2011).

than excellence, demotivated staff, and even an erosion of professional ethics, are all to blame.’

According to Dr Motsoaledi, the NCS signalled a lofty new direction for the health system:

‘The National Core Standards reflect a vision for South Africa’s health services, rather than introducing a list of new requirements. They focus on what needs to be done to meet that vision.’

The main purpose of the National Core Standards is to:

- . Develop a common definition of quality care which should be found in all health establishments in South Africa, as a guide to the public and to managers and staff at all levels;
- . Establish a benchmark against which health establishments can be assessed, gaps identified and strengths appraised; and
- . Provide for the national certification of compliance of health establishments with mandatory standards.

The NCS are structured into seven cross-cutting domains, with a domain being defined as an area where quality or safety might be at risk. The first three domains (Patient Rights, Safety, Clinical Governance and Care, and Clinical Support Services) directly impact on the core business of the health system, i.e., delivering quality health care to patients. The remaining domains (Public Health, Leadership and Corporate Governance, Operational Management, and Facilities and Infrastructure) make up the support system, ensuring that the system delivers its core business – quality care.

The first three domains are particularly pertinent to this discussion, they are described as follows:

‘The domain of Patient Rights sets out what a hospital or clinic must do to make sure that patients are respected and their rights upheld, including getting access to needed care and to respectful, informed and dignified attention in an acceptable

and hygienic environment, seen from the point of view of the patient, in accordance with Batho Pele principles and the Patient Rights Charter.⁷⁴

‘The Patient Safety, Clinical Governance and Clinical Care domain covers how to ensure quality nursing and clinical care and ethical practice; reduce unintended harm to health care users or patients in identified cases of greater clinical risk; prevent or manage problems or adverse events, including health care associated infections; and support any affected patients or staff.’⁷⁵

‘The Clinical Support Services domain covers specific services essential in the provision of clinical care and includes the timely availability of medicines and efficient provision of diagnostic, therapeutic and other clinical support services and necessary medical technology, as well as systems to monitor the efficiency of the care provided.’⁷⁶

Each domain is made up of sub-domains, which comprise a set of standards that define what is expected to be delivered in terms of quality care and best practice. Each standard is linked to a number of criteria (the elements setting out the requirements to achieve compliance with the standard). Criteria are measurable and achievable as reflected in the measures. Measures are the means or evidence for determining whether or not the criterion has been met and form the basis of the Assessment Tool (used for both self-assessments and the compliance audit). Measures are also risk rated into three descending levels: vital, essential and developmental. The assessment tool produces reports on compliance with standards and gives a percentage score per domain, sub-domain or standard.⁷⁷

Domain 2: Patient Safety, Clinical Governance and Clinical Care, is made up of the following six sub-domains: Patient care; Clinical management of priority health

⁷⁴ *Id.* 17.

⁷⁵ *Id.* 21.

⁷⁶ *Id.* 25.

⁷⁷ *Id.* 13.

conditions; Clinical leadership; Clinical risk; Adverse events; and Infection prevention and control. These sub-domains include various standards, which are linked to criteria. The criteria, for instance, calls for among others: procedures to be in place to optimise health outcomes, guidelines to implement priority programmes and initiatives, establishment of quality committees, a clinical risk policy and protocol for the health establishments, appropriate safety measures to be carried out in particular clinical circumstances, the implementation of an adverse events policy and procedure, healthcare establishments to actively encourage reporting, a system to monitor adverse events, an infection prevention and control policy and hand-hygiene programmes.⁷⁸

The NCS are part of the development of a new regulatory framework within the health sector. Their effective enforcement is intended to see to it that the health, safety and welfare of patients are protected. An independent body (the Office of Health Standards Compliance) will undertake external audits of health care establishments, and through an accreditation and certification process it will ensure compliance with the NCS.⁷⁹

3.3.1. SIX FAST-TRACK AREAS

Quality improvement is a long-term commitment and process. However, the Department of Health, through patient complaints, identified six critical areas which required immediate attention. Managers are expected to ensure that they are compliant with these six fast-track areas in as short a time as possible. These fast-track areas are a subset of the most critical standards: 1) Values and attitudes of staff; 2) Cleanliness; 3) Waiting times; 4) Patient safety and security; 5) Infection prevention and control; and 6) Availability of basic medicines and supplies.

3.3.2. BASELINE AUDIT

A subset of the NCS, which included the six fast-track priority areas, were employed to conduct a baseline audit of all public health facilities between May 2011 and May 2012.⁸⁰ At the start of the audit the National Department of Health estimated that there

⁷⁸ *Id.* 22.

⁷⁹ *Id.* 8.

⁸⁰ Health (2013) 1.

were 4 300 public health facilities. Perhaps, the fact that there was a large disparity between this estimate and the actual number of facilities (3 880), foreshadowed the findings which revealed the disorderly state of the system. The audit, conducted by a consortium of partners, assessed infrastructure, classification of facilities, compliance with priority areas of quality and function, human resources, access and range of services offered, and geographic positioning (GPS) for location of facilities.

The overall objective of the audit was to collect baseline data from all public health facilities in the country using standardised measurement tools provided by the National Department of Health. The data collected were subsequently captured into the National Core Standards database. Ultimately, the audit sought to assess the feasibility of the proposed National Health Insurance scheme (which likely explains the political sensitivity of the report).

The National Department of Health were not very forthcoming with the findings. Only a summary report was released, which revealed that only two of the six priority areas obtained more than a 50% compliance score. Positive and caring attitudes (30%) and patient safety (34%) were found to have the weakest compliance scores. The Department initially wanted to suppress the full results. However, the City Press, a weekly newspaper, used the Promotion of Access to Information Act to obtain the full-length report.⁸¹ They reported on the truly appalling findings contained therein. For example, only one hospital out of 394 passed all acceptable standards, 93% of hospital wards did not possess the adequate and functional equipment needed to ensure maternal and infant safety, just 32 of the facilities audited complied with infection prevention and control, and only two facilities could guarantee patients' safety.⁸²

⁸¹ "Exclusive: Inside the hospitals audit" City Press (2014-02-02) <http://www.news24.com/Archives/City-Press/Exclusive-Inside-the-hospitals-audit-20150429>; "Shock audit's SOS for hospitals" City Press (2013-03-24) <http://www.news24.com/Archives/City-Press/Shock-audits-SOS-for-hospitals-20150429>.

⁸² Zinhle, 'Clinics are on the mend', *City Press*, 2014; Zinhle, 'Exclusive: Inside the Hospitals Audit', *City Press*, 2014.

3.4. NATIONAL PLANNING COMMISSION - DIAGNOSTIC REPORT

The National Planning Commission's Diagnostic Report, released in June 2011, identified the weaknesses in the public health system as one of nine primary challenges facing the country.⁸³ In a frank assessment, it took into account the quadruple disease burden and the role that our history of racial segregation played in compounding the poor health outcomes; however, it stated that the government bears much of the responsibility for the current state of affairs. Failure to effectively manage policy and implementation reforms have contributed significantly to the 'collapse' of the system. Some of the more severe policy lapses relate to the treatment of staff:

'The status and role of professionals in the health system is undermined. The rise of silo-based management systems eroded discipline and management authority.'⁸⁴ Training capacity has also been reduced, leading to 'a massive shortage of skilled staff in the health system'. The response from policy-makers has been inappropriate in many instances, 'resulting in the system lurching from crisis to crisis'. Although, the government has correctly attempted to transition to a primary health care focus, 'the quality of care in the primary sector is unsatisfactory and clinics often run out of essential medicines'. Furthermore, '[I]llegitimate public perceptions of substandard care also prevent people from using these clinics.' This has meant that the 'shift of resources out of the hospital system has not achieved better health outcomes or lower patient loads'.

According to the report, the Minister of Health supports this assessment of the health system (yet, you would not say so based on his insistence on blaming the private sector for all the system's ills in making a case for NHI). The report makes the, seldom acknowledged, point that the 'collapse of the public health sector prompted a portion of the population to opt out of the public health system'. Accordingly, the private sector has competed with the public sector for skilled personnel. In some cases, it has managed to lure individuals away. Heavy workloads and poor working conditions in the public sector, as opposed to more money, are likely the deciding factors. Nevertheless, the report goes on to state that, whilst 'competition for skilled staff is certainly a factor,

⁸³ Commission *Diagnostic overview* (2011).

⁸⁴ *Id.* 21.

it cannot explain poor health outcomes in the population in general, or the poor quality of public health care'.⁸⁵

Health financing also received sensible consideration. It was noted that South Africa's spending was equal to other middle-income countries, but that this level of spending was likely too low given our disease burden. As for how the additional money would be raised, the report took a much more conservative view than of that espoused by the Health Minister: 'More resources are required, but it is not clear whether the financing model itself needs amending.'⁸⁶ Indeed, it was noted that health financing in South Africa 'is progressive, even though healthcare access and outcomes are not'.⁸⁷ Looking ahead, the report anticipated recent calls for health reform that are justified by supposed quality gains:

'In this context, it is not clear whether an insurance model on its own will lead to either additional resources or better health outcomes. The need for institutional reforms that link the public and private sectors more closely, to narrow the gap in quality of care, to enable more choice for more people and to jointly raise the quantities of people trained is critical. Hospital management is an area where greater collaboration and partnership could raise standards at minimal extra cost. Policies aimed at reducing the cost of private health care over time are necessary and would also have broader social benefits.'⁸⁸

3.5. NATIONAL PLANNING COMMISSION - NATIONAL DEVELOPMENT PLAN 2030

The National Development Plan 2030⁸⁹, one of South Africa's most important policy documents, reaffirmed the National Planning Committee's stance on healthcare:

'South Africa's broken public health system must be fixed. While greater use of private care, paid for either by users or health insurance, is part of the solution, it

⁸⁵ *Ibid.*

⁸⁶ *Id.* 22.

⁸⁷ *Ibid.*

⁸⁸ *Ibid.*

⁸⁹ Commission *National Development Plan 2030* (2012) 484.

is no substitute for improving public health care. A root- and-branch effort to improve the quality of care is needed, especially at primary level.’

‘By 2030, the health system should provide quality care to all, free at the point of service, or paid for by publicly provided or privately funded insurance. The primary and district health system should provide universal access, with a focus on prevention, education, disease management and treatment. Hospitals should be effective and efficient, providing quality secondary and tertiary care for those who need it. More health professionals should be on hand, especially in poorer communities.’⁹⁰

‘Building a national health insurance system is an important objective. There are four prerequisites to its success: improving the quality of public health care, lowering the relative cost of private care, recruiting more professionals in both the public and private sectors, and developing a health information system that spans public and private health providers. These reforms will take time, require cooperation between the public and private sectors.’⁹¹

Nine priorities that highlight the key interventions needed to achieve the goals of the 2030 vision were set out. Priority 2 specified the actions needed across different levels to strengthen the health system. It noted the important of role that the proposed Office of Health Standards Compliance (OHSC) would play in promoting quality by measuring, benchmarking and accrediting actual performance against standards for quality.⁹² As the report indicates, ultimately, successful health reform depends on the ability of the state to provide quality care:

‘The success of NHI in South Africa will depend on the functioning of the public health system.’ The Commission declared support for efforts aimed at improving

⁹⁰ *Id.* 51.

⁹¹ *Id.* 52.

⁹² *Id.* 337.

the public health system, 'starting with the auditing of facilities and setting appropriate standards.'⁹³

4. CONCLUSION

Although South Africa has only recently begun to explicitly emphasise patient safety, a number of policy and legislative interventions have been undertaken to try to improve the quality of care patients receive (interventions have not directly targeted safety, but may have tangentially sought to impact it as well).

Immense challenges had to be overcome in the post-Apartheid healthcare system. Expanded access was prioritised at first, to see to it that the immediate needs of traditionally under-served communities were met. Evidence of poor quality care prompted the Department of Health to adopt plans and strategies to ameliorate the situation. This led to the adoption of the Batho Pele Principles, the Patients' Rights Charter and other policies aimed at bettering the care patients received.

Unfortunately, many of the lofty ideals espoused by these policies were never realised. The absence of proper leadership, competent management and a failure to enact important provisions of the National Health Act relating to standards compliance, likely hindered their actualisation. The introduction of the National Core Standards seeks to correct some of these missteps. And it is significant and important to note that safety is recognised as one of the 'core' domains.

A subset of the National Core Standards, have been used to conduct a baseline audit of state facilities. Even though the results were unsurprisingly abysmal, at least it seems to have galvanised stakeholders and suggests that a renewed commitment to improved quality and safer care exists. The establishment of the Office of Health Standards Compliance, which will finally bring the long-awaited, much-needed Chapter 10 of the

⁹³ *Id.* 344.

National Health Act into operation, is indicative of this renewed commitment. This crucial entity is discussed in the following chapter.

CHAPTER 12. THE SOUTH AFRICAN HEALTHCARE SYSTEM - THE OFFICE OF HEALTH STANDARDS COMPLIANCE

1. INTRODUCTION

As the government seeks to introduce National Health Insurance (NHI) as a mechanism to deliver universal healthcare, the provision of quality and, above all, safe care will become all the more important. The Minister of Health has described the establishment of the Office of Health Standards Compliance as a ‘precondition’ for the successful transition to NHI. This chapter will examine this crucial entity and the norms and standards it aspires to transfuse into the South African healthcare system – particularly those pertaining to patient safety.

2. NATIONAL HEALTH INSURANCE

The National Health Insurance Green Paper was released on the 12th of August 2011.¹ It set out the governments ambitious plan for healthcare reform, the ultimate goal being the achievement of universal coverage. Whether the NHI, as currently proposed, would be the best mechanism with which to cure the ailing public health system remains to be seen.² However, the consequences of introducing a flawed scheme, that is unable to adequately address the underlying shortcomings of the public system, will have a devastating effect on the provision of quality care and patient safety. Of course, all the components of the scheme and how they function as a whole, would indirectly influence quality and safety. For purposes of this discussion, the focus will be on the aspects in the proposal which are more directly related to quality and safety.

¹ Health *National health insurance in South Africa: policy paper. Government Notice: 657 of 12th August 2011, Gazette Number 34523* (2011).

² Oosthuizen (2014) LLM *repository.up.ac.za*. For a thorough discussion and criticism of the proposed NHI scheme, see Chapter 4.

The Green Paper acknowledged that the public sector suffers from pervasive quality problems and noted that failures in the six priority areas (mentioned earlier) are frequently cited and experienced by patients. In fact, according to the National Department of Health, although access to care had increased in recent years ‘quality of healthcare has deteriorated or remained poor’, to such an extent that it has now become a barrier to access.³ As such, the Department stated that, ‘improvement of quality in the public health system is at the centre of the health sector's reform endeavour’.⁴ It was also admitted that poor quality care has driven members of the public to the private sector, sometimes at considerable extra personal cost. What is lacking from the description of the quality concerns are the causes of the concerns. These are not addressed at all. The failure to be able to adequately identify the systemic problems may lead to the failure to adequately rectify and improve these problems. The emphasis is placed on how the quality failures drive the public to the private sector and the costs they then incur, rather than scrutinising the causes of the failures and setting out substantive strategies to remedy the situation.

Nevertheless, one of the primary objectives of the NHI is to ‘provide improved access to quality health services for all South Africans’.⁵ To ensure that quality healthcare services would be provided under the NHI, government would rely on massive investments in health infrastructure, quality improvement plans and the establishment of the Office of Health Standards Compliance (OHSC).⁶ The Office would play a key role in the promotion of quality and safe care in terms of its accreditation and certification function. Only accredited providers, that comply with the prescribed quality standards, will be able to contract with the NHI fund and deliver healthcare services. The National Health Amendment Bill, which would provide for the establishment of an OHSC, was tabled in the National Assembly on 15 November 2011.⁷

³ Health (2011) 6.

⁴ *Id.* 9.

⁵ *Id.* 18.

⁶ *Id.* 31.

⁷ National Health Amendment Bill [B24-2011].

3. THE OFFICE OF HEALTH STANDARDS COMPLIANCE

During a Departmental Briefing on the 14th of February 2012, the Department of Health led by the Minister Motsoaledi, presented the National Health Amendment Bill to the Parliamentary Portfolio Committee for Health.⁸ At the second reading debate the Minister indicated that the Bill would ‘revolutionise’ healthcare in South Africa.⁹ He also stated that the proposed NHI would never be successful without quality healthcare in the public sector. In this respect, the Minister expressed his view that the OHSC would be one of the ‘preconditions’ for the successful introduction of NHI. Requiring a complete overhaul of the manner in which public hospitals were currently run. The Minister acknowledged the assistance of the British Government and the Care Quality Commission (CQC). The OHSC, would to a large extent, mirror its UK counterpart. The Office will consist of three units. The first unit would be the inspectorate. Many of the inspectors had already begun to receive training from the CQC at the time of the briefing. The second unit would be a Health Ombudsperson. The Minister described the ombudsperson’s role in relation to the other professional bodies (in a somewhat insulting and nonsensical manner) by distinguishing between the quality concerns of ‘well-to-do people’ and ‘ordinary members of the public’:

‘This unit will function as an area where members of the public will lodge complaints about the negative experiences they may have encountered during their visits to health facilities. These complaints will of course range from poor staff attitudes, long waiting times, non-availability of drugs, safety and security concerns etc. Again there has been confusion during public hearings about the role of this unit, vis-à-vis professional bodies like the Health Professions Council of South Africa (HPCSA), the South African Nursing Council (SANC) and the South African Pharmacy Council (SAPC). These professional bodies usually deal with individual professional misconduct like negligence, unethical behaviour or unprofessional behaviour. It is usually well-to-do people who know about these

⁸ National Health Amendment Bill [B24-2011]: briefing by Minister of Health, Parliamentary Committee on Health, 14 February 2012. <https://pmg.org.za/committee-meeting/13947/>.

⁹ National Health Amendment Bill [B 24B-2011]: second reading debate, Minister of Health, National Assembly, 14 August 2012. <https://pmg.org.za/hansard/18322/>.

professional bodies and how to approach them. Ordinary members of the public are usually at a loss on how to address their concerns.’

Supposedly, the Minister wanted to differentiate between accountability for poor performance at the individual professional level and accountability at the institutional level, as he went on to say:

‘Honourable Speaker we hope then that with the establishment of the OHSC our institutions will be on their tender hooks. [sic] Each and every health facility manager will have to take full accountability for their actions and for omissions that may lead to some of the adverse events our facilities experience quite often.’¹⁰

3.1. THE NATIONAL HEALTH AMENDMENT ACT 2013

The National Health Amendment Act was assented to on the 24th of July 2013.¹¹ It was announced that the Act, except for sections 2 and 3, would come into operation on the 2nd of September 2013.¹² Sections 2 and 3 came into operation a year later on the 1st of September 2014.¹³

Finally, after more than a decade, Chapter 10 of the National Health Act was enacted, providing for the establishment of the Office of Health Standards Compliance.¹⁴

3.1.1. OBJECTS OF THE ACT

The OHSC was established as a juristic person, with the object of protecting and promoting the health and safety of health care users.¹⁵ To achieve these objectives the OHCS will monitor and enforce the compliance of prescribed norms and standards in

¹⁰ National Health Amendment Bill [B 24B-2011]: second reading debate, Minister of Health, National Assembly, 14 August 2012. <https://pmg.org.za/hansard/18322/>.

¹¹ Act No. 12 of 2013: National Health Amendment Act, 2013 (GN529 in GG36702 of 24 July 2013).

¹² National Health Amendment Act (12/2013): Commencement of the National Health Amendment Act (GN38 in GG36787 of 30 August 2013).

¹³ National Health Amendment Act (12/2013): Commencement of certain sections of the National Health Amendment Act (GN38 in GG37730 of 10 June 2014).

¹⁴ The commencement of S 77-79 is yet to be proclaimed.

¹⁵ S 78 National Health Act 61 of 2003. Commencement to be proclaimed.

health establishments. Furthermore, complaints relating to non-compliance will be considered and investigated in a procedurally fair, economical and expeditious manner.¹⁶

3.1.2. FUNCTIONS OF THE OFFICE

The functions of the OHCS are set out in section 79 and include: a) advising the Minister on matters relating to the determination of norms and standards; b) inspection and certification of health establishments as either compliant or non-compliant; c) investigation of complaints where the norms and standards have not been met; d) monitoring risk indicators as an early warning system and immediately reporting any breaches of norms and standards to the Minister; e) identification of areas which require intervention and making recommendations to ensure compliance with the prescribed norms and standards; f) publication of information relating to the prescribed norms and standards; g) recommendation of quality assurance and management systems for the national health system; h) keeping records of all its activities; and i) advising the Minister on any matter referred to it by the Minister.¹⁷

The OHSC may also issue guidelines to assist health establishments, collect or request information relating to prescribed norms and standards, and liaise with and negotiate cooperative agreements with any other regulatory authority.¹⁸

3.1.3. THE OFFICE OF HEALTH STANDARDS COMPLIANCE BOARD

The Office functions under the control of the Board, which is responsible for determining the policy and conducting the required planning in connection with the functions of the Office.¹⁹ The Board is appointed by the Minister and consists of between 7 and 12 members who possess the relevant qualifications, skills and expertise.²⁰ A Board,

¹⁶ S 78. Commencement to be proclaimed.

¹⁷ S 79(1). Commencement to be proclaimed.

¹⁸ S 79(2). Commencement to be proclaimed.

¹⁹ S 79A.

²⁰ S 79B.

consisting of 12 members, has been appointed by the Minister; they will serve as members of the Board for a period of three years.²¹ Committees may be established to assist the Board with the performance of its functions and the exercise of its powers.²²

The Board in consultation with the Minister is also responsible for the appointment of the Chief Executive Officer of the Office.²³ The CEO, as head of the Office, has a number of functions in terms of the Act. These include, amongst others, the appointment of employees of the Office in accordance with an organisational structure approved by the Board in consultation with the Minister.²⁴ The CEO may enter into contracts with persons or organisations, or appoint expert or technical committees to assist the Office in the performance of its functions.²⁵

The CEO must also take appropriate action to ensure that the Ombud's findings and recommendations are implemented and may, subject thereto, request the intervention of the Minister, a member of the executive council responsible for health in the province or a member of the municipal council responsible for health if a complaint relates to a matter falling under the national department or that particular province or municipality.²⁶

3.1.4. HEALTH OFFICERS AND INSPECTORS

The Minister, relevant member of the Executive Council or mayor of a municipal council may designate any person in the employ of the national department, province or municipality, as the case may be, as a health officer.²⁷ As mentioned above, the CEO appoints qualified persons as inspectors.²⁸ They are issued with a certificate, which

²¹ National Health Act (61/2003) as amended: Appointment of Members to the Board of the Office of Health Standards Compliance (GN65 in GG37282 of 29 January 2014); National Health Amendment Act (12/2013): Call for Nominations of Suitable Candidates to serve as Members on the Board of the Office of Health Standards Compliance (GN774 in GG40106 of 30 July 2016).

²² S 79G.

²³ S 79H.

²⁴ S 79I(1).

²⁵ S 79I(3)

²⁶ S 79I(4) and (5).

²⁷ S 80(1).

²⁸ S 80(2).

must be kept in their possession and showed to persons affected by their actions.²⁹ The health officers and inspectors performing their functions in terms of the Act have the powers of a peace officer and may exercise any of the powers conferred on a peace officer by law.³⁰

3.1.5. THE OMBUD

The Minister must, after consultation with the Board, appoint an Ombud.³¹ The Ombud is located within the Office, and reports to the Minister.³²

The Ombud may consider, investigate and dispose of complaints relating to norms and standards in a fair, economical and expeditious manner.³³ Complaints may involve an act or omission by a person in charge of or employed by a health establishment or facility.³⁴

In conducting an investigation, the Ombud may: be assisted by any person contemplated in section 81(2)(c)³⁵; obtain affidavits or declarations from any person; direct any person to appear before him or her; direct any person to give evidence or produce any documentation relating to the matter under investigation; and interrogate such a person.³⁶ The Ombud may also request an explanation from any person and require any person appearing as a witness to give evidence under oath or after having made an affirmation.³⁷ The Ombud may, when considering or investigating a complaint, require the assistance of or refer the complaint to any other authority established in terms of legislation or any other appropriate and suitable body or entity to investigate

²⁹ S 80(3) and (4).

³⁰ S 80(4)(c).

³¹ S 81(1).

³² S 81(3).

³³ S 81A(1).

³⁴ S 81A(2).

³⁵ S 81A(3)(a). This paragraph erroneously refers to a section not contained in the Act, the legislature probably meant to refer to S 81(3)(c).

³⁶ S 81A(3)(b).

³⁷ S 81A(3)(c) and (d).

similar complaints.³⁸ Such authority, body or entity must provide the assistance required and report to the Ombud on progress made in relation to complaints referred to it.³⁹

A report together with recommendations on appropriate action must be submitted to the CEO after each investigation.⁴⁰ If the CEO fails to Act in accordance with the findings, the Ombud may request the intervention of the Minister.⁴¹

3.1.6. INDEPENDENCE, IMPARTIALITY AND ACCOUNTABILITY OF OMBUD

The Act provides that the Ombud, when dealing with any complaint, is independent and impartial, and must perform the functions in good faith without fear, favour, bias or prejudice.⁴² The Minister, national department and Office is obliged to afford the Ombud assistance and support to enable the Ombud to perform his or her functions effectively and efficiently.⁴³

There are concerns about the independence of the Ombud seeing that he or she is appointed and reports to the Minister, rather than the Board.⁴⁴ The Minister is also responsible for the determination of remuneration and other terms and conditions of service of the Ombud.⁴⁵ Furthermore, the Minister may terminate the employment of the Ombud.⁴⁶

3.1.8. INSPECTIONS

The Act provides for inspections of health establishments and certain other premises. Health officers may enter any premises, excluding a private dwelling, whereas an

³⁸ S 81A(6).

³⁹ S 81A(7).

⁴⁰ S 81A(9).

⁴¹ S 81A(10).

⁴² S 81B(2).

⁴³ S 81B(3).

⁴⁴ S 81(1).

⁴⁵ S 81(4).

⁴⁶ S 81(6).

inspector may enter any health establishment at any reasonable time in order to: inspect such premises or health establishment to ensure compliance with the Act; question any person who may possess relevant information; require that documentation and health records be produced by the person in charge; and take samples of any substance or photographs relevant to the inspection.⁴⁷

If any norm, standard or provision of the Act is not complied with, a compliance notice may be issued to the person in charge of the premises or health establishment.⁴⁸ The compliance notice remains in force until the relevant provision of the Act has been complied with and a compliance certificate has been issued.⁴⁹ Compliance certificates are only valid for four years and must be renewed before or on the expiry date in a prescribed manner.⁵⁰

3.1.8. NON-COMPLIANCE WITH PRESCRIBED NORMS AND STANDARDS

More details about the consequences of non-compliance are contained in section 82A of the Act.⁵¹ If a health establishment fails to comply with any prescribed norm or standard a compliance notice may be issued to the person in charge of that establishment.⁵² The compliance notice must set out the following: a) the health establishment to which the notice applies; b) the prescribed norms and standards which have not been complied with; c) details of the nature and extent of non-compliance; d) the steps required and the period over which such steps must be taken; and e) the penalties that may be imposed in the event of continued non-compliance.⁵³

⁴⁷ S 82(1).

⁴⁸ S 82(3).

⁴⁹ S 82(4).

⁵⁰ S 82(7).

⁵¹ S 82A.

⁵² S 82A(1).

⁵³ S 82A(2).

The compliance notice issued in terms of this section remains in force until the Office issues a certificate of compliance or until it is set aside by the tribunal after considering an appeal.⁵⁴

The Office may take certain steps if a person in charge of a health establishment fails to comply with the notice. These steps will be influenced by the nature, extent, gravity and severity of the contravention and include: a) issuing a written warning; b) requiring a written response from the health establishment; c) recommending that a relevant authority take appropriate and suitable action against persons responsible for the non-compliance; d) revoking the compliance certificate and recommending that the Minister temporarily or permanently closes the health establishment or part thereof that poses a serious risk to public health or health care users; e) imposing fines on a person or health establishment; and f) referring the matter to the National Prosecuting Authority for prosecution.⁵⁵

The CEO must inform the head of a national or provincial department, the municipal manager or the head of a health establishment of any persistent non-compliance.⁵⁶

3.1.9. ENVIRONMENTAL HEALTH INVESTIGATIONS

Health officers, registered as environmental health practitioners, are entitled to investigate conditions, which violate rights contained in section 24(a) of the Constitution, constitute pollution detrimental to health, or are likely to cause a health nuisance or constitute a health nuisance.⁵⁷ A compliance notice is then issued to the person determined to be responsible for such condition.⁵⁸

⁵⁴ S 82A(3).

⁵⁵ S 82A(4).

⁵⁶ S 82A(5).

⁵⁷ S 83(1).

⁵⁸ S 83(3).

3.1.10. ENTRY AND SEARCH OF A PREMISES OR HEALTH ESTABLISHMENTS

Health officers or inspectors, accompanied by a police official may, on the authority of a warrant, enter any premises or health establishment in order to conduct a search or to seize certain relevant items.⁵⁹ A warrant may be issued by a judge or magistrate in relation to the premises or health establishment on or from which there is reason to believe an act has been or is being committed in contravention of the Act and if there are reasonable grounds to believe that there is evidence available in or upon such premises or health establishment of a contravention of the Act.⁶⁰

A health officer or inspector may enter or search a premises or health establishment without a warrant, if a person competent to do so consents thereto or if there are reasonable grounds to believe that a warrant would be issued in terms of the Act, but that the delay in obtaining the warrant would defeat the object thereof.⁶¹

The Act explicitly states that any entry upon or search of a premises or health establishment must be conducted with strict regard to decency and good order, and must take into account a person's rights to dignity, freedom and security, and privacy.⁶²

3.1.11. APPEALS AGAINST DECISIONS OF THE OFFICE OR OMBUD

The Act provides that any person aggrieved by a decision of the Office or any finding and recommendation of the Ombud, may within 30 days after gaining knowledge thereof, lodge a written appeal with the Minister.⁶³ The Minister must then, upon receipt of such a written appeal, appoint an independent ad hoc tribunal and submit the appeal to it for adjudication.⁶⁴ The tribunal consists of a chairperson, who must be a retired

⁵⁹ S 84(1).

⁶⁰ S 84(5).

⁶¹ S 86.

⁶² S 86A.

⁶³ S 88A(1).

⁶⁴ S 88A(2).

judge or magistrate, and two persons appointed on account of their knowledge of the health care industry.⁶⁵

Decisions of the Office or Ombud may be confirmed, set aside or varied by the tribunal and it must notify the parties of its finding.⁶⁶

3.1.12. OFFENCES AND PENALTIES

There are a number of offences created by the Act, the failure to comply with a compliance notice being one of them.⁶⁷ If convicted of an offence a person would be liable on conviction to a fine or to imprisonment for a period not exceeding 10 years, or to both a fine and imprisonment.⁶⁸

3.1.13. CONCLUSION

The establishment of an OHSC is welcomed and a much needed step in ensuring that quality care is provided in the health sector. There are however concerns about the independence thereof. Political interference may prohibit the proper functioning of the Office and will make it impossible for it to live up to its potential or serve its designated purpose. The Office will impact on many stakeholders in the sector, which further necessitates its impartiality and independence.

The OHSC's work has already started; inspectors have been trained and are carrying out voluntary 'mock' inspections to develop the tools, procedures and the prescribed norms.⁶⁹ Inspections will become mandatory in the near future, for both the public and private sectors.⁷⁰

⁶⁵ S 88A(3).

⁶⁶ S 88A(4).

⁶⁷ S 89(1).

⁶⁸ S 89(2).

⁶⁹ Matsoso and Fryatt "National Health Insurance: the first 16 months." *S Afr Med J* (2013) 103 156.

⁷⁰ *Ibid.*

3.2. REGULATIONS – THE OPERATIONAL FRAMEWORK

On the 2nd of November 2016, the procedural regulations pertaining to the functioning of the Office of Health Standards Compliance and handling of complaints by the Ombud, came into operation.⁷¹

These regulations set out the procedures and processes of the Office, as it relates to the collection of information, inspection, certification, and management of non-compliance.⁷² They apply to all categories of health establishments referred to in section 35 of the Act.⁷³ However, Reg. 3(2) states that: ‘with the exception of Chapter 7, these Regulations will come into force in relation to each category of health establishment only once the norms and standards for such category of health establishment have been established.’⁷⁴ Proposed Norms and Standards were first published for public comment in February 2015.⁷⁵ They were revised and re-published in January 2017.⁷⁶ At the time of writing they have not yet been established. Consequently, the procedural regulations pertaining to the functioning of the Office have also not come into operation.

The OHSC presented its 2014/15 findings on health facilities at a briefing on 16 March 2016 to the Parliamentary Portfolio Committee for Health.⁷⁷ Due to a lack of resources, the Office only managed to inspect approximately 10% of the public health facilities in

⁷¹ National Health Act (61/2003): Procedural regulations pertaining to the functioning of the Office of Health Standards Compliance and handling of complaints by the Ombud (GN1365 in GG40396 of 2 November 2016, replacing GN1275 in GG40350 of 13 October 2016, which contained errors).

⁷² Reg. 2.

⁷³ Reg. 3(1); S 35 of the National Health Act 61 of 2003, which commenced 1 March 2012, states that the Minister may by regulation classify health establishments. This was done in terms of regulation: National Health Act (61/2003): Regulations: Categories of hospitals (GN185 in GG35101 of 2 March 2012).

⁷⁴ Reg. 3(2).

⁷⁵ National Health Act (61/2003): Norms and standards regulations in terms of section 90(1)(b) and (c): applicable to certain categories of health establishments (GN109 in GG38486 of 18 February 2015).

⁷⁶ National Health Act (61/2003): Norms and standards regulations applicable to different categories of health establishments (GN10 in GG40539 of 4 January 2017).

⁷⁷ Parliamentary Health Committee briefing, Public Health Facilities audit results: Office of Health Standards Compliance (OHSC), 16 March 2016. <https://pmg.org.za/committee-meeting/22233/>.

South Africa, far short of the 25% target it set for itself. Mr Bafana Msibi, the acting Chief Executive Officer, noted some of the disturbing findings: Good Pharmacy Practice was often not followed; expired medication remained on shelves; expiration dates of the medication had been manually changed by staff; patients were being tested and consulted in open areas, compromising privacy and confidentiality; protocols on infection prevention and control practices were not adhered to; unsterilized instruments were used on patients; resuscitation trolleys were not properly stored; patients were found to be sleeping on the floor and left unattended; situations were recorded where two babies were put in the same incubator; poor storage of medical records; sharps were not safely managed and disposed correctly; poor waste disposal and storage of general waste; cleanliness was a big issue; and it was common to find patient safety compromised.

Board members of the OHSC lamented the fact that the Office could not take any steps against underperforming facilities to try and remedy the dire situation.⁷⁸

There are clearly, serious problems in our public health facilities. Many are indicative of leadership and organisational governance failings, often compounded by constrained or mismanaged resources. Unfortunately, since the Norms and Standards have not been promulgated, the Office is unable to legally enforce compliance or hold institutions accountable to ensure that these conditions, which would almost inevitably result in patient harm, cannot persist. The absence of regulations has also meant that private healthcare facilities could not be inspected.

3.2.1. THE OMBUD

The procedures and processes for the consideration, investigation and disposal of complaints by the Ombud, which are set out in Chapter 7, are operational.⁷⁹ The

⁷⁸ Kahn, 'Hospital watchdog lacks power to enforce standards', *Business Day*, 2016 1.

⁷⁹ Reg. 2 and 3. National Health Act (61/2003): Procedural regulations pertaining to the functioning of the Office of Health Standards Compliance and handling of complaints by the Ombud (GN1365 in GG40396 of 2 November 2016, replacing GN1275 in GG40350 of 13 October 2016, which contained errors).

aspects regulated in this chapter include:⁸⁰ who may lay complaints; how to lay complaints; requests for additional information; screening of complaints; referrals from other entities and the public; cooperation with other entities; complaint investigations; progress reports; a fixed period for completing investigations (within 6 months, unless extended); a public investigation register; submission of investigation reports; referrals to and reports from other statutory authorities; and the confidentiality of information.

Professor Malegapuru Makgoba was appointed as the first Health Ombud (commencing his work the on the 1st of June 2016).⁸¹ One of the Ombud's firsts tasks was to investigate the deaths of nearly 100 mentally ill patients in the Gauteng Province.⁸²

3.2.2. NORMS AND STANDARDS REGULATIONS APPLICABLE TO DIFFERENT CATEGORIES OF HEALTH ESTABLISHMENTS

Although, they are yet to come into force, the regulations setting out the Norms and Standards applicable to different categories of health establishments, marks the strongest commitment yet to improve the quality and safety of care in South Africa.⁸³ The Norms and Standards are the foundation of the OHSC. As mentioned, the Office is incapable of fulfilling its mandate in their absence.

From the outset, it is made clear that the purpose of the regulations is 'to promote and protect the health and safety of users and health care personnel'.⁸⁴ The immense positive potential of the regulations, is reflected by the mere fact that critical patient safety concepts have, for the first time, found formal legal acknowledgement and potential implementation. It is encouraging just to see concepts such as, 'adverse

⁸⁰ Chapter 7 (Reg. 32-50).

⁸¹ National Assembly, Minister of Health Budget Vote speech, 10 May 2016. <https://pmg.org.za/briefing/22491/>.

⁸² Makgoba "The Report into the 'Circumstances Surrounding the Deaths of Mentally Ill Patients: Gauteng Province'" (2017).

⁸³ National Health Act (61/2003): Norms and standards regulations applicable to different categories of health establishments (GN10 in GG40539 of 4 January 2017).

⁸⁴ Reg. 3.

incidents', 'clinical risk', 'quality', 'safe' and 'user safety' defined.⁸⁵

It could, perhaps, be useful to highlight some of the more significant aspects that would be governed by the regulations, seeing as these are meant to be encapsulated in policies developed for the Ideal Clinic initiative (which will be discussed hereafter).

3.2.2.1. USER RIGHTS

Provision is made for the realisation of users' rights, giving effect to matters which have previously only formed part of the Patients' Rights Charter.⁸⁶ For instance, the 'dignity of users' is (idealistically) provided for as follows:

'Dignity of users – 4. (1) All health establishments must provide services in a manner that is respectful of users' rights, facilitates informed choice, minimises harm, and acknowledges cultural and individual values and beliefs.'⁸⁷

Then there are also provisions aimed at: ensuring users have adequate information⁸⁸; clear signage is displayed⁸⁹; systems of referral are maintained⁹⁰; emergency care can be accessed⁹¹; delays are reduced⁹²; waiting periods for elective procedures are shortened⁹³; and users' experience care is monitored⁹⁴.

The regulations also require a complaint management system to be implemented in all health establishments:

'Complaints, compliments and suggestions – 12. (1) All health establishments must ensure that users complaints, compliments and suggestions are recognised,

⁸⁵ Reg. 1.

⁸⁶ Chapter 2 (GN10 in GG40539 of 4 January 2017).

⁸⁷ Reg. 4.

⁸⁸ Reg. 5.

⁸⁹ Reg. 6.

⁹⁰ Reg. 7.

⁹¹ Reg. 8.

⁹² Reg. 9.

⁹³ Reg. 10.

⁹⁴ Reg. 11.

reported and analysed, and that this information is used to improve quality.⁹⁵

3.2.2.2. CLINICAL GOVERNANCE AND CLINICAL CARE

Provision is also made for aspect surrounding clinical governance and clinical care.⁹⁶ Users' health records need to be maintained and must contain a number of prescribed details, including the filing of the patient's informed consent.⁹⁷ Clinical management systems and procedures must be established in respect of national priority health conditions.⁹⁸ Health establishments are also expected to undertake monthly clinical audits in this regard.⁹⁹

Aspects relating to clinical leadership and clinical risk are also regulated:

'Clinical leadership and clinical risk – 15. (1) All health establishments must establish and maintain systems, structures and programmes that are appropriate to the health establishment and the services it provides, to mitigate clinical risk and promote clinical leadership for the purpose of safeguarding the quality and safety of the health care services provided by the establishment.'¹⁰⁰

This includes clinical leadership structures that oversee quality and safety.¹⁰¹ These structures are responsible for the establishment, maintenance and implementation of quality improvement plans, that address various quality and safety issues.¹⁰²

Provision is also made for clinical risk management:

'Clinical risk management – 16. (1) All health establishments must maintain a system for identifying, minimising and mitigating reasonably foreseeable clinical risks to the health and safety of users and healthcare personnel that is appropriate

⁹⁵ Reg. 12.

⁹⁶ Chapter 3 (GN10 in GG40539 of 4 January 2017).

⁹⁷ Reg. 13(2)(e).

⁹⁸ Reg. 14.

⁹⁹ Reg. 14(2)(c).

¹⁰⁰ Reg. 15.

¹⁰¹ Reg. 15(2)(a).

¹⁰² Reg. 15(2)(c).

for the health establishment.¹⁰³

User safety incidents are also regulated:

‘User safety incidents – 17. (1) All health establishments must have a user safety programme to safeguard users against the risks associated with unsafe and inappropriate care.’¹⁰⁴

A functional user safety structure must oversee the user safety programme.¹⁰⁵ The health establishment must have a guideline or standard operating procedure that outlines the approach to identifying, categorising and monitoring user safety incidents.¹⁰⁶ A surveillance system must be maintained, so that incidents can be reported, investigated and corrected.¹⁰⁷ Patients must be informed if they have been affected by a safety incident, and be kept informed of the progress and outcome of any investigation.¹⁰⁸

User safety incidents are defined as follows:

‘an event or circumstance that could have resulted, or did result in harm to a user as a result of the health care services provided, and not due to the underlying health condition. An incident can be a near miss, no harm incident or harmful incident (adverse event)’¹⁰⁹

Provision is also made for processes to protect users undergoing high-risk procedures:

‘Users undergoing high risk procedures – 19. (1) Health establishments must implement and maintain processes to protect users undergoing high risk procedures that are appropriate to the type of establishment and the scope of

¹⁰³ Reg. 16.

¹⁰⁴ Reg. 17.

¹⁰⁵ Reg. 17(2)(a).

¹⁰⁶ Reg. 17(2)(b).

¹⁰⁷ Reg. 17(2)(c).

¹⁰⁸ Reg. 17(2)(f).

¹⁰⁹ Reg. 17(3)(b).

service it offers.¹¹⁰

Systems must be in place to guide the safe administration of medication and safe injection practices. Safety checks are also required to be done before, during and after surgery.¹¹¹ Although, it is not specified, this seems to correspond with the WHO's Global Patient Safety Challenges: Clean Care is Safer Care (launched 2005), Safe Surgery Saves Lives (launched 2008), and Medication Without Harm (launched 2017).¹¹² The regulations may also imply that safety checklists could receive wider adoption.

Infection prevention and control programmes are required to be maintained and health care waste must be managed appropriately.¹¹³

3.2.2.3. CLINICAL SUPPORT SERVICES

The regulations applicable to clinical support services are found in Chapter 4.¹¹⁴ These include provision relating to medicines and medical supplies.¹¹⁵ Specific protocols must be in place to protect patients against medication errors.¹¹⁶ Health establishments must ensure that diagnostic services are safe and that systems are in place to report adverse incidents.¹¹⁷ Blood services and the reporting of adverse blood reactions are also provided for in the regulations.¹¹⁸

Provision is also made in the regulations for the management of medical equipment.¹¹⁹ The unavailability or lack of maintenance has plagued the public sector for decades.

¹¹⁰ Reg. 19.

¹¹¹ Reg. 19(2).

¹¹² Organization (2005); Organization (2008) *World Health Organization*; Donaldson et al. "Medication Without Harm: WHO's Third Global Patient Safety Challenge" *Lancet* (2017) 389 1680; Organization "Medication Without Harm" (2017).

¹¹³ Reg. 20 and 21.

¹¹⁴ Chapter 4 (GN10 in GG40539 of 4 January 2017).

¹¹⁵ Reg. 23 and 24.

¹¹⁶ Reg. 23(2)(e).

¹¹⁷ Reg. 25.

¹¹⁸ Reg. 26.

¹¹⁹ Reg. 28.

This provision is particularly relevant in light of the recent reports of cancer patients being denied life-saving treatment due to non-functioning radiotherapy machines.¹²⁰

‘Medical equipment management – 28. (1) Health establishments must ensure that the establishment’s medical equipment is available and functional.’¹²¹

3.2.2.4. HEALTH PROMOTION AND DISEASE PREVENTION

Chapter 5 of the regulations make provision for health promotion and disease prevention.¹²² This includes provisions aimed at: outbreaks, health emergencies and disaster preparedness and environmental controls.¹²³

3.2.2.5. LEADERSHIP AND GOVERNANCE

It has long been recognised that leadership and governance failures have contributed significantly to the dysfunctional state of the public health system. Chapter 6 of the regulations seeks to address these deficiencies:¹²⁴

‘Oversight, leadership and accountability – 33. (1) All health establishments must have a functional oversight leadership structure to manage the regulated obligations of the establishment.’¹²⁵

¹²⁰ South African Human Rights Commission, Investigative Report, ‘Dr Imran Keeka, DA, MPL vs. Addington Hospital and 3 others KwaZulu Natal’, (Complaint File Ref: KZ/1516/0451), 15 June 2017.

¹²¹ Reg. 28(1).

¹²² Chapter 5 (GN10 in GG40539 of 4 January 2017).

¹²³ Reg. 30-32.

¹²⁴ Chapter 6 (GN10 in GG40539 of 4 January 2017).

¹²⁵ Reg. 33.

3.2.2.6. OPERATIONAL MANAGEMENT

Various matters related to operational management are provided for in Chapter 7, including:¹²⁶ human resource management¹²⁷; occupational health and safety¹²⁸; transport management¹²⁹; and health record management¹³⁰.

Health establishments must also ensure that they have effective information systems in place to inform the delivery of safer care:

‘Information management – 37. (1) All health establishments must establish systems to produce accurate and timely information to inform managerial and clinical decision-making on the safety, reliability and efficiency of the health care services provided by the establishment.’¹³¹

3.2.2.7. FACILITIES AND INFRASTRUCTURE

Chapter 8 of the regulations deal with matters related to facilities and infrastructure, including:¹³² management of buildings and grounds¹³³; building engineering services¹³⁴; communication systems¹³⁵; security services¹³⁶; general waste management¹³⁷; linen services¹³⁸; and food services¹³⁹.

¹²⁶ Chapter 7 (GN10 in GG40539 of 4 January 2017).

¹²⁷ Reg. 34.

¹²⁸ Reg. 35.

¹²⁹ Reg. 36.

¹³⁰ Reg. 38.

¹³¹ Reg. 37.

¹³² Chapter 8 (GN10 in GG40539 of 4 January 2017).

¹³³ Reg. 40.

¹³⁴ Reg. 41.

¹³⁵ Reg. 42.

¹³⁶ Reg. 43.

¹³⁷ Reg. 44.

¹³⁸ Reg. 45.

¹³⁹ Reg. 46.

4. CONCLUSION

The Office of Health Standards Compliance, which gives effect to a much needed and notably absent component of the health system, is finally becoming a reality. The Office faces an immense challenge. The public health system, where the vast majority of South African citizens receive their care, is marred by serious systemic quality and safety problems.

The establishment of the OHSC and the regulations that have been published marks the strongest commitment yet to addressing these problems. For the sake of the entire health care system, we can only hope that it lives up to its potential. Several aspects and concepts related to patient safety will for the first time receive formal legal recognition and become enforceable when the regulations are promulgated. Unfortunately, this has not yet happened, and the OHSC is still not fully operational.

It is much too early to tell whether these legally encapsulated notions will be effectively translated into practical improvements in quality and safety. Failure to actualise lofty policy ideals is somewhat of a theme in South Africa. Concerns regarding the Office's independence, especially in light of the massive role it will play in the transition towards NHI, have been alluded to. Any political or special interest interference will greatly undermine its functioning and mandate. The overall capacity of the Office, owing to the immensity of its task and the dire state of the system, is another cause for concern.

That being said, the OHSC is definitely a step in the right direction and one hopes it can receive the support it requires to fulfil its vision of 'safe and quality healthcare for all South Africans'.

CHAPTER 13. THE SOUTH AFRICAN HEALTHCARE SYSTEM – THE IDEAL CLINIC AND IMPROVEMENT STRATEGIES

1. INTRODUCTION

The National Department of Health started the 'Ideal Clinic' initiative in July 2013 to systematically improve and correct the problems in public sector Primary Health Care (PHC) clinics.¹ This initiative began as a response to the severe deficiencies that were uncovered by the 2011/12 Baseline Audit.² It is also a key part of the government's National Health Insurance implementation plan.³

The initiative seeks to transform PHC facilities to ensure that they conform to NHI standards, as determined by the Office of Health Standards Compliance.⁴ In other words, the Ideal Clinic programme is the Department of Health's internal quality improvement mechanism, aimed at ensuring compliance with norms and standards, monitored and enforced by the external 'independent' entity – the OHSC. Seeing as the OHSC will have an accreditation function, the efforts to improve quality are all the more important.⁵

This chapter will discuss the Ideal Clinic initiative. It will consider the components and elements pertaining to patient safety, as well as the pertinent guidelines and policies.

¹ National Department of Health, South Africa. Ideal Clinic South Africa. <https://www.idealclinic.org.za>.

² Health (2013) 1.

³ National Department of Health (2017d) 3. National Health Act, 2003: National Health Insurance Policy: Towards Universal Health Coverage (GN627 in GG40955 of 30 June 2017).

⁴ Burger et al. "Strengthening the measurement of quality of care" *South African Health Review* (2016) 191.

⁵ Fryatt and Hunter "The Ideal Clinic in South Africa: planning for implementation" (2014) *South African Health Review* 23.

1.1. OPERATION PHAKISA

Operation Phakisa was launched in July 2014, with the aim of fast-tracking certain critical aspects identified in the National Development Plan.⁶ It is an adaptation of the Big Fast Results Methodology adopted by Malaysia. Phakisa, meaning ‘hurry up’ in Sesotho, is government’s attempt to implement priority programmes better, faster and more effectively. It is described as a results-driven approach, which involves clear plans and targets, continuous monitoring of progress and practical public application.

2. THE IDEAL CLINIC INITIATIVE

Operation Phakisa identified healthcare, and specifically the Ideal Clinic initiative, as one of the priority areas that could benefit from this results-driven approach.⁷ The Ideal Clinic Realisation and Maintenance (ICRM) Lab was launched on the 12th of October 2014 in order to scale up the Ideal Clinic initiative throughout the country.⁸ The ICRM lab brought together 164 senior participants from across the health system to develop detailed, sustainable plans and solutions to the greatest challenges facing the Primary Health Care (PHC) system. The ICRM programme seeks to transform PHC in line with broader national priorities, such as: Chapter 10 of the National Development Plan 2030⁹; Medium Term Strategic Framework (MTSF) 2014-2019¹⁰; and the National Health Insurance policy¹¹. Ultimately, the ICRM programme hopes to ensure that all of South Africa’s 3 507 PHC facilities will be Ideal Clinics by 2019.¹²

⁶ Department of Planning, Monitoring and Evaluation, South Africa. Operation Phakisa. <http://www.operationphakisa.gov.za/pages/home.aspx>

⁷ *Ibid.*

⁸ Ideal Clinic Realisation and Maintenance (ICRM) Lab; National Department of Health (2015).

⁹ Commission (2012) 484.

¹⁰ South and National *Medium-term strategic framework (MTSF) 2014-2019* (2014).

¹¹ National Department of Health (2017d).

¹² Ideal Clinic Realisation and Maintenance (ICRM) Lab; National Department of Health (2015). National Department of Health, South Africa. Ideal Clinic South Africa. <https://www.idealclinic.org.za>.

The Department of Health defines an 'Ideal Clinic', as follows:

'An Ideal Clinic is a clinic with good infrastructure, adequate staff, adequate medicine and supplies, good administrative processes and adequate bulk supplies that use applicable clinical policies, protocols, guidelines as well as partner and stakeholder support, to ensure the provision of quality healthcare services to the community. An Ideal Clinic cooperates with other government departments as well as with the private sector and non-governmental organisations to address the social determinants of health.'¹³

2.1. THE COMPONENTS AND ELEMENTS OF AN IDEAL CLINIC

Realising and maintaining an Ideal Clinic requires a number of components to be in place:¹⁴ 1. Administration; 2. Integrated Clinical Services Management; 3. Medicines, Supplies and Laboratory Services; 4. Human Resources for Health; 5. Support Services; 6. Infrastructure; 7. Health Information Management; 8. Communication; 9. District Health System Support; 10. Implementing Partners and Stakeholders

Each component is made up of sub-components, which in turn consist of a number of elements.¹⁵ There are currently 10 components, 32 sub-components and 207 elements that make up an Ideal Clinic. The elements are weighted according to three categories:¹⁶

- Vital (10 elements) - Extremely important (vital) elements that require immediate and full correction. These are elements that affect direct service delivery to and clinical care of patients and without which there may be immediate and long-term adverse effects on the health of the population.
- Essential (86 elements) - Very necessary (essential) elements that require resolution within a given time period. These are process and structural elements that indirectly affect the quality of clinical care given to patients.

¹³ National Department of Health "Ideal Clinic Manual: Version 17" (2017) 1.

¹⁴ National Department of Health, *Ideal Clinic Definitions, Components and Checklists* 2.

¹⁵ *Id.* 3.

¹⁶ *Id.* 5.

- Important (110 elements) - Significant (important) elements that require resolution within a given time period. These are process and structural elements that affect the quality of the environment in which healthcare is given to patients.

2.2. INTEGRATED CLINICAL SERVICES MANAGEMENT

The second component, Integrated Clinical Services Management (ICSM), is a key pillar and will play a significant part in the realisation of an Ideal Clinic.¹⁷ ICSM is intended to help facilities achieve compliance with Domain 2 of the National Core Standards, i.e., Patient Safety, Clinical Governance and Clinical Care. It also comprises seven of the 32 Ideal Clinic sub-components and 55 indicators.

The World Health Organisation defines Integrated Health Services as:

‘The organisation and management of health services so that people get the care they need, when they need it, in ways that are user friendly, achieve the desired results and provide value for money’¹⁸

The Department of Health describes ICSM as:

‘ICSM is a health system strengthening model that builds on the strengths of the HIV programme to deliver integrated care to patients with chronic and/or acute diseases or who come for preventative services by taking a patient-centric view that encompasses the full value chain of continuum of care and support.’¹⁹

‘Integrated care is holistic care, provided to a person based on the individual user’s need, rather than a programmatic approach there is an awareness of their health as a whole, rather than only one clinical aspect of it. Integration of care involves arranging services so that they are not disjointed, and for the user it is care that is seamless, smooth and easy to navigate, rather than the organisation of services to suit the service provider. The services offered to the user are coordinated and

¹⁷ National Department of Health “Integrated Clinical Services Management Manual” (2017c) 21.

¹⁸ World “Integrated health services—what and why” *Technical brief* (2008) 1 1.

¹⁹ National Department of Health (2017) 1.

there is a reduction number of stages in an appointment and the number of separate visits required to a health facility.²⁰

A standardised questionnaire which is translated into a dashboard (Ideal Clinic components, sub-components and elements) is employed to track the progress of facilities over time.²¹ An Ideal Clinic Manual has been developed to assist managers to achieve the dashboard's various elements.²² The Manual also references the required documents, policies, guidelines and standard operating procedures for each element.²³

3. IDEAL CLINIC - DOCUMENTS, POLICIES, GUIDELINES AND STANDARD OPERATING PROCEDURES

The latest and most encouraging developments in the quality and safety sphere have taken place under the Integrated Clinical Services Management component of the Ideal Clinic Realisation and Maintenance initiative.²⁴ Some of the more relevant aspects will be discussed. They will be presented, as they are found in the Ideal Clinic Manual (Version 17), classified by sub-components and the elements they consist of

3.1. CLINICAL GUIDELINES AND PROTOCOLS

***Sub-component 9** - Clinical guidelines and protocols: Monitor whether clinical guidelines and protocols are available, whether staff have received training on their use and whether they are being appropriately applied.²⁵*

3.1.1 PATIENT SAFETY INCIDENT REPORTING AND LEARNING

'Commitment for Ideal Clinic elements 56 – 57: The facility manages patient's safety incidents effectively to ensure that harm to patients is reduced.

²⁰ National Department of Health (2017c) 26.

²¹ National Department of Health, *Ideal Clinic Definitions, Components and Checklists*.

²² National Department of Health (2017) 1.

²³ National Department of Health, South Africa. Ideal Clinic South Africa. <https://www.idealclinic.org.za>.

²⁴ *Id.* 12.

²⁵ *Id.* 27.

56. National Guideline for Patient Safety Incident Reporting and Learning is available

57. Patient safety incident records comply with the National Guideline for Patient Safety Incident Reporting and Learning²⁶

Facilities are expected to have the National Guideline for Patient Safety Incident Reporting and Learning. A facility/district specific Standard Operating Procedure (SOP) must be developed using the 'National Guideline for Developing a Facility Specific SOP for Patient Safety Incidents Reporting and Learning'. A staff member must be assigned to ensure compliance with the facility's SOP to manage Patient Safety Incidents. Patient Safety Incident Management forms need to be completed whenever a patient safety incident occurs. Records need to be kept up to date, this includes a patient safety incidents register and monthly statistics on patient safety incidents. Steps must also be taken to identify system failures, by analysing the data collected and kept in these records.

3.1.2. NATIONAL GUIDELINE FOR PATIENT SAFETY INCIDENT REPORTING AND LEARNING

3.1.2.1. INTRODUCTION

The National Guideline for Patient Safety Incident Reporting and Learning was published in April 2017.²⁷ The Guideline was developed to comply with the World Health Organisation's recommendation that all countries should have an effective and sustainable National-level Patient Safety Incident Reporting and Learning System.²⁸ It was developed with the help of WHO consultants and the inputs received at a WHO

²⁶ *Id.* 29.

²⁷ National Department of Health *National Guideline for Patient Safety Incident Reporting and Learning* (2017a). While there are adverse event reporting systems in South Africa that deal with specific issues such as medication, immunisation, infectious diseases and so on, there is, as yet, no formal adverse event reporting system in South Africa dealing with clinical errors. This is the first step towards such a standardised national system.

²⁸ World "WHO draft guidelines for adverse event reporting and learning systems" *From Information to action* (2005); Larizgoitia et al. "WHO Efforts to Promote Reporting of Adverse Events and Global Learning" *J Public Health ResJournal of Public Health Research* (2013) 2 e29.

inter-regional consultation workshop on patient safety incident reporting and learning systems in Africa and Asia Pacific, held in Colombo, Sri Lanka, in March 2016.²⁹ Its development was also informed by the Ministerial Medico-Legal Committee, which was established in 2014. The Committee held a Medico-Legal Summit on 9 and 10 January 2015, where one of the recommendations was the implementation of a uniform National Reporting System of Adverse Events.³⁰

The guideline provides a very rudimentary introduction to patient safety incidents (PSI) and outlines the need for a national reporting system.³¹ It aims to give direction regarding the management of PSI reporting, feedback to affected parties and learning to prevent patient harm. In essence, it describes a national standardised system for managing PSIs.

3.1.2.2. PRINCIPLES

The guideline briefly sets out some of the principles that should underlie this system. It should be managed according to these principles:³²

- Just culture – Staff that report patient safety incidents should be free from fear of victimisation solely for reporting PSIs. The Just culture supports a ‘learning organisation’ that investigates incidents instead of blaming individuals.
- Confidentiality – The identities of the patient, reporter or institution should be kept anonymous and only known to staff directly involved in the management of a PSIs as well as managerial staff that are indirectly involved in the further management of the incident.
- Timely – Reports are analysed promptly. Once the organisation is notified of PSIs, investigation should be conducted immediately.

²⁹ World “WHO Inter-regional consultation on patient safety incident reporting and learning systems in Africa and the Asia Pasific regions: 22-24 March 2016, Colombo, Sri Lanka: meeting report” (2016).

³⁰ Team, *Declaration Medico-Legal Summit*, 2016.

³¹ National Department of Health (2017a).

³² *Id.* 11.

- Responsive – Participating organisations commit to the immediate implementation of recommendations.
- Openness about failures – Patients and their families/support persons are offered an apology and told what went wrong and why.
- Emphasis on learning – The system is oriented towards learning from mistakes and consistently employs improvement methods for achieving this.

3.1.2.3. WHO MINIMUM INFORMATION MODEL

The South African system will be administered in line with the WHOs, lowest tier Minimum Information Model.³³ This model refers to ‘a minimal common architecture for the core concepts considered to be essential for information and comparison purposes of patient safety incident reports, while additional concepts can be included and customized based on every context’.³⁴ The data categories under this Model are: incident identification; incident type; incident outcomes; resulting actions; and reporter.

3.1.2.4. MANAGEMENT OF PSIs

The following steps are indicated for the management of PSIs:³⁵

Step 1: Identifying PSIs –

Mechanisms to detect PSIs include: Reporting by health professionals; retrospective patient record review; focus teams; external sources; follow-up record review; surveys on patients’ experience of care; safety walk rounds; data from information systems; and research studies.

Step 2: Immediate action taken –

Immediate actions to mitigate the harmful consequences of the incident are taken: providing immediate care; making the situation safe to prevent immediate recurrence; gathering basic information from staff; notify security if applicable.

³³ *Id.* 12.

³⁴ World “Minimal information model for patient safety incident reporting and learning systems: user guide” (2016). World Health Organization, Minimal Information Model for Patient Safety. http://www.who.int/patientsafety/implementation/information_model/en/.

³⁵ National Department of Health (2017a) 15.

Step 3: Prioritisations –

A standardised, objective measure of severity should be allocated to each incident. The Severity Assessment Code (SAC) should be used to prioritise all notifications: SAC 1 (serious harm or death occurred); SAC 2 (moderate harm); and SAC 3 (minor or no harm).

Step 4: Notification –

Data should be recorded and analysed in order to improve patient safety: Record keeping (South Africa will employ structured reporting); incident notification to management; and initial notification to patient (disclosure).

With regard to disclosure, the guideline states:

‘Initial disclosure should take place as early as possible after the incident. Information should be provided to the patient and family in a clear and simple language, and the occurring error recognised and explained. The provider should share with the patient and/or their family or carer what is known about the incident and what actions have been taken to immediately mitigate or remediate the harm to the patient. The discussion should focus on the condition as it currently exists i.e. no assumptions and uncertain future actions should be communicated at this stage. It is the obligation of the health care organization to provide support or assistance as required to patients, family and health professionals involved. Patients, family and healthcare professionals often also require psychological support.

Disclosure involves health care providers as well as patients. Depending on the severity and impact of the PSI, people to be called and the venue for disclosure should be carefully decided on. The health care provider at the service site may disclose some of the less serious PSI, such as close calls. More serious PSIs may be communicated in designated areas such as the duty room or manager’s office.

The following, depending on careful assessment of circumstances, may be communicated to the patient or representative: the facts of the harm and incident known at that time; steps taken for ongoing care of the patient; an expression of sympathy by the health care provider or organisation; a brief overview of the investigative process that will follow including time lines and what the patient should expect from the analysis; an offer of future meetings as well as key contact information; time for patients and or representative to ask questions; where necessary offer practical and emotional support; plan for future investigation and treatment required; remedial action taken; the relevant health professional involved can at this stage convey their apology in a sincere manner; systems to support the health professionals involved should also be in place.³⁶

Step 5: Investigation –

All notified incidents require investigation at an appropriate level. The SAC applied in the prioritisation stage guides the level of investigation. PSIs should be investigated by means of systems Root Cause Analysis. In cases where staff was found to be the cause of the incident a Just Culture should be applied (reference is made to Marx’s classification and Reason’s algorithm).³⁷

Investigations will be concluded under the following circumstances:

‘Investigation of PSIs should be concluded within 60 working days from the occurrence of the incident. A PSI is viewed as concluded under the following circumstances: The case has been investigated and the committee for review of PSIs has concluded an outcome with recommendations; written confirmation has been received that the establishment is being sued and therefore the case will be further managed by a court of law; the case has been referred to the Labour Relations section for further management.

³⁶ *Id.* 21.

³⁷ *Id.* 24.

In the last two instances although the case will be closed on the PSI Management Reporting System, the outcome of the investigations conducted by the relevant organisations/sections should be noted in the PSI reporting form once it has been concluded by either a court of Law or the Labour Relations section.³⁸

One can foresee problems with this proposed investigation process. Some investigations may be so complex that 60 days would be an arbitrary, unreasonable timeframe. Although, a swift conclusion would be desired and appropriate for straightforward cases, an inadequate period for investigation may impact the viability and reliability of more intricate investigations. Another concern would be, the fact that legal proceedings would seem to halt investigations. Legal proceedings could take years to be finalised and the limitations of courts as a patient safety investigative forum must be considered. A court of law is primarily concerned with adjudicating individual behaviour, determining whether damage was negligently caused, so as to necessitate compensation. It is the antithesis of a system approach to error and could only be tangentially informative when it comes to identifying defects in patient safety. Just culture precepts and confidentiality (without legislative protection) would also be defeated by an adversarial court process, further impeding the transparency required during safety-centred investigations. It is my submission that concurrent safety investigations should at a minimum be undertaken, regardless of external processes. This would at least signal a real intention on the part of management to learn from errors.

Step 6: Classification –

A uniform classification system according to the Minimal Information Model. All PSIs should be classified according to the following classes: agents (contributing factors); incident type; and incident outcome.³⁹

³⁸ *Ibid.*

³⁹ *Id.* 25.

Step 7: Analysis –

Data should be analysed and recommendations for change must be made and implemented. There are three indicators to monitor PSIs: PSI case closure rate; SAC 1 incident reported within 24 hours rate; and PSI case closure within 60 working days rate. The data for these indicators should be collected from the PSI registers that are completed on a monthly basis.

Step 8: Implementation of recommendations –

Recommendations from the investigations and reviews should be implemented to ensure the development of better systems to ensure improved practices. Patient Safety committees at various levels in the health system are responsible for ongoing monitoring that is required to ensure recommendations are addressed in a timely manner and to evaluate the success of any action taken to achieve improvement.

Step 9: Learning –

The fundamental role of PSI reporting systems is to enhance patient safety by learning from failures of the health-care system. Reporting can lead to learning and improved safety through: the generation of alerts regarding significant new hazards; feedback; and analysing reports.

The Guideline indicates that the patient is entitled to feedback or post-analysis disclosure:

‘Achieving a culture of patient safety requires open, honest and effective communication between the health care providers and patients. It is important that all avenues related to the occurrence of adverse events be fully investigated and made known to the patient, relatives or legal representative/s. Giving wrong information is dangerous and where there is suspicion of litigation, the facility should consult the legal representative of the provincial health department.’⁴⁰

⁴⁰ *Id.* 28.

The Guideline, clearly indicates that disclosure is tempered by litigation concerns.⁴¹ It notes that leadership or the legal counsel has to decide what information should be disclosed. It would be interesting to see how the practical application of this proposal aligns with the ideals, especially in light of the serious burden of malpractice litigation currently facing provincial health departments.

3.1.2.5. PATIENT SAFETY COMMITTEES

These steps are to be overseen and managed by Patient Safety Committees at different levels throughout the health system.⁴² Hospitals, Community Health Centres, sub-district and district offices, provincial offices and national offices are expected to establish Patient Safety Committees. The Guideline gives direction on the terms of reference of the Committees, as well as who the members of the committees can be. It also requires committees to adopt facility specific Standard Operating Procedures (SOP) for PSI reporting and learning. The SOP must be developed using the National Guideline for Developing a Facility Specific SOP for Patient Safety Incidents Reporting and Learning. This document is basically a template of the Guideline and includes a number of standardised forms as annexures.

The Patient Safety Committees will be critical to the successful implementation of the proposed patient safety policy.

3.1.3. CLINICAL AUDIT

‘Commitment for ideal clinic element 58 – 60: Quality clinical care is maintained by conducting regular clinical audits.

58. National Clinical Audit Guideline is available

59. Clinical audits are conducted quarterly on priority health conditions

60. Clinical audit meetings are conducted quarterly in line with the guidelines⁴³

⁴¹ *Ibid.*

⁴² *Id.* 31.

⁴³ National Department of Health (2017) 30.

Facilities are expected to have the National Clinical Audit Guideline and the Implementation Guideline. Quarterly clinical record audits are to be conducted on the files of patients diagnosed with priority health conditions. These audited results must be collated and analysed. Areas identified for improvement must be added to the facility's quality improvement plan and implemented within the agreed upon timeframe. Facilities have to discuss the implementation outcomes at quarterly Clinical audit meetings.

3.1.4. NATIONAL CLINICAL AUDIT GUIDELINE

The Guideline confirms the importance of clinical audit and the role it plays in improving patient care.⁴⁴ Indeed, the Policy on Quality in Health Care for South Africa (2001) and the abbreviated version (2007), required that all health professionals in health facilities participate in Clinical Audit.⁴⁵ However, the Guideline notes that findings of NCS baseline audit and information extracted from provincial quarterly reports continuously demonstrate that clinical audits are either not done, or only done in occasionally on some priority health programmes.⁴⁶ Thus, resulting in an obvious lack of informed quality improvement projects. The Guideline, still in draft form, was published in October 2016 to try and remedy the situation.⁴⁷

The Quality Assurance manager/coordinator should shoulder overall responsibility for the management of clinical audit in the facility. The Quality Assurance manager plays a crucial role in this regard, and should:

'Empower health care providers to conduct, plan, implement and sustain a facility-wide clinical audit programme; Ensure clinical audit meetings take place; Encourage, guide and support health care providers in all clinical disciplines on the process and areas for clinical audit; Establish clinical audit teams; Monitor clinical audit processes on a frequent basis; Keep records of clinical audits, its

⁴⁴ National Department of Health *1st Draft national clinical record audit implementation guideline for primary health care facilities* (2017b); National Department of Health *A guideline for clinical audit in public health facilities (Draft)* (2016).

⁴⁵ Health (2007).

⁴⁶ National Department of Health (2016) 5.

⁴⁷ National Department of Health, South Africa. Ideal Clinic South Africa. <https://www.idealclinic.org.za>.

findings, the interventions and the impact thereof; Report to senior management on the clinical audits conducted and the outcome thereof.⁴⁸

Perhaps, most importantly, as it relates to the current discussion, the Quality Assurance manager must 'develop links to information sources on quality of care, such as complaints, litigation, critical (adverse) incident reporting and risk management, so that lessons can be learned and clinical audit activity can be refined.'⁴⁹

The Manager of Chief Executive Officer of the health facility also has an important role to play in creating an environment that promotes clinical audit. However, as the Guideline indicates, 'the real success of any clinical audit hinges on the commitment, experience and expertise of the Clinical Manager.'⁵⁰ Clinical audit and quality improvement interventions should form part of the key performance areas of all the relevant Clinical Managers in the facility. The clinical manager should attend all clinical audit meetings and present to the health facility's Quality Assurance committee the following: Information on clinical audit activities taking place; quality improvement interventions that are recommended and undertaken; and the obstacles that may affect the successful implementation of any quality improvement intervention.⁵¹

A 1st Draft National Clinical Record Audit Implementation Guideline for Primary Health Care Facilities was published in July 2017.⁵²

Sub-component 12 - Patient Experience of Care: Monitor whether an annual patient experience of care survey is conducted and whether patients are provided with an opportunity to complain about or compliment the facility and whether complaints are managed within the prescribed time

⁴⁸ *Id.* 18.

⁴⁹ *Ibid.*

⁵⁰ *Id.* 19.

⁵¹ *Ibid.*

⁵² National Department of Health (2017b).

3.1.5. FEEDBACK MANAGEMENT

'Commitment for Ideal Clinic elements 86 and 89: Ensure that patient's complaints/compliments/suggestions are attended to within the prescribed time frame.

86. The National Guideline to Manage Complaints/Compliments/Suggestions is available

87. The complaints/compliments/suggestions records compliance with the National Guideline to Manage Complaints/Compliments/Suggestions

88. 90% of complaints received are resolved

89. 90% of complaints received are resolved within 25 working days.⁵³

Facilities must obtain the National Policy to Manage Complaints, Compliments and Suggestions. A facility or district specific Standard Operating Procedure (SOP) must be developed using the National Guideline for Developing a Facility Specific SOP to Manage Complaints, Compliments and Suggestions. A staff member must be assigned to ensure compliance with the facility's SOP and to ensure that the procedure to manage complaints, compliments, and suggestions is followed. Records must be kept up to date in accordance with the policy. These records must be analysed to identify trends in system failures, that can then be added to the facility's quality improvement plan.

3.1.6. NATIONAL GUIDELINE TO MANAGE COMPLAINTS, COMPLIMENTS AND SUGGESTIONS IN THE HEALTH SECTOR OF SOUTH AFRICA

The Patients' Right Charter and the National Health Act make provision for the right to complain, to have that complaint investigated and to receive a full response.⁵⁴ The Guideline, published in April 2017, seeks to uphold that right by providing information

⁵³ National Department of Health (2017) 42.

⁵⁴ Health (1999) 1; S 18, 78 and 81A(1) of the National Health Act 61 of 2003.

to the public on how to file a complaint, compliment or suggestion, and what response they can then expect.⁵⁵ It also provides guidance to the health sector on how to manage complaints and harness their information to inform strategies to improve the quality of health services. The establishment of the OHSC is perhaps, the main driving factor, since it necessitates an efficient and effective national standardised complaints management system that can deliver on the higher demands set by the Health Ombud. In light of this fact, as the Guideline notes, it has become imperative to improve the overall management of patient feedback.⁵⁶

The Guideline can be traced back to April 2003 and has gone through a number of revisions. It was also published as a National Protocol in August 2014. A decision to revise the Protocol to become a National Guideline was triggered by reports of health establishments' poor feedback management from the Auditor General, Department of Public Service and Administration, Department of Public Service and Administration and OHSC in 2015.⁵⁷

The key objectives that underlie the Guideline are:⁵⁸ to respect the patient's right to complain or give compliments/suggestions; to resolve problems and satisfy the concerns of the patient or their families/supporting persons; to provide a simple complaints, compliments and suggestions procedure everybody can understand; to provide health service managers with a means to extract lessons on quality and to subsequently improve services for patients; to ensure fairness for staff and patients alike; to strive for honesty and thoroughness; to build staff morale.

Another one of the key objectives, pertinent to this discussion, is:

'To avoid unnecessary litigation: Long delays in resolving complaints often lead to great frustration and to subsequent litigation. Unnecessary litigation as a means

⁵⁵ National Department of Health *National guideline to manage complaints, compliments and suggestions in the health sector of South Africa* (2017).

⁵⁶ *Id.* (Preamble).

⁵⁷ *Id.* (Acknowledgments).

⁵⁸ *Id.* 1.

to resolve a complaint is not cost-effective, thus innovative ways of avoiding such cases should at all times be sought.⁵⁹

The Guideline notes that patients have particular reasons for making their grievances known, such as:⁶⁰ to get acknowledgement; to receive an apology; to receive an explanation; to prevent recurrence; to ask for compensation or special consideration; and to seek retribution (although, uncommon).

3.1.6.1. CLINICAL GOVERNANCE, COMPLAINT MANAGEMENT AND PATIENT SAFETY INCIDENT MANAGEMENT

In accordance with the guideline, complaints management forms an integral part of clinical governance.⁶¹ As it is a mechanism that seeks to ensure that patients receive safe, accountable and effective care.

The Guideline notes that complaints are often the first indicator of a PSI, making them a very important source of safety information.⁶² Therefore, an effective complaints management system is considered essential. It must be able to assist in identifying the severity of an incident, as well as whether the incident should be classified as a PSI. Furthermore, the Guideline indicates that an effective and responsive system can be utilised to avoid the complaint from developing into litigation.

If a complaint is classified as a PSI or it leads to litigation, 'the further management thereof (e.g. investigation and resolution) will be done through procedures as set out in the National Guideline for Patient Safety Incident Reporting and Learning and structures set up at provincial level to manage cases of litigation respectively'. The Guideline further specifies that, if legal proceedings are instituted, 'the further investigation of the complaint as a complaint will cease immediately, because any report emanating from

⁵⁹ *Id.* 2.

⁶⁰ *Id.* 3.

⁶¹ *Id.* 8.

⁶² *Id.* 9.

such investigation could lead to the use thereof as evidence in a court of law, thus the case becomes *sub-judice*.⁶³

3.1.6.2. SYSTEM TO LODGE AND MANAGE COMPLAINTS

The Guideline sets out a three-stage system for managing complaints:⁶⁴

Stage 1: Aims to resolve the complaint at the health establishment, i.e. at the point of service and as quickly and amicably as possible. Health establishments should resolve complaints in less than 25 working days to allow for the escalation of complaints to district or provincial offices.

Stage 2: Aims to review and investigate complaints that were not resolved to the satisfaction of the patient or their families/supporting persons during Stage 1. This stage ensures that complaints are escalated to the district manager or provincial head of health.

Stage 3: Aims to review and investigate complaints that were not resolved to the satisfaction of the patient or their families/supporting persons during Stages 1 and 2, that warrant the attention and intervention of other institutions. Once the time frame for resolving complaints has lapsed, the patient or their families/supporting persons are entitled to approach other institutions. It is at this stage that the OHSC or the legal system comes into play.

Complaints that directly relate to the professional conduct of health professionals can be lodged directly at the relevant Professional Council or Professional Board, or can be referred to these entities by the relevant health establishment during Stage 1, 2 or 3.⁶⁵

⁶³ *Ibid.*

⁶⁴ *Id.* 10.

⁶⁵ *Id.* 13.

3.1.6.3. STEPS TO EFFECTIVELY MANAGE COMPLAINTS

The manager of a health establishment will be responsible and held accountable for ensuring complaints are managed according to the guideline and the following three steps:⁶⁶

Step 1: enabling complaints – arrangements that enable people to lodge complaints to health establishments

Step 2: responding to complaints – ensuring that complaints are dealt with in a prompt, objective, caring and confidential manner; and

Step 3: accountability and learning – using complaints to demonstrate accountability and stimulate organisational improvement

3.1.6.4. RESOLUTION OF COMPLAINTS

According to the Guideline, once the investigation of a complaint has been concluded the patients or families/supporting persons should be redressed, in order to reach a fair and reasonable resolution in an amicable manner.⁶⁷

The responses or remedies set out in the Guideline include:⁶⁸

- An apology, explanation or an acknowledgement of responsibility;
- Remedial action that may include: the review or changing of a decision on the service or care provided to an individual patient; revising published material; revising a procedure to prevent the recurrence of a wrong event or incident; and the training of staff members or strengthening of their supervision; or any combination of the above.

⁶⁶ *Ibid.*

⁶⁷ *Id.* 16.

⁶⁸ *Ibid.*

3.1.6.5. TYPES OF RESOLUTION

A complaint is viewed as having been resolved under the following circumstances:⁶⁹ the patient is satisfied or redress is done; when a complaint proceeds to litigation; or when a complaint is a PSI and should be managed as such.

3.1.6.6. IDENTIFYING SYSTEM FAILURES AND REPORTING

Health establishments must follow trends of the types of complaints received, to identify the most common system failures.⁷⁰ Provision is made for the categorisation of complaints (e.g. staff attitude, patient care, hygiene and cleanliness etc.). Once a significant system failure has been identified the root cause should be identified and addressed in order to improve the quality of care.

Health establishments should on a quarterly basis submit reports to their district/provincial office, on all the complaints they have received and resolved. Provincial offices should submit reports quarterly to the National office.⁷¹

3.1.6.7. IMPLEMENTATION BY COMPLAINT, COMPLIMENT AND SUGGESTION COMMITTEES

All health establishments, district offices, provincial offices and national office should have a Complaint, Compliment and Suggestion Committee (CCSC).⁷² The Committee's main objective is to oversee the effective management of complaints, compliments and suggestions

3.1.6.8. CONCLUSION

The three (very recently published) guidelines, discussed above, are certainly to be welcomed and represent a very encouraging development in South Africa's journey

⁶⁹ *Id.* 17.

⁷⁰ *Id.* 19.

⁷¹ *Id.* 20.

⁷² *Id.* 25.

towards safer care. Patient safety is finally beginning to receive recognition and serious attention from policymakers. We are still at a very early stage of our journey and only time will tell how these guidelines and policies get put into practice. As such, it is difficult to evaluate these interventions. Nevertheless, some concerns have been noted.

Clinical audits have been included in policy documents before, but have rarely been conducted. This may have been due to management and leadership issues, resource and capacity constraints, or a lack of effective oversight and accountability. Will the factors, which prevented compliance with the previous policies be adequately addressed, or will the new guideline remain nothing more than a 'good idea on paper'?

The same concerns apply to the management of complaints. Complaints' management has also long been required, but has generally been neglected. This neglect might have contributed to dissatisfied patients, unresolved systemic problems and even litigation, wasting valuable resources. One hopes that the new guidelines, especially the one on PSIs, will not encounter the same disregard. It will be interesting to see what steps, if any, are taken to ensure that they do not.

Other concerns relate to the completeness of the regulatory and legislative framework surrounding the Patient Safety Incident Reporting and Learning guideline, as well as capacity and resource constraints.

Should there perhaps, be assurances in place to protect individuals who report safety information, either from discipline within the organisation or civil/criminal liability? Would staff be willing to come forward in the absence of such protection. Superficial references to a just culture will not be enough to allay these fears. It may be worth considering the approaches that have been adopted by aviation and other industries in this regard.

The guideline makes provision for an incident reporting system, but it remains to be seen how it will be effectively managed or how fragmentation will be prevented.

The OHSC regulations, which are not yet in force, very loosely prescribe how such a system should look and function.

It is essentially left up to the discretion of health establishments. It is uncertain how oversight and enforcement will work, or how such a system's effectiveness will be demonstrated. This is an area that may require more consideration. The OHSC or another specialised entity or organisation may be better placed to centrally administer such a system. Legislative intervention, exclusively aimed at establishing a standardised national reporting system and which would specifically provide for patient safety related efforts, with an oversight and accountability mechanism, should be considered. These systems require committed leadership and a strong safety culture to succeed, interventions aimed at fostering both should not be ignored.

The management of the PSI system is currently seemingly entrusted to Patient Safety Committees at various spheres of the health system. These committees will be made up of designated members of staff. It is not clear, whether this means that already overworked staff will be expected to manage PSIs, in addition to their other responsibilities. The work of these committees, would be time consuming, resource intensive and require special training and expertise. It is unclear how such a system will be actualised and maintained in the absence of additional formal regulatory structures and incentives.

These are serious concerns, which would significantly impact the sound operation and ultimate effectiveness of such a system. Hopefully, these matters will be addressed once the policies and proposed interventions are translated into action, otherwise the guidelines would just pay lip service to real improvement.

That being said, at least patient safety is on the agenda.

3.1.7. ADDITIONAL GUIDELINES

In addition to the Guidelines discussed, there are other relevant documents, policies, guidelines and standard operating procedures that would indirectly assist in the

provision of safer care:⁷³ National Quality Improvement Guideline; National Cleanliness Guideline; National guidelines on priority health conditions; ICSM compliant package of clinic guidelines; protocol on resuscitation; National Policy on Infection Prevention and Control; National Guideline for the management of sharps, safe injection practices, patient care equipment and wound care; National Patient Experience of Care (PEC) Guideline; National Policy for the Management of Waiting Times; Standard Operating Procedure for the management and safe administration of medicines; Staff satisfaction survey; Standard operating procedure for managing general and health care risk waste; District Health Management Information System Policy; and National Referral Policy.

4. CONCLUSION

The Ideal Clinic programme is the Department of Health's internal quality improvement initiative. It seeks to transform healthcare facilities to ensure that they conform to the norms and standards required for the successful implementation of the government's National Health Insurance scheme. These norms and standards will be monitored and enforced by the Office of Health Standards Compliance. Although the details have not been set out, the OHSC will supposedly also have an accreditation function. Meaning that only accredited facilities that are found compliant will be able to contract and provide services in the NHI.

This raises a number of concerns. Chief of these, is the conflict of interest that may arise if the Office fails to fulfil its mandate in a sufficiently independent manner, free from governmental and political interference. It may face significant pressures to conduct their affairs pursuant to certain external objectives and agendas.

Since the Office will play such a crucial role in assessing healthcare service providers and seeing as its findings would have huge financial and other consequences, it is critical that the Office remains above reproach and unhindered in its efforts. This includes providers in the private-, as well as providers in the public sector. If for instance,

⁷³ National Department of Health, South Africa. Ideal Clinic South Africa. <https://www.idealclinic.org.za>.

political interference meant that public providers could more easily pass inspections and be found compliant, poor quality and safety will continue to plague the health system and it will remain a barrier to care.

There needs to be a strong commitment to improvement and real accountability. A huge responsibility rests on the shoulders of the OHSC. If their power is abused to further political ideals, e.g. withholding accreditation in the private sector to unfairly diminish competition, thus favouring comparatively substandard public facilities, to unreasonably fast-track NHI implementation, it could have disastrous consequences.

Any undue influence could also, to a lesser extent, negate the vision of the OHSC. If the benchmark for compliance with standards is too low or not adequately enforced, improvements will never be realised. If the Ideal Clinic manual and dashboard becomes no more than a checkmark-exercise, with no real-world results, it would be pointless.

Research should be conducted to determine whether the achievement of Ideal Clinic status, actually leads to better health outcomes. It should be ascertained if and how well the clinical policies, protocols, and guidelines contribute to quality and safer care. This process must be transparent. It may very well be that this dashboard/checklist, corresponds to other checklists employed in patient safety, in that the underlying culture and commitment proves to be the decisive factor in its successful implementation.

Reading through the vital elements, one wonders why this is not already the norm, some of the requirements are the absolute basics. If the bar is this low (and rarely achieved), one begins to understand how big the quality chasm must be.

(The 10 Vital elements are: 1. Sharps are disposed of in impenetrable, tamperproof containers; 2. Sharps containers are disposed of when they reach the limit mark; 3. There is at least one functional, wall-mounted room thermometer in the medicine room/dispensary; 4. The temperature of the medicine room/dispensary is recorded daily; 5. The temperature of the medicine room/dispensary is maintained within the safety range; 6. Cold chain procedure for vaccines is maintained; 7. 90% of the

medicines on the tracer medicine list are available; 8. Resuscitation room is equipped with functional, basic resuscitation equipment; 9. Emergency trolley is restored daily or after each use; 10. Oxygen cylinder with pressure gauge is available in resuscitation/emergency room.)

It seems as though it may be possible to check off many of the elements without much difficulty and if this is done in the absence of real commitment to improvement, patients will continue to have less than ideal experiences in the Ideal Clinics.

Having considered the legal and policy interventions that have been aimed at improving the quality and safety of care in the South African healthcare system, the focus now turns to the medical malpractice system. As suggested earlier, the two systems are (in some very important respects) interrelated and should not be considered in isolation.

In essence, both systems seek to meet the needs of patients. It can be argued that keeping patients from harm, might be their most important commonality in this regard. Yet, both systems have often failed to support and further this central objective. In fact, tensions between the systems may have hindered, instead of helped. If one accepts that patients, and particularly their safety, should ultimately be the principal concern of both systems, one begins to realise that they have not been aligned to meet this objective. Unsound practices may have been incentivised by this misalignment, to the detriment of safety in particular. In addition, the lack of congruity exaggerates inherent deficiencies and problems in both systems.

This chapter provides a broad overview of the current South African medical malpractice situation. It considers the extent, consequences and possible causes thereof. The overview serves to provide a backdrop and seeks to contextualise recent developments, which have included calls for reform (discussed in the next chapter).

CHAPTER 14. THE SOUTH AFRICAN MEDICAL MALPRACTICE SITUATION

1. INTRODUCTION

In recent years South Africa has seen a sharp increase in medical malpractice litigation.¹ A number of factors have likely contributed to this increase and both the public and private healthcare sectors have been adversely affected.² It seems as though the proliferation of claims for the adverse consequences of medical intervention, which has been a rising global trend, has eventually reached our shores (and our courts).³ Not only has there been an increase in the frequency of claims, but the amounts that have been claimed have also risen significantly.

The Minister of Health has blamed the high costs of medical litigation on the legal profession, stating that doctors are being ‘unmercifully’ targeted by attorneys.⁴ Stakeholders in the medical fraternity have called for urgent action to be taken to address the issue. They share the view of the Minister that the increase in medical litigation poses a serious threat to the health system as a whole and have suggested that government intervenes by implementing ‘tort’ reform measures.⁵

2. THE EXTENT OF THE CURRENT MEDICAL MALPRACTICE SITUATION

The lack of accurate empirical information regarding the extent of medical malpractice (and the incidence of adverse events) in South Africa is problematic. This paucity of reliable data severely hinders any sound assessment of current conditions or perceived

¹ Pepper and Slabbert (2011) 6 *South African Journal of Bioethics and Law* 60.

² Oosthuizen and Carstens (2015).

³ Strauss *Doctor, patient and the law: a selection of practical issues* (1994) 243.

⁴ “Motsoaledi wages war against lawyers” *Medical Chronicle* 10 October 2011.

⁵ “Medical litigation: A national health crisis requiring urgent solutions” *Medical Chronicle* 7 November 2011.

trends. The underlying causes will, consequently, be hard to determine and harder to address. Informed debate and appropriate responses will remain elusive in the absence of concrete evidence. Vested interests may seize the opportunity presented by this information-vacuum and the crisis-narrative to advance their own agendas.

Nonetheless, media and other reports provide a general idea of the current medical malpractice situation.

2.1. HEALTH PROFESSIONS COUNCIL OF SOUTH AFRICA: THE INCIDENCE OF UNPROFESSIONAL CONDUCT CASES

Medical practitioners do not only have to contend with civil claims, they are also held accountable for unprofessional conduct by the HPCSA.⁶ The objective of a disciplinary inquiry of this nature differs from that of a civil claim, in that the focus is not on compensation for damages suffered by the patient, but rather on upholding the standards of the profession and protecting the interests of the public.⁷ This fact is also reflected in the disciplinary powers of the professional boards and the penalties that may be imposed by it.⁸ If found guilty of improper or disgraceful conduct a registered practitioner will be liable to one or more of the following penalties: a) A caution or a reprimand and a caution; b) suspension for a specified period from practising or performing acts specially pertaining to his or her profession; c) removal of his or her name from the register; d) a prescribed fine⁹; e) a compulsory period of professional service as may be determined by the professional board; or f) the payment of the costs of the proceedings or a restitution or both. Potential claimants often lodge complaints with the HPCSA with the purpose of determining their chances of success in a civil suit.

⁶ S 41 Health Professions Act 56 of 1974.

⁷ *Veriava v President, SA Medical and Dental Council* 1985 2 SA 293 (T). Where the court stated that: "The council is thus truly a statutory *custos morum* of the medical profession, the guardian of the prestige, status and dignity of the profession and the public interest in so far as members of the public are affected by the conduct of members of the profession to whom they had stood in a professional relationship."

⁸ S 42(1) Health Professions Act 56 of 1974.

⁹ The maximum fine that may be imposed is R70 000. Health Professions Act (56/1974): Regulations: Fines which may be imposed by a committee of enquiry against practitioners found guilty of improper or disgraceful conduct (GN632 in GG33385 of 23 July 2010).

The disciplinary proceedings and its outcome are used to test the waters for further prospective litigation.

The HPCSA has indicated that more than 200 medical practitioners were found guilty in 306 cases of malpractice between 2008 and 2012.¹⁰ The council issued 283 fines and 137 suspensions to doctors for misconduct during the same period.¹¹

Annual reports published by the HPCSA indicate that the Council has received between 2600-3000 complaints per year consistently since 2010/2011.¹² Suspensions have risen slightly over the period, from 27 in 2010/11 to 73 in 2014/15. In 2014/15 there were also 57 fines, 102 admission of guilt fines, and 4 erasures.¹³ The Office of the Ombudsman was established to mediate cases of minor transgressions. The average turnaround time for the finalisation of complaints in the Office of the Ombudsman is 97 days.¹⁴ The Medical and Dental Professions Board accounts for 92% (622) of the complaints. In 2015/16 the Ombudsman finalised 82% of the 676 complaints referred for mediation. The majority of complaints related to fees (53%), followed by complaints relating to communication (29%) and those related to medical reports (18%).

There are a surprisingly low number of complaints if one considers that there are more than 40 000 medical practitioners alone registered with the HPCSA.¹⁵ This could be interpreted as meaning practitioners very infrequently make themselves guilty of unethical conduct or that very few instances of unethical conduct get reported to the HPCSA. An investigation into the frequency and categories of unprofessional conduct, as well as the sanctions imposed between 2007-2013, found that:

¹⁰ "248 doctors found guilty of incompetence" Times Live (2012-10-19)

<http://www.timeslive.co.za/Feeds/inethealth/article6946309.ece> (accessed on 30 April 2014).

¹¹ HPCSA Annual Report 2010/2011 (2010) 27; HPCSA Annual Report 2011/2012 (2011) 33.

¹² HPCSA Annual Report 2014/2015 (2015) 39.

¹³ HPCSA Annual Report 2014/2015 (2015) 39.

¹⁴ HPCSA Annual Report 2015/2016 (2016) 30.

¹⁵ "Statistics" Health Professions Council of South Africa (2017-08-14)

<http://www.hpcsa.co.za/Publications/Statistics>.

‘Relatively few medical practitioners (between 0.11% and 0.24%) are annually found guilty of unprofessional conduct. The annual average number of guilty decisions per guilty medical practitioner ranged between 1.29 and 2.58. The three most frequent sanctions imposed were fines between ZAR10 000 and ZAR15 000 (28.29%), fines between ZAR1 000 and ZAR8 000 (23.47%) and suspended suspensions between 1 month and 1 year (17.37%). The majority of the unprofessional conduct involved fraudulent behaviour (48.4%), followed by negligence or incompetence in evaluating, treating or caring for patients (29%).’¹⁶

Nortjé and Hoffmann draw attention to the concerning fact that the HPCSA almost exclusively imposes financial or suspended suspension period penalties.¹⁷ The authors argue that ethical awareness training for the transgressors would be more appropriate and aligned with the Council’s mandate:

‘The implication is that ethical misconduct may increasingly be regarded by healthcare professionals as merely a business/financial risk but not primarily as an ethics and integrity matter. As a result, one potential way that healthcare professionals manage this risk could be to merely increase their contributions to a professional liability insurance plan. However, this reaction would not benefit society at large and patients in particular. Rather, the process of changing behaviour *inter alia* should always include reflection and opportunities to actively challenge healthcare professionals to develop and mature their moral reasoning and ethical conduct skills.’¹⁸

¹⁶ Hoffmann and Nortjé “Patterns of unprofessional conduct by medical practitioners in South Africa (2007–2013)” *South African Family Practice* (2016) 58 108.

¹⁷ Nortjé and Hoffmann “Seven year overview (2007–2013) of ethical transgressions by registered healthcare professionals in South Africa” *Health SA Gesondheid* (2016) 21 46.

¹⁸ *Ibid.*; Nortje and Hoffmann “Ethical misconduct by registered psychologists in South Africa during the period 2007–2013” *South African Journal of Psychology* (2015) 45 260.

Despite the relatively low number of complaints received and the fact that this number has stayed relatively stable over a number of years, the Council has still raised concerns about improper and unethical conduct on the part of the medical profession.¹⁹

The previous Registrar and Chief Executive Officer of the HPCSA, Dr Mjamba-Matshoba, is reported to have said that, an increase in medical errors was a big concern and that her office and the health department were investigating the situation.²⁰ In March 2012 the HPCSA launched an awareness campaign to educate the public and practitioners on their rights and responsibilities.²¹ This initiative was launched in response to some of the aforementioned developments.²² The acting CEO (now President) of the HPCSA, Dr Letlape, said a decline in levels of professionalism among healthcare practitioners and the increasing costs of medical negligence necessitated the need for greater public awareness of patients' rights and responsibilities when accessing healthcare.²³

These statements have been criticised by the South African Private Practitioners Forum and the South African Medical Association who have indicated that the awareness campaign would encourage litigation and lead to an increase in the practice of defensive medicine.²⁴ The Medical Protection Society has also strongly refuted the claim that a decrease in the levels of professionalism is to blame for the current situation, although

¹⁹ "Report medical malpractice – council" News24 (2012-03-19) <http://www.news24.com/SouthAfrica/News/Report-medical-malpractice-council-20120319>; "SA doctors incensed by 'ambulance chasing' campaign" Mail & Guardian (2012-04-17) <https://mg.co.za/article/2012-04-17-sa-doctors-outraged-by-ambulancechasing-campaign>.

²⁰ "248 doctors found guilty of incompetence" Times Live (2012-10-19).

²¹ HPCSA Media Statement: HPCSA embarks on health and human rights awareness campaign. (2012-03-19).

²² *Ibid.*

²³ "Patients 'need educating on rights, responsibilities'" Business Day (2012-08-08).

²⁴ "HPCSA's 'Report a doc' campaign likely to hike medical costs" Medical Chronicle (2012-05-07) <http://www.medicalchronicle.co.za/hpcsa%E2%80%99s-%E2%80%98report-a-doc%E2%80%99-campaign-likely-to-hike-medical-costs/> (accessed on 30 April 2014).

they agree that patients should be better educated about their rights and responsibilities.²⁵

Dr Letlape dismissed the profession's fears as 'hearsay and speculation':

'Litigation has nothing to do with optimal care. If you know the issues relating to your profession, keep up with your knowledge and know what constitutes the international clinical guidelines or protocols for management of particular illnesses in SA and stick to those, there is no problem. As long as you are treating according to what the reasonable doctor considers is best practice, that will be enough.'²⁶

The Council has come under severe criticism from both doctors and patients. These criticisms have cast doubt on the Council's ability to protect the public and guide the profession.²⁷ There are allegations that the Council has been politicised and that management failures have had detrimental consequences.²⁸ Practitioners have raised concerns about the poor service they receive, often having to wait months before they even obtain a response from the Council.²⁹ Patients are also dissatisfied with their dealings with the Council.³⁰ Many feel that the regulatory body unfairly protects

²⁵ Howarth et al. (2013) 103 *S Afr Med J* 453.

²⁶ "HPCSA's 'report a doc' campaign likely to hike medical costs" *Medical Chronicle* (04-2012) <https://www.medicalchronicle.co.za/hpcsas-report-a-doc-campaign-likely-to-hike-medical-costs/>.

²⁷ "Health Professions Council tried to stop exposure of Eastern Cape health crisis" *Daily Maverick* (2013-11-05) <http://www.dailymaverick.co.za/article/2013-11-05-health-professions-council-tried-to-stop-exposure-of-eastern-cape-health-crisis/> (accessed on 30 April 2014).

²⁸ Van Niekerk (2009) 99 *SAMJ: South African Medical Journal* 203. Also see the reply to this editorial comment by the (then) CEO of the HPCSA, Mkhize "HPCSA: A mess in the Health Department's pocket" *SAMJ: South African Medical Journal* (2009) 99 484.

²⁹ "HPCSA and Docs – A relationship on the rocks?" *Medical Chronicle* (2012-09-03) <http://www.medicalchronicle.co.za/hpcsas-and-docs-a-relationship-on-the-rocks/> (accessed on 30 April 2014); <https://www.dailymaverick.co.za/article/2013-10-31-slow-unresponsive-and-unconcerned-how-the-health-professions-council-hurts-patients/#.Wb5GKK2B1IA>; Bateman "Long-awaited autonomy in sight for SA's doctors" *SAMJ: South African Medical Journal* (2016) 106 7.

³⁰ De Viliers (2011) 22 *South African Family Practice*.

members of the medical profession.³¹ These feelings are exacerbated by the apparent inefficiencies with regard to professional conduct inquiries.³² Inquiries often take years to be resolved.³³ This not only affects patients who may have valid complaints, but most certainly the doctors involved as well. Potential claimants often lodge complaints with the HPCSA with the purpose of determining their chances of success in a civil suit. The disciplinary proceedings and its outcome are used to test the waters for further prospective litigation. Patients want someone to be held accountable in the event of unprofessional conduct and are adversely affected by the delays. Practitioners also have valid grievances about the time-consuming processes and the stress caused thereby.³⁴ The Supreme Court of Appeal addressed the disturbing state of affairs, noting that it reflects badly on the HPCSA and will affect the public confidence in the regulatory body.³⁵ The concerns are troubling, especially if one has regard for the immense importance of the HPCSA in its dual role as protector of the public and guardian of the profession.

2.1.1. MINISTERIAL TASK TEAM

On 10 March 2015, the Minister of Health, appointed a Ministerial Task Team to investigate allegations of administrative irregularities, mismanagement and poor governance at the HPCSA. On 25 October 2015, the Task Team presented their report to the Minister.³⁶

³¹ "HPCSA 'protecting' hypocritical oafs" Mail & Guardian (2013-08-02) <http://mg.co.za/article/2013-08-02-00-hspca-protecting-hypocratic-oafs> (accessed on 30 April 2014); "Health professionals smacked on the wrist" Mail & Guardian (2014-01-03) <http://mg.co.za/article/2014-01-02-health-professionals-smacked-on-the-wrist> (accessed on 30 April 2014).

³² Redelinghuys "A preliminary investigative system to disciplinary inquiries of the Health Professions Council of South Africa, with specific reference to Maxillo-Facial and Oral Surgery" (2013) 147. Where the author makes several proposals, after a detailed analysis of the preliminary investigative system.

³³ Roux v Health Professions Council of South Africa 2012 1 All SA 49 (SCA) [34].

³⁴ Schultz "Malignant persecution of doctors by the HPCSA." *S Afr Med J* (2011) 102 10.

³⁵ Roux v Health Professions Council of South Africa 2012 1 All SA 49 (SCA) [34].

³⁶ Team "Report of the Ministerial Task Team (MTT) to Investigate Allegations of Administrative Irregularities, Mismanagement and Poor Governance at the Health Professions Council of South Africa (HPCSA): a Case of Multi-System Failure" (2015) 1.

The background to the investigation was set out as follows:

‘There has been a progressive increase in the number of complaints made against the Health Professions Council of South Africa (HPCSA) by individual practitioners, professional associations, training institutions and other organizations. The complaints accused the HPCSA of poor communication, prolonged delays in processing applications for registration, unfair processes followed in professional conduct enquiries, and failure to provide guidance in resolving challenges affecting the health professions. The complaints against the HPCSA culminated in the submission of more than 30 anonymous letters (apparently by HPCSA staff) to the office of President of the HPCSA between November 2014 and January 2015, which alleged maladministration, irregularities, mismanagement and poor governance at the HPCSA.’³⁷

The Task Team concluded that the HPCSA was found to be in ‘a state of multi-system organisational dysfunction which is resulting in the failure of the organisation to deliver effectively and efficiently on its primary objects and functions in terms of the Health Professions Act 56 of 1974.’³⁸ They recommended that the Minister institute disciplinary and incapacity proceedings against the Registrar/CEO (Dr Mjamba-Matshoba), COO and General Manager of Legal Services. The report indicated that these individuals were unfit for office. The General Manager of Legal Services, who did not cooperate with the investigation, was deemed to be responsible for the dysfunctional system of professional conduct enquiries, which had prejudiced practitioners and the public.

The Task Team recommended that: an interim executive management team be appointed; incoming and future Councils of the HPCSA should undergo a structured induction process to ensure an understanding and appreciation by all its members of their legal and governance obligations; and the Minister should institute a full organisational review.³⁹

³⁷ *Id.* 7.

³⁸ *Id.* 11.

³⁹ *Ibid.*

On this last point, the Task Team proposed a new governance and administrative structure, stating that:

‘The time has come to review the value of the HPCSA after 15 years of its establishment. This report reveals deep systemic dysfunction of the organisation which was extended from a single professional board (as the South African Medical and Dental Council for medical and dental practitioners) to a mega-organisation of 12 professional boards. There is a lack of coherence and cohesion in this large dysfunctional multi-professional organisation.’⁴⁰

They recommended that the HPCSA be unbundled:

‘It is the view of the MTT that the best interests of the health system are not served by the current structure and organisation of the HPCSA. The MTT recommends that consideration be given to the unbundling of the HPCSA into at least two entities: the historic Medical and Dental Council (which constitutes a third of the current membership of the HPCSA) and a Health and Rehabilitation Council (for the rest of the professional membership of the HPCSA). These new Councils would join the South African Pharmacy Council, the South African Nursing Council and other autonomous councils in the Forum of Statutory Health Professions Councils.’⁴¹

The HPCSA initially ignored the recommendations, referring to them as: ‘advices or proposals and therefore not binding’. They wanted to set up an internal committee to investigate the complaints.⁴²

However, a new Council with Dr Letlape as President, was appointed in October 2015 and mandated to address all the matters raised in the Ministerial Task Team Report.⁴³

⁴⁰ *Id.* 68.

⁴¹ *Ibid.*

⁴² “HPCSA ignores recommendations of ministerial task team” Bhekisisa (2016-01-06) <http://bhekisisa.org/article/2016-01-06-hpcs-a-ignores-recommendations-of-ministerial-task-team>.

⁴³ “Media Statement: HPCSA’s actioning of the Ministerial Task Team recommendations” Health Professions Council of South Africa (2016-01-27)

In January 2016, the South African Medical Association (SAMA) released a press statement wherein they noted, with extreme concern, the reported intransigence of the Health Professions Council (HPCSA) in implementing the recommendations of the Ministerial Task Team. They were particularly concerned that the management of the HPCSA had failed to initiate the proposed structural reform process. They also declared their dismay for the fact that, several of the officials mentioned in the report had failed to resign. SAMA called on Dr Letlape, to transform the HPCSA in line with the recommendations of the report.⁴⁴

The HPCSA released a press statement in reply criticising SAMA, but also indicated that they were putting corrective measures in place and keeping the Minister abreast of their progress in addressing matters raised in the report.⁴⁵

SECTION27 has also voiced its concern about the lack of transparency around the progress that has been made around the implementation of the Ministerial Task

http://www.hpcsa.co.za/Uploads/editor/UserFiles/downloads/publications/Press_Release_2016/Media_Release_MTT.pdf.

⁴⁴ “Media Release: SAMA Calls on the Minister to take action regarding the HPCSA” South African Medical Association (2016-01-26) https://www.samedical.org/cms_uploader/viewArticle/211; Bateman (2016) 106 *SAMJ: South African Medical Journal* 7.

⁴⁵ “Media Statement: HPCSA’s response to the SAMA media statement dated 26 January 2016” Health Profession Council of South Africa (2016-01-27) http://www.hpcsa.co.za/Uploads/editor/UserFiles/downloads/publications/Press_Release_2016/Media%20Release_SAMA.pdf; “Media Statement: HPCSA’s actioning of the Ministerial Task Team recommendations” Health Professions Council of South Africa (2016-01-27) http://www.hpcsa.co.za/Uploads/editor/UserFiles/downloads/publications/Press_Release_2016/Media_Release_MTT.pdf.

Team.⁴⁶ The organisation had to file a Promotion of Access to Information Act application in order to get access to the full report (only a summary was released).⁴⁷

The Registrar/CEO and the Chief Operations Officer, who were implicated in the Task Team's report, vacated their positions at the end of April 2016.⁴⁸

It is too early to tell whether the new management of the HPCSA will be able to address the severe deficiencies noted in the report.⁴⁹

2.2. CIVIL CLAIMS

Malpractice liability encompasses a wide range of causes.⁵⁰ Patients can institute claims against healthcare providers if they have suffered damages due to the conduct of the medical practitioners or hospital staff involved in their treatment. As the relationship between the parties is governed by the law of obligations, a claim may be based on either contract or delict. However, a breach of a duty of care and negligence may underlie both a breach of contract and delict, in which case the conduct will result in liability for both.⁵¹ Medical practitioners and hospital staff may thus incur liability, inter alia, for: Professional negligence; assault due to the absence of informed consent; an invasion of privacy as a result of an unwarranted disclosure of details concerning the patient; the performance of an unnecessary procedure; and breach of contract if they failed to perform an operation agreed upon.⁵²

⁴⁶ "Media Statement: HPCSA: Concern about lack of transparency around implementation of MTT recommendations" Section27 (2016-06-01)

<https://doctorsportal.mediclinic.co.za/Lists/News/DoctorsDispForm.aspx?ID=1502&RootFolder=%2FLists%2FNews&Source=https%3A%2F%2Fdoctorsportal%2Emediclinic%2Eco%2Eza%2FNews%2Easpx>.

⁴⁷ This is the link to the full report (provided for the reader's convenience): <http://section27.org.za/wp-content/uploads/2016/05/Report-of-the-Ministerial-Task-Team-to-Investigate-Allegations-at-the-HPCSA.pdf>.

⁴⁸ "HPCSA axes top officials" Bhekisisa (2016-04-26) <http://bhekisisa.org/article/2016-04-26-hpcsa-axes-top-officials>.

⁴⁹ "Medical and Dental Professions Board NEWS" Health Professions Council of South Africa (2016-12) http://www.hpcsa.co.za/Uploads/editor/UserFiles/downloads/medical_dental/MDBnews.pdf.

⁵⁰ For an overview of the law as it relates to medical malpractice, see: Oosthuizen (2014) LLM *repository.up.ac.za*.

⁵¹ Slabbert *Medical law in South Africa* (2011) 69.

⁵² Strauss (1994) 243.

2.2.1. THE PUBLIC SECTOR

In 2010, it was reported that nearly 2 000 doctors in the public and private sectors were facing negligence claims.⁵³ Of those claims, 80% stemmed from incidents which occurred in the public sector.⁵⁴ Some of the largest damage awards have been paid to victims of substandard care in the public sector. R36.8 million, the largest pay-out yet, was awarded to a patient diagnosed with cerebral palsy.

Information on the true extent of the medical malpractice burden in the public sector has generally been hard to come by. In June 2013 the Minister of Health, in answering a parliamentary question on the number of claims instituted against the department, declined to give the exact figures. The Minister did indicate that the escalation of medico-legal claims and associated legal costs were a top priority of the Department, in that it posed a serious threat to the survival of both the public and private health systems.⁵⁵

More recent parliamentary replies have, however, been able to shed some light on the current litigation situation:

In May 2015, the Minister of Health was able to provide the figures actually spent on litigation by the national and provincial departments of health from 2011/12 to 2014/15.⁵⁶ These figures are presented in Table 1.

In April 2015, the Minister was asked the following:

‘Whether his department was studying developments in New Zealand or any other country to find a solution to the reluctance of young medical practitioners to become gynaecologists because of the prohibitive costs of insurance that they would have to bear annually without any caps put on such insurance’ and ‘what

⁵³ "Thousands of doctors 'negligent'" Sunday Times (2010-06-06).

⁵⁴ "Thousands of doctors 'negligent'" Sunday Times (2010-06-06).

⁵⁵ Parliamentary Question Number 627 (2013-03-28) https://pmg.org.za/question_reply/460/.

⁵⁶ Parliamentary Question Number 443 (2015-02-27) https://pmg.org.za/question_reply/549/.

action is he going to take to avert an impending shortage of (i) gynaecologists, in particular, and (ii) any other category of specialist medical personnel?⁵⁷

The Minister replied, as follows:

‘There is no need to study any developments in any country. We already know why young doctors are reluctant to become gynaecologists. We have had a medico-legal summit which made recommendations. A task team has been appointed to study the recommendations and set up a plan of action.’

Apparently, the Minister did not believe it necessary to learn from other countries’ experiences or approaches to the problem. He is clearly, very confident in the recommendations and the appointed task team.

In September 2015, the Minister was asked the following:

- (3)(a) how many patients in State hospitals have (i) died or (ii) been injured due to negligence or deliberate actions by the employees and/or management of State hospitals in each year from 1 January 1995 up to the latest specified date for which information is available and (b) what type of malpractices in State hospitals have brought about the most (i) deaths and (ii) injuries;
- (4)(a) how much compensation has been paid out in the specified period, (b) on what legal grounds were the payments made and (c) how many of the payments took place due to (i) court orders or (ii) settlement agreements;
- (5) what steps has he taken and will he take to reduce the number of deaths and injuries in State hospitals?

To which the Minister replied:

- (3) Honourable Member, death of a patient due to a deliberate action by employees and/or management of state hospitals to me means murdering such a patient – that is what deliberate action will mean to me.

⁵⁷ Parliamentary Question Number 1497 (2015-04-14) https://pmg.org.za/question_reply/549/.

We have never had a report of such.

- (4) Since the various litigations are directed at provinces and not at the Minister, and payments are done by provinces, I am still collecting this data.
- (5) Honourable Member, it will to a long way for you to be a bit specific about the deaths you are referring to, in order to help me answer your question.

Number of deaths from what? HIV/AIDS? TB? Pneumonia? Diarrhoea? Diabetes, Stroke, Cancer? Hepatitis? Meningitis? Heart failure? Liver failure? Prematurity?

And what type of injuries – motor vehicle accidents? Gunshots wounds? Assault? Stab wounds? Burn wounds? What exactly?⁵⁸

It is hard to tell whether the Minister really did not understand the gist of the question, whether he was merely being evasive, or if he just had very little respect for parliamentary procedure and was being deliberately obtuse.

Eventually, in December 2015, the Minister provided the most complete picture yet of the public-sector litigation landscape.⁵⁹ Information was provided for both the national and provincial departments of health regarding: the amounts claimed and awards actually paid, amounts budgeted for litigation and damages, the five most common events claimed for, hospitals with the highest number of claims against them, and the steps that were being taken to address the high number of negligence claims. The figures, as they pertain to 2011/12 to 2013/14 are provided below in Table 2.

It was recently reported that more than 5500 claims for medical negligence have been lodged against the state since 2014.⁶⁰

⁵⁸ Parliamentary Question Number 3533 (2015-09-18) <https://pmg.org.za/committee-question/1564/>.

⁵⁹ Parliamentary Question Number 3381 (2015-08-21) <https://pmg.org.za/committee-question/1896/>.

⁶⁰ “More than 5,500 medical negligence claims against the state since 2014” TimesLive (2017-10-30) <https://www.sowetanlive.co.za/news/2017-10-30-more-than-5500-medical-negligence-claims-against-the-state-since-2014/>.

2.2.2. PROVINCIAL HEALTH DEPARTMENTS LITIGATION BURDEN DISCREPANCIES

The information publically provided by the Minister in his parliamentary replies and by the Chief Litigation Officer of the Department of Justice and Constitutional Development during the Medico-Legal Summit is presented in the following three tables. It is concerning to note the absence of some records and the discrepancies in the amounts that were provided. The North West is the only province with figures that correspond across all three tables. The amounts are the same for the Free State across Table 1 and 2. Consistent amounts for the Eastern Cape are also found in Table 2 and 3.

It is not clear why these discrepancies exist, especially for financial years gone by. Some of the divergences are quite large. One thing is certain, the debate around medical malpractice and possible reforms, cannot be conducted without accurate reliable data. There is too much at stake, and too many ulterior agendas and conflicting interests.

Province	2011/12	2012/13	2013/14
Gauteng			
Eastern Cape	R68 558 445.27	R94 689 268.23	R134 570 588.97
Northern Cape	R10 287 277.90	R218 560.00	R12 249 662.00
KwaZulu Natal	R49, 221, 493.92	R56, 806, 519.72	R208, 460, 451.50
Western Cape			
North West	R753 602.57	R7 899 232.50	R12 959 528.18
Limpopo	R3 863 017.12	R7 308 503.41	R20 116 859.24
Free State	R5 473 097.65	R2 935 534.00	R673 373.00
Mpumalanga	R17 614 054.79	R11 310 058.70	R44 408 386.64
Total			

[Table 1 - Question No. 443 Date: 27 February 2015]

Province	2011/12	2012/13	2013/14
Gauteng			
Eastern Cape	R25 336 038.35	R44 743 495.84	R49 513 108.93
Northern Cape			
KwaZulu Natal	R41 357 533.80	R49 400 941.94	R123 885 303.21
Western Cape	R15 900 800.00	R6 197 147.05	R22 587 000.00
North West	R753 602.57	R7 899 232.50	R12 959 528.18
Limpopo	R11 394 831.08	R4 114 165.00	R22 033 040.50
Free State	R5 473 097.00	R2 935 534.00	R673 373.00
Mpumalanga	R5 056 370.00	R220 000.00	R44 193 741.66
Total			

[Table 2 - Question No. 3381 Date: 21 August 2015]

Province	2011/12	2012/13	2013/14
Gauteng	R 30 930 758.24	R 124 846 892.41	R 153 612 355.49
Eastern Cape	R 25 336 038.35	R 44 743 495.84	R 49 513 108.93
Northern Cape	R 705 000.00		R 7 107 000.00
KwaZulu Natal	R 10 762 367.72	R 14 767 477.56	R 205 312 356.94
Western Cape	R 15 860 000.00	R 11 710 000.00	R 15 680 000.00
North West	R 753 602.57	R 7 899 232.50	R 698 940.17
Limpopo	R 3 457 954.27	R 6 844 259.18	R 21 959 395.55
Free State	R 988 604.43	R 327 192.00	R 673 373.00
Mpumalanga	R 13 252 319.44	R 11 310 058.70	R 44 408 386.64
TOTAL	R 102 046 645.02	R 222 448 608.19	R 498 964 916.72

[Table 3 - Chief Litigation Officer of the Department of Justice and Constitutional Development – Medico-Legal Summit Date: March 2015]

2.2.3. PROVINCIAL HEALTH DEPARTMENTS AND THE COST OF MALPRACTICE

The institutional weaknesses and systemic challenges present in the public sector have made it especially susceptible to malpractice litigation. As a result, the respective provincial health departments have had to deal with ever escalating medical malpractice

costs. The threat posed by the financial implications of medical malpractice are emphasised by the figures presented below.⁶¹

2.2.3.1. GAUTENG

In 2014 it was reported that there were 306 negligence claims in total, of which 155 relate to injuries sustained at birth.⁶² The Chris Hani Baragwanath hospital, by itself, was facing 86 medical malpractice claims equalling roughly R420 million.⁶³ These figures are even more troubling when one considers that the department had lost all medical negligence cases between 2010 and 2013.⁶⁴ In a written response by Gauteng Health MEC Gwen Ramokgopa to questions from the DA, it was revealed that the provincial health department has since January 2015, paid more than R1 billion to settle 185 medical negligence claims. Of these claims, 76% involved babies who suffered brain-damage at birth. Chris Hani Baragwanath hospital was again reported to have the largest medical negligence bill, having paid R514 million to 44 claimants. The hospital is also the source of four of the five largest damage awards. As well as the largest payout, yet. Apparently, no disciplinary action has been taken against any of the staff involved in the incidents.⁶⁵

⁶¹ The figures presented were obtained from the latest available annual reports and media coverage related to the increase in claimed amounts.

⁶² "Bara facing 86 medical negligence claims – Jack Bloom" Politicsweb (2014-01-16) <http://www.politicsweb.co.za/politicsweb/view/politicsweb/en/page71616/page71654?oid=512696&sn=Detail&pid=71654> (accessed on 30 April 2014).

⁶³ "Bara facing 86 medical negligence claims – Jack Bloom" Politicsweb (2014-01-16) <http://www.politicsweb.co.za/politicsweb/view/politicsweb/en/page71616/page71654?oid=512696&sn=Detail&pid=71654> (accessed on 30 April 2014). This amount is the highest for all public hospitals in Gauteng.

⁶⁴ "Gauteng DoH faces R3.7bn in legal claims - Jack Bloom" Politicsweb (2013-11-17) <http://www.politicsweb.co.za/politicsweb/view/politicsweb/en/page71619?oid=457441&sn=Detail&pid=71619> (accessed on 30 April 2014). It was reported that the Gauteng health department is facing 1002 medico-legal cases amounting to R3.415 billion. These figures were given to the Public Accounts Committee of the Gauteng Legislature.

⁶⁵ "R1bn payouts for medical negligence, but no action against health staff" City Press (2017-05-23) <http://citypress.news24.com/News/r1bn-payouts-for-medical-negligence-but-no-action-against-health-staff-20170523>.

The Department's latest annual report reveals that contingent liabilities for medico-legal claims have increased from R10.07 billion in 2015, to R13.4 billion in 2016.⁶⁶ In response to the rising litigation burden the Department has indicated that two law firms have been appointed to conduct a legal audit of all litigation matters from 2005 to date. This process will be aimed at reducing costs, minimising or reducing unnecessary litigation and identifying key factors that contribute to litigation cases.⁶⁷ The Legal Services division will also work more closely with the Serious Adverse Events Unit. Concerning, obstetrics and gynaecology, the MEC has sent letters to all hospital CEOs instructing all institutions to report all serious adverse events to Legal Services within 24 hours. This is so that Legal Services can assist by providing appropriate advice to the hospital management before patients are discharged. Mediation will also form part of the strategy. The Department is also piloting a new informed consent form to avoid litigation stemming from operations performed with insufficient information.⁶⁸

2.2.3.2. EASTERN CAPE

The Eastern Cape health department faced claims of R447 million in the 2009/2010 financial year.⁶⁹ The amount increased to R715 million in the 2010/2011 financial year.⁷⁰ It was reported that 98% of litigation related to birth and birth trauma.⁷¹ According to the Department's latest annual report its contingent liabilities for legal claims have increased from R8.2 billion in 2015, to R13.4 billion in 2016.⁷²

⁶⁶ Gauteng Department of Health Annual Report 2016/2017 (2016) 269.

⁶⁷ Gauteng Department of Health Annual Report 2016/2017 (2016) 14.

⁶⁸ Gauteng Department of Health Annual Report 2016/2017 (2016) 144.

⁶⁹ Eastern Cape Department of Health Annual Report 2009/2010 (2009) 415. The amount encompasses all legal claims against the department and does not indicate the amount of claims specifically related to medico-legal matters.

⁷⁰ Eastern Cape Department of Health Annual Report 2010/2011 (2010). This amount, again, includes all legal claims against the department, not only medico-legal claims. Also see "EC pays R50m in health claims" Daily Dispatch (2011-09-02).

⁷¹ "Claims for negligence up to R3bn" Daily Dispatch (2015-06-22)

<http://www.dispatchlive.co.za/news/2015/06/22/claims-for-negligence-up-to-r3bn/>; "EC health faces R4.8bn in law suits" Daily Dispatch (2015-10-16) <http://www.dispatchlive.co.za/news/2015/10/16/ec-health-faces-r4-8bn-in-law-suits/>.

⁷² Eastern Cape Department of Health Annual Report 2016/2017 (2016) 549.

The total amount actually paid out in legal settlements during the financial year is set out as follows in the report:

‘The scourge of medico legal claims continued to place enormous financial pressure on the health resources where for the year under review, a total of R259.931 million was paid towards medico legal settlements and R59.107 million paid to the State Attorney.’⁷³

The description of claims as a ‘scourge’, should perhaps, rather be directed at the underlying causes of the claims if progress is to be made in their reduction.

Nonetheless, the Department outlined their plans to address this ‘scourge’:⁷⁴

A Health Ombudsperson will be appointed with effect from 01 February 2016; a panel of medico legal experts are to be appointed; targeted interventions will be introduced at four priority hospitals to prevent Cerebral Palsy; an Electronic Patient Records Management System will be implemented; and a ‘feasibility study to create regional centres or partnerships with available service providers to deal with Cerebral Palsy patients in a bid to reduce future medical costs’ will be undertaken.

As for those deemed responsible for medico legal claims:

‘The Accounting Officer must ensure that, after thorough investigation, disciplinary action is taken against the officials in the nursing profession and medical profession who are responsible for the medico-legal claims against the Department where there is evidence of negligence on their part.’⁷⁵

The report indicates that the Office of the State Attorney has also been engaged to determine in terms of Treasury Regulations 12.2 whether any officials should be held

⁷³ Eastern Cape Department of Health Annual Report 2016/2017 (2016) 14.

⁷⁴ Eastern Cape Department of Health Annual Report 2016/2017 (2016) 14.

⁷⁵ Eastern Cape Department of Health Annual Report 2016/2017 (2016) 195.

liable in law. According to the report, both debt recovery measures and legal proceedings will be instituted against these implicated officials.⁷⁶

This is concerning. If done inappropriately, it would amount to a ‘blame game’, ensuring that all mistakes will be concealed and errors will go unreported. An environment of fear is not conducive to the establishment of a just culture and may end up hampering true accountability.

The Supreme Court has also recently criticised the MEC for wasted expenditure related to an unfounded appeal:

‘The uncontradicted evidence is that the medical staff at BOH were negligent and caused the plaintiff to suffer harm. The special plea was plainly unmeritorious. Leave to appeal should have been refused. In the result, scarce public resources were expended: a hopeless appeal was prosecuted at the expense of the Eastern Cape Department of Health and ultimately, taxpayers; and valuable court time and resources were taken up in the hearing of the appeal. Moreover, the issue for decision did not warrant the costs of two counsel.

In the result, the following order is issued: The appeal is dismissed with costs.⁷⁷

Despite, this scathing judgement and other reported cases of devastating negligence at the hands of the department, it was reported that the Eastern Cape government spokesperson Sizwe Kupelo blames ‘unscrupulous lawyers’ for the ballooning costs:

‘We've heard stories of patients being touted, who heard adverts on national radio stations and newspapers and people being touted to lodge complaints against the department.’⁷⁸

⁷⁶ Eastern Cape Department of Health Annual Report 2016/2017 (2016) 189.

⁷⁷ MEC Health, Eastern Cape v Mkhitha (1221/15) 2016 ZASCA 176 (25 November 2016).

⁷⁸ “EC Health Dept facing R14b in medical negligence suits” EWN (2016-09-10) <http://ewn.co.za/2016/09/10/EC-health-dept-facing-R14b-in-medical-negligence-suits>.

The Eastern Cape faces the highest number of claims of all the provincial health departments – 524 claims, concerning mostly maternity and orthopaedic cases.⁷⁹

2.2.3.3. NORTHERN CAPE

In 2005/2006 the Northern Cape health department faced medico-legal claims amounting to R17.7 million.⁸⁰ This figure has almost certainly increased since then, but information on the state of affairs in the Northern Cape is hard to come by. It was reported that the department has spent more than R23 million on legal fees since 2007.⁸¹ The latest annual report reveals that contingent liabilities related to medico legal cases have increased from R174 million in 2015, to R342 million in 2016.⁸² To address this increase the Department has re-established a Clinical Complaints Review Committee to investigate possible cases of negligence, which lead to medico-legal claims. A Loss Management Committee was also re-established to investigate losses and recommend disciplinary measures to the Accounting Officer, where applicable.⁸³

2.2.3.4. KWAZULU-NATAL

In 2013, it was reported that there were 515 medical malpractice claims against the KwaZulu-Natal department of health, some of which dating back to 2004.⁸⁴ The department had to spend R376 million on lawsuits in 2008/2009 and R547 million in 2009/2010.⁸⁵ According to the latest annual report the contingent liabilities relating to medico legal matters increased from R6.7 billion in 2015, to R9.9 billion in 2016.⁸⁶

⁷⁹ “More than 5,500 medical negligence claims against the state since 2014” Times Live (2017-10-30) <https://www.timeslive.co.za/news/south-africa/2017-10-30-more-than-5500-medical-negligence-claims-against-the-state-since-2014/>.

⁸⁰ Northern Cape Department of Health Annual Report 2005/2006 (2005) 14.

⁸¹ “Botched operations blight SA” The Sunday Independent (2010-05-02).

⁸² Northern Cape Department of Health Annual Report 2016/2017 (2016) 292.

⁸³ Northern Cape Department of Health Annual Report 2016/2017 (2016) 18.

⁸⁴ “KZN health faces 1 356 legal claims” City Press (2013-09-05) <http://www.citypress.co.za/news/kzn-health-faces-1-356-legal-claims/> (accessed on 30 April 2014).

⁸⁵ “Botched operations blight SA” The Sunday Independent (2010-05-02) <http://www.iol.co.za/news/south-africa/botched-operations-blight-sa-1.482422> (accessed on 30 April 2014).

⁸⁶ KwaZulu-Natal Department of Health Annual Report 2016/2017 (2016) 351.

To address the problem the Department established the Office of the Ombud as prescribed by the KZN Health Act, 2009. The Department hopes that, by resolving complaints, the Ombud would be able to minimise the number of cases against the Department. On 31 March 2015, the Department also launched the National Complaints Management Protocol.⁸⁷

The MEC for Health in the province, Dr Sibongiseni Dhlomo, has recently made the news for all the wrong reasons. It was reported that he was facing contempt charges for his department's failure to comply with two high court orders compelling them to hand over medical records in two separate medical negligence cases.⁸⁸

Although the MEC could not confirm how many cases the department was defending, he pleaded with patients not to sue over medical negligence, and rather accept special public medical attention. The MEC has slammed 'scrupulous' lawyers for suing the department.⁸⁹ He has also reportedly made the extraordinary claim that: 'Some lawyers go as far as encouraging patients to steal their medical files in order to lodge a case against the department.'⁹⁰

⁸⁷ KwaZulu-Natal Department of Health Annual Report 2016/2017 (2016) 181.

⁸⁸ "MEC told to supply records" The Mercury (2017-06-06) <https://www.iol.co.za/mercury/news/mec-told-to-supply-records-9580502>; "Turnaround time for negligence cases with child births 'could take years'- lawyers" News24 (2017-06-08) <http://www.news24.com/SouthAfrica/News/turnaround-time-for-negligence-cases-with-child-births-could-take-years-lawyers-20170608>.

⁸⁹ It is believed that he meant 'unscrupulous'.

⁹⁰ "KZN Health MEC begs patients not to sue over negligence" The Mercury (2017-04-20) <https://www.iol.co.za/news/crime-courts/kzn-health-mec-begs-patients-not-to-sue-over-negligence-8735147>; "Turnaround time for negligence cases with child births 'could take years'- lawyers" News24 (2017-06-08) <http://www.news24.com/SouthAfrica/News/turnaround-time-for-negligence-cases-with-child-births-could-take-years-lawyers-20170608>.

The South African Human Rights Commission has also detailed how the Department has failed its cancer patients.⁹¹ Some have called for the MEC's resignation for the part he played in KwaZulu-Natal's current oncology crisis.⁹²

The Department has also been chastised for its failure to keep adequate medical records, which severely hampers any defence they might have in medical negligence cases. Punitive cost orders have also been made for the Department's poor management of litigation.

In the *Madida obo M*-case the Judge noted that many of the Department's problems could be overcome if the law was simply obeyed:⁹³

[81] The growth of malpractice suits has been sudden. It might have caught the defendant unprepared. With the escalation of claims over the past five years the problems may seem overwhelming and insurmountable. These bespoke remedies could assist in fixing the problems. But this case shows that they are fixable if the law is simply obeyed. The challenge then is to implement measures to ensure that the law is obeyed.

[82] In this case the defendant was in a weak position not because of anything that the plaintiff or her lawyers did or did not do. It must be remembered that the plaintiff's case was based entirely on the medical facts produced by the hospital. The defendant's case was weak for two reasons both of which are violations of the rule of law. As sector specific rules these rules enjoy the support of the health professions. In the first instance the duty to keep medical records is a statutory

⁹¹ South African Human Rights Commission, Investigative Report, 'Dr Imran Keeka, DA, MPL vs. Addington Hospital and 3 others KwaZulu Natal', (Complaint File Ref: KZ/1516/0451), 15 June 2017.

⁹² "Fire KZN health MEC or cancer patients face Esidimeni crisis, say DA" Times Live (2017-06-19) <https://www.timeslive.co.za/news/2017-06-19-fire-kzn-health-mec-or-cancer-patients-face-esidimeni-crisis-say-da/>; "KZN Health MEC blocked SAHRC probe illegally – DA" Medical Brief (2017-08-23) <https://www.medicalbrief.co.za/archives/kzn-health-mec-blocked-sahrc-probe-illegally-da/>.

⁹³ *Madida obo M v MEC for Health for the Province of Kwa-Zulu Natal* (14275/2014) [2016] ZAKZPHC 27 (14 March 2016).

obligation. The second rule is the professional protocols that required a medical officer to attend and manage high risk labour. Both rules and especially the rule relating to the keeping of the records are non-discretionary requiring strict compliance. If management of a risky labour is open to the exercise of discretion that discretion has to be exercised reasonably by the medical officer not the nursing staff who are unskilled to manage the kind of life threatening complications that can and did arise in this case.

[83] The institutional remedies in this case as in every case in which medical records are not supplied to persons authorised to receive them is obvious: Efficient systems must be in place for preparing and preserving hospital and medical records in order to comply with the National Health Act and the Guidelines. This is a non-negotiable absolute requirement non-compliance with which will continue to escalate the claims and costs against the defendant. Given the instrumentality of this institutional deficit to malpractice costs, and for no better reason than that it is the law, the defendant must look to holding the custodians of the records personally accountable, if necessary on pain of discipline, criminal prosecution or both. Similarly the doctor on duty on the night that [S.....] was born has to account for his non-attendance on the plaintiff at crucial times of her labour.

[84] Without compliance with these rules the defendant would not be able to defend itself effectively against escalating malpractice claims. Compliance with both rules is unrelated to either the volume of patients or the number of claims being lodged. They are about having efficient systems in place and law abiding, accountable employees responsive to patient needs.'

The following was said in the Smith-case, in respect to the reckless manner in which the Department conducted litigation:⁹⁴

'[63] I considered the arguments advanced by the defendant for an adjournment. In my view it was inexcusable that the defendant should not have discovered

⁹⁴ Smith v MEC for Health, Province of KwaZulu-Natal (3826/12) [2016] ZAKZPHC 68 (2 August 2016).

properly and not produced proper expert notices and summaries timeously. No explanation whatsoever had been given to me for the statement by *Adv Mthembu* that there were no records to be discovered. When *Mr Chetty* made the application, he had before him a bundle of documents which clearly entailed considerably more than the documents which had already been used and handed up to me at the outset of the trial. In my view it was simply unacceptable that the State could conduct litigation in this manner. Mrs Smith is currently 85 years of age and was injured in May of 2010. Six years had elapsed during which the defendant had every opportunity properly to prepare its case. That it did not do so demonstrates that the defendant's case has been recklessly prepared. I had no hesitation in dismissing all three of the applications by the defendant.'

'[149] With regard to the question of costs, it is in my view appropriate to award Mrs Smith her costs on an attorney and client scale. I do so as a measure of displeasure at the defendant's conduct and the conduct of his/her attorneys in defending the action in the manner which they did, as I have set out in detail in this judgment.'

Recent news reports suggest that the KwaZulu-Natal health system is in a dire state.⁹⁵

2.2.3.5. WESTERN CAPE

The Western Cape department of health faced R87 million in medico-legal claims in the 2011/2012 financial year.⁹⁶ In 2012/2013 the amount increased to R118 million.⁹⁷ According to the latest annual report the contingent liabilities related to medico legal

⁹⁵ "Collapsing KZN Health may lose specialist training accreditation – HPCSA" Medical Brief (2017-05-31) <https://www.medicalbrief.co.za/archives/collapsing-kzn-health-may-lose-specialist-training-accreditation-hpcsas/>; "KZN cancer patients sent home with panados as treatment waiting lists grow" Bhekisisa (2017-09-21) <http://bhekisisa.org/article/2017-09-21-the-malignant-province-kzn-and-the-unbearable-wait-to-die>; "KZN health dept given deadline to finalise turnaround plan" News24 (2017-09-10) <http://www.news24.com/SouthAfrica/News/kzn-health-dept-given-deadline-to-finalise-turnaroud-plan-20170910>.

⁹⁶ Western Cape Department of Health Annual Report 2011/2012 (2011) 342.

⁹⁷ Western Cape Department of Health Annual Report 2012/2013 (2012) 474.

matters actually decreased from R193 million in 2015, to R182 million in 2016.⁹⁸ Surprisingly, medico legal payments were less than the budgeted amounts.⁹⁹

From 2005 to 2015 there were 350 new cases formally brought against the Department, 208 are active claims before the High Court. According to the Department there has been a 25% increase in case-load per annum from 2010 to 2015. Between 20-25% of cases appear to be indefensible.¹⁰⁰

The Department has identified the following contributory factors in relation to claims: medical error resulting in loss, injury, or death; poor communication; outcomes not matching expectations; and attorneys' contingency fees and increased targeting.

The Department has adopted a pro-active approach to address the burden of litigation, by containing errors, dealing with errors and managing litigation effectively. This approach has produced some encouraging results and should be studied, and perhaps, imitated in other provincial health departments.¹⁰¹

2.2.3.6. NORTH WEST

The North West department of health faced medical negligence claims amounting to R12.4 million in 2009/2010, which increased marginally to R13 million in 2010/2011.¹⁰² However, in November 2013 the department had to pay out R13.3 million in damages in a single case, after negligent conduct resulted in an infant being blinded.¹⁰³ According to the latest annual report, contingent liabilities related to medical negligence claims decreased from R39.9 million in 2014, to R36.1 million in 2015.¹⁰⁴

⁹⁸ Western Cape Department of Health Annual Report 2016/2017 (2016) 305.

⁹⁹ Western Cape Department of Health Annual Report 2016/2017 (2016) 21.

¹⁰⁰ Western Cape Department of Health Annual Report 2016/2017 (2016) 163.

¹⁰¹ Western Cape Department of Health Annual Report 2016/2017 (2016) 163.

¹⁰² North West Department of Health Annual Report 2010/2011 (2010) 145.

¹⁰³ "Hospital horrors costing SA plenty" The Times (2014-01-17).

¹⁰⁴ North West Department of Health Annual Report 2015/2016 (2015) 298.

It was reported that the Department has paid out R41 million between 2011 and 2015. The number of cases also doubled from 27 cases in 2011/12, to 53 for the 2014/15 period.¹⁰⁵ The North West provincial health spokesperson, Tebogo Lekgethwane, attributed the increase to staff shortages and budget shortfalls.

2.2.3.7. LIMPOPO

In 2012, it was reported that the Limpopo health department was dealing with more than 300 malpractice cases, with claims amounting to more than R320 million.¹⁰⁶ The latest annual report indicates that the Department faces contingent liabilities, which have increased from R762 million in 2014, to R1.35 billion in 2015.¹⁰⁷ The Department notes that they have encountered challenges in the financial year with ‘high numbers of reported and unreported adverse events’, ‘high litigation costs due to medico-legal claims’. They also admitted to encountering challenges with ‘poor quality of health care services’, which is most likely an important contributory factor to their ‘high litigation costs’ challenge.¹⁰⁸

These challenges are not specifically addressed in the annual report, but a Departmental Litigation Management Policy to deal with the management of lawsuits and related matters has apparently been developed.¹⁰⁹

2.2.3.8. FREE STATE

In the 2007/2008 financial year the Free State department of health was facing R19 million in medico-legal claims, which increased to R25 million in 2008/2009.¹¹⁰ In 2010/2011 the department faced claims totalling R40 million. After incurring almost double that amount in liabilities during the following year, the closing balance for

¹⁰⁵ “Negligence costs North West health department R41m” City Press (2017-02-10) <http://citypress.news24.com/News/negligence-costs-north-west-health-department-r41m-20170210>.

¹⁰⁶ “How Limpopo was looted – the inside story” CityPress (2012-07-14) <http://www.citypress.co.za/politics/how-limpopo-was-looted-the-inside-story-20120714/> (accessed on 30 April 2014).

¹⁰⁷ Limpopo Department of Health Annual Report 2015/2016 (2015) 403.

¹⁰⁸ Limpopo Department of Health Annual Report 2015/2016 (2015) 390.

¹⁰⁹ Limpopo Department of Health Annual Report 2015/2016 (2015) 122.

¹¹⁰ Free State Department of Health Annual Report 2008/2009 (2008) 239.

2011/2012 stood at R106 million.¹¹¹ The latest annual report reveals that contingent liabilities related to medico legal claims increased from R540 million in 2015, to R940 million in 2016.¹¹²

According to the annual report, the Department will focus on the implementation of a clinical governance policy and litigation reduction strategy to address the increased costs.¹¹³

A recent media report indicates that the Department is currently facing 225 claims.¹¹⁴

2.2.3.9. MPUMALANGA

In 2010/2011 the Mpumalanga health department spent R21 million on medical negligence claims.¹¹⁵ This is up from the R19 million it spent in 2009/2010, and the R666 643 it spent in 2008/2009.¹¹⁶ In 2011/2012 the department was facing R160 million worth of claims related to medical negligence and unpaid services.¹¹⁷ The latest annual report reveals that contingent liabilities relating to medical negligence claims have increased from R1.45 billion in 2015, to R2.36 billion in 2016.¹¹⁸

2.2.4. SYSTEMIC PROBLEMS IN THE PUBLIC HEALTH SYSTEM

Medical malpractice and the cost of litigation could have a devastating effect on the public health sector and this could be exacerbated by the implementation of a National Health Insurance mechanism that does not adequately address the underlying problems of the healthcare system.¹¹⁹ A number of factors contribute to the dire state

¹¹¹ Free State Department of Health Annual Report 2011/2012 (2011) 168.

¹¹² Free State Department of Health Annual Report 2016/2017 (2016) 371.

¹¹³ Free State Department of Health Annual Report 2016/2017 (2016) 40.

¹¹⁴ "Health faces R1.5bn claims" The New Age (2017-05-08) <http://www.pressreader.com/south-africa/the-new-age-free-state/20170508/281479276326364>.

¹¹⁵ "Province pays for negligence" CityPress (2011-08-17) <http://www.citypress.co.za/news/province-pays-for-negligence-20110817/> (accessed on 30 April 2014).

¹¹⁶ "Botched operations blight SA" The Sunday Independent (2010-05-02).

¹¹⁷ "Province pays for negligence" CityPress (2011-08-17).

¹¹⁸ Mpumalanga Department of Health Annual Report 2016/2017 (2016) 370.

¹¹⁹ See Oosthuizen (2014) LLM *repository.up.ac.za*.

of public health care. Management problems persist and are aggravated by a lack of accountability. The failure to get primary health care and the district health system to function effectively has had a grave impact. Severe human resource constraints caused by poor policy and budget decisions have led to increased workloads, with many functions often performed by inexperienced personnel who are unable to be assisted by more senior practitioners.¹²⁰ Infrastructure and equipment are in a desperate condition and frequent shortages in supplies lead to a reduced standard of care. In addition, a huge number of patients rely on public services, a number which will increase if the NHI is implemented.

All these factors compromise the standard of care patients receive in the public sector and could potentially lead to more litigation. There has even been judicial recognition that substandard medical treatment could be expected in the public sector.¹²¹ Seeing that provincial health departments have fixed annual budgets, these claims and the legal costs associated therewith have a direct impact on the ability to finance healthcare.¹²² Money spent on medical malpractice claims, cannot be spent on improving the provincial health system.¹²³ This could lead to a further decline in the quality of care provided, which would inevitably lead to even more malpractice litigation.

2.2.5. THE PRIVATE SECTOR

The private sector has also been severely affected by the increase in malpractice claims and awards. In 2010 it was reported that the Medical Protection Society was assisting 895 members with active negligence claims and had a 1 000 potential claims awaiting

¹²⁰ Seggie (2013) 103 *S Afr Med J* 433.

¹²¹ *S v Tembani* 2007 1 SACR 355 (SCA) 367. Also see Carstens (2008) 23 *SA Publiekreg= SA Public Law* 173. where the author welcomes the concrete judicial recognition of the compromised reality of public health care services in the country, but notes that a principled approach should have been followed in adjudicating the matter.

¹²² Coetzee (2010) 20 *Obstetrics and Gynaecology Forum* 111; Pepper and Slabbert (2011) 6 *South African Journal of Bioethics and Law* 29.

¹²³ Malherbe "Counting the cost: The consequences of increased medical malpractice litigation in south africa" *S. Afr. Med. J. South African Medical Journal* (2013) 103 84.

assessment.¹²⁴ Outstanding claims in excess of R1 million, were 1 in 5, an increase of nearly 550% compared to ten years ago, while claims over R5 million surged by 900%, in the past five years.¹²⁵ In the four years leading up to 2011 the Medical Protection Society experienced a 30% increase in the frequency of medical negligence claims reported in South Africa.¹²⁶ During the period of 2008-2010 the cost of reported negligence claims rose by 132%.¹²⁷ There are serious concerns about this development, especially if one considers that the cost of an average claim has virtually doubled every five years.¹²⁸ More recent figures reported by the MPS, indicate that claim sizes have increased by approximately 14% on average between 2009 and 2015. Their data also indicated that the long-term average claim frequency for doctors in 2015 was around 27% higher than in 2009.¹²⁹ According to the MPS, their data indicates that over the six-year period from 2011 to 2016, there was a 35% increase in the number of claims being made against healthcare professionals in South Africa.¹³⁰

In June 2013 the highest ever private sector medical malpractice pay-out was awarded to an 11-year-old patient who suffered brain damage as a result of a series of unsuccessful operations. The matter was settled out of court after the MPS conceded liability and agreed to pay R25 million.¹³¹ Roughly 70% of all claims are settled out of court.¹³² Most claims relate to adverse consequences of cosmetic surgery, children born with brain damage, birth defects not diagnosed in a timely manner and unnecessary Caesarean sections.¹³³

¹²⁴ Correspondence between the Medical Protection Society and their members, regarding membership renewal and subscription rates 2010.

¹²⁵ Correspondence between the Medical Protection Society and their members, regarding membership renewal and subscription rates 2010.

¹²⁶ Bown "Counting the cost of litigation" *Medical Protection Society Casebook* (2012) 20 9.

¹²⁷ Bateman (2011) 101 *SAMJ: South African Medical Journal* 216.

¹²⁸ Howarth et al. (2013) 103 *S Afr Med J* 453.

¹²⁹ Howarth and Hallinan (2016) 106 *S Afr Med J* 141.

¹³⁰ "The cost of rising claims and complaints" Medical Protection Society (2017-07-01) <http://www.medicalprotection.org/southafrica/casebook>.

¹³¹ "Brain damage leads to SA's highest-ever medical payout" Sunday Times (2013-06-16).

¹³² "Thousands of doctors 'negligent'" Sunday Times (2010-06-06).

¹³³ "Thousands of doctors 'negligent'" Sunday Times (2010-06-06).

2.2.5.1. THE COST OF INDEMNITY INSURANCE

The increase in medical malpractice litigation has had a significant effect on the indemnity insurance premiums of healthcare practitioners. Statistically, obstetricians, spinal surgeons and paediatricians doing neonatal work, are more likely to face the most expensive claims.¹³⁴ These are thus also the specialities with the highest subscription rates. Neurosurgeons and spinal surgeons fall in the 'super high risk' category and had an annual subscription rate of R318 190 in 2014.¹³⁵ Obstetricians have the highest subscription rate and had to pay the MPS an annual subscription rate of R330 000 for indemnity insurance that same year.¹³⁶ The subscription rates are not listed on the MPS's website anymore, however, reports have indicated that obstetricians had to pay up to R850 000 for indemnity insurance in 2017.¹³⁷ Concerns have been raised about the escalating costs of insurance premiums.¹³⁸ In 2012, UK-based insurer Lloyd's, stopped providing indemnity cover for obstetricians in South Africa as a result of the immense costs involved with claims relating to infants.¹³⁹

According to Dr Graham Howarth (important to note that he is the MPS Head of Medical Services for Africa), not only is it becoming unaffordable to provide indemnity cover, it is becoming unaffordable to purchase indemnity cover.¹⁴⁰ Clearly, the MPS have a vested interest, however, Howarth paints this bleak picture: Obstetricians starting out in

¹³⁴ Bateman (2011) 101 *SAMJ: South African Medical Journal* 216.

¹³⁵ MPS Subscription Rates 1 January – 31 December 2014.

<http://www.medicalprotection.org/Default.aspx?DN=49f05d50-63ab-4dd3-8ac5-f3cd4a8341ad> (accessed on 30 April 2014).

¹³⁶ *Ibid.* In 2010 the subscription rate was R139 000.

¹³⁷ "R1m bill: No one left to deliver our babies?" *Fin24* (2017-04-06)

<http://www.fin24.com/Economy/r1m-bill-no-one-left-to-deliver-our-babies-20170406>.

¹³⁸ Bateman "High-risk specialties threatened by runaway legal costs: izindaba" *South African Medical Journal* (2016) 106 9.

¹³⁹ "Litigation: a Killer Epidemic with no Cure?" *Medical Chronicle* (2012-08-06)

<http://www.medicalchronicle.co.za/litigation-a-killer-epidemic-with-no-cure/> (accessed on 30 April 2014).

¹⁴⁰ Howarth (2011) 4 *South African Journal of Bioethics and Law* 85.

private practice will not be able to generate enough income initially to be able to afford the subscription rates.¹⁴¹ Whereas, experienced practitioners who perform less deliveries will also not be able to afford the higher premiums and may instead stop practicing obstetrics entirely.¹⁴² With the potential liabilities the high risk specialities could incur they cannot afford not to have indemnity cover and continue practicing in those high risk areas either, as one successful claim and the resulting legal costs could be financially devastating.¹⁴³

The escalating costs of necessary insurance cover for high risk specialities may bring about even more unwanted consequences. Practitioners, especially the ones in rural and low-population urban areas, may not be able to treat enough patients or perform enough operations to be able to afford the expensive premiums.¹⁴⁴ It may not be financially viable to continue their practice or they may relocate to more populated areas. This, in turn will deprive those communities of access to already scarce specialist care.¹⁴⁵ Medical students and doctors at the start of their careers may even be deterred from practicing in certain specialities due to the costs and the potential threat of litigation.¹⁴⁶

2.2.5.2. DEFENSIVE MEDICINE

There is some evidence (albeit, mixed) to suggest that an increased litigation risk has an effect on how medicine is practiced.¹⁴⁷ Practitioners indicate that they are more likely to practice defensively in order to avoid complaints or malpractice claims. A survey

¹⁴¹ Howarth (2013) 23 *Obstetrics and Gynaecology Forum* 33.

¹⁴² *Ibid.*

¹⁴³ Howarth (2011) 4 *South African Journal of Bioethics and Law* 85; Howarth et al. (2013) 103 *S Afr Med J* 453; Howarth and Carstens "Can private obstetric care be saved in South Africa" *S Afr J BL* (2014) 7 69; Howarth et al. (2014) 104 *S Afr Med J* 752.

¹⁴⁴ Malherbe (2012) 103 *S Afr Med J* 83.

¹⁴⁵ *Ibid.*

¹⁴⁶ Lambert et al. "Doctors' reasons for rejecting initial choices of specialties as long-term careers" *Medical education* (2003) 37 312; Mello and Kelly "Effects of a professional liability crisis on residents' practice decisions" *Obstetrics & Gynecology* (2005) 105 1287.

¹⁴⁷ Paik et al. (2017) 51 *J Health Econ* 84.

conducted by the MPS found that 76% of private general practitioners in South Africa were aware of the growth in medical negligence claims and complaints, and as a result thereof 58% indicated that they have changed the way in which they practice.¹⁴⁸ Compassion-centred care may be substituted with defensive medicine.¹⁴⁹ Defensive medicine has been described as “a deviation from sound medical practice that is induced primarily by a threat of liability”.¹⁵⁰ As discussed earlier, this threat of liability is avoided by engaging in assurance or avoidance behaviour.¹⁵¹ Assurance behaviour includes the over-ordering of diagnostic tests, unnecessary patient referrals and the prescription of more medication than medically indicated.¹⁵² Apart from being wasteful and expensive, this behaviour may either reduce or improve quality.¹⁵³ Additional care may have some benefits; however it could also expose patients to other risks.¹⁵⁴ It may also raise the expected legal standard of care.¹⁵⁵ Avoidance behaviour has a negative effect on patient care, high risk patients and interventions are avoided by doctors either restricting or stopping their practice altogether.¹⁵⁶ This behaviour reduces access to care.¹⁵⁷

If surveys are to be believed, we may be seeing the effects of defensive medicine locally. A study conducted by the MPS revealed that 86% of practitioners now keep more detailed medical records, which is no doubt a positive development.¹⁵⁸ However,

¹⁴⁸ “Counting the costs of GP claims” Medical Protection Society (2013-07-01)

<http://www.medicalprotection.org/southafrica/practice-matters/issue-1---july-2013/counting-the-cost-of-gp-claims>.

¹⁴⁹ Pepper and Slabbert (2011) 6 *South African Journal of Bioethics and Law* 32.

¹⁵⁰ Studdert et al. (2005) 293 *JAMA* 2609.

¹⁵¹ *Id.* 2612.

¹⁵² *Ibid.*

¹⁵³ *Id.* 2616.

¹⁵⁴ *Ibid.*

¹⁵⁵ *Ibid.*

¹⁵⁶ *Id.* 2613.

¹⁵⁷ *Id.* 2617.

¹⁵⁸ “Counting the costs of GP claims” Medical Protection Society (2013-07-01)

it was also revealed that 65% of practitioners acknowledged that they conduct more investigations and 67% indicated that they now refer more patients for a second opinion as a result of increased litigation risks.¹⁵⁹ A further concern is the fact that 61% of practitioners indicated that they have chosen to stop treating certain conditions or performing certain procedures and 29% said they had a lower threshold for removing patients from the practice list.¹⁶⁰ The implications of defensive medicine in the South African healthcare context are evident. As a result thereof healthcare may become more expensive, health-resources would unnecessarily be expended, and access to care would be diminished.

However, as mentioned earlier, these self-reported increases in defensive medicine should be interpreted with caution, especially where malpractice insurers are involved.

3. PATIENTS PAY THE PRICE

Patients stand to lose the most.¹⁶¹ They are the ones who have to contend with the direct effects of malpractice and may ultimately, in a cruel twist, end up having to face the indirect consequences of increased malpractice litigation as well. Healthcare costs may increase and there may be a diminution in their access to care. It is understandable that practitioners complain about the increases in indemnity insurance and malpractice awards, as from their point of view it directly affects their take-home earnings.¹⁶² However, these increased liability costs are eventually passed on to the patient in the form of more expensive healthcare services.¹⁶³ Of course there will be practitioners who

<http://www.medicalprotection.org/southafrica/practice-matters/issue-1---july-2013/counting-the-cost-of-gp-claims>.

¹⁵⁹ This falls into the assurance behaviour category.

¹⁶⁰ This can be classified as avoidance behaviour.

¹⁶¹ Seggie (2013) 103 *S Afr Med J* 433.

¹⁶² As mentioned above, some practitioners may even have to discontinue or relocate their practice. This is bad for the practitioner involved and worse for the patients, who will be deprived of his or her expertise and care.

¹⁶³ Strauss "Geneesheer, pasient en die reg: 'n delikate driehoek" *JS Afr. L.* (1987) 7; Weiler "The case for no-fault medical liability" *Md. L. Rev.* (1993a) 52 908; Mello et al. (2007) 4 *Journal of Empirical Legal Studies* 835. With regard to hospitals bearing the costs of injuries due to medical management, the authors found that more than

will not be able to pass on the costs and as a consequence will not be able to continue their practices. Obstetricians are particularly vulnerable in this regard, as they have seen dramatic increases in premiums over the past few years.¹⁶⁴ If the trend continues many obstetricians in private practice may be forced to stop practicing or change specialities.¹⁶⁵ With no one in the private sector to deliver their babies, expectant mothers will have to turn to public facilities.¹⁶⁶ With the public sector already under strain, the consequences could be disastrous.¹⁶⁷ The resource limitations in the public sector could affect the quality of care the patients receive, which would in turn lead to an increase in malpractice claims against the state.¹⁶⁸

3.1. A FAULTY SYSTEM

The burden of iatrogenic injury is large. Developing countries, such as South Africa, may suffer more adverse events due to systemic factors.¹⁶⁹ Adverse events associated with management errors cause distress, disability, permanent impairment, and death. Many preventable mistakes lengthen hospital stay and result in an increased consumption of health resources. A significant number of patients are injured, many due to the negligent conduct of practitioners and medical personnel, yet there is evidence to suggest that only a fraction of these patients institute claims.

70% of the costs are externalised to other parties, including the insured patients, their families and health insurers. The authors also stated that the percentage could be even higher, as they could not measure whether the hospitals raised prices as a means of passing the externalised costs on to consumers and insurers. The authors concluded that “the direct costs of adverse events do not fall on hospitals to a significant enough extent to create strong economic incentives for safety improvement”.

¹⁶⁴ “Litigation: a Killer Epidemic with no Cure?” *Medical Chronicle* (2012-08-06).

¹⁶⁵ MacLennan et al. “Who Will Deliver Our Grandchildren?: Implications of Cerebral Palsy Litigation” *JAMA* (2005) 294 1688; Mello et al. “Effects of a malpractice crisis on specialist supply and patient access to care” *Annals of surgery* (2005) 242 621; Howarth (2013) 103 *S Afr Med J* 513.

¹⁶⁶ Howarth (2011) 4 *South African Journal of Bioethics and Law* 85.

¹⁶⁷ Howarth (2013) 23 *Obstetrics and Gynaecology Forum* 33.

¹⁶⁸ Malherbe (2012) 103 *S Afr Med J* 83.

¹⁶⁹ Wilson et al. (2012) 344 *BMJ* e832.

The studies conducted in other countries have raised a number of questions. Why do so few injured patients institute claims, why are fewer still compensated, what are the effects of these injuries on the healthcare system, and what can be done to address the problem? It is very likely that South Africa faces many of the same issues identified by these other countries. It could be that those patients who lodge malpractice claims locally, represent only a small fraction of patients who were actually injured by negligent treatment and that fewer still will receive compensation. Patients who go uncompensated, will however still have to live with and bear the physical, psychological and financial burden of those injuries. Research into the prevalence of adverse events, negligence and malpractice in South Africa is required.

3.1.1. OBSTACLES IN OBTAINING COMPENSATION

Injured patients who do eventually decide to file claims face a number of challenges. Litigation is a costly endeavour and medical malpractice cases often take years to be resolved. The patients who are able to afford litigation, frequently find it very difficult to prove negligence on the part of the practitioners or hospital personnel involved. A number of factors may contribute to the difficulty of the undertaking.

3.1.2. THE BURDEN OF PROOF

In civil cases the onus of proof lies with the patient. To succeed with a claim, liability needs to be established on a preponderance of probabilities.¹⁷⁰ The inherent nature of medicine and the fact that tragic outcomes are often inevitable complicates matters. Practitioners cannot guarantee that treatment will be successful and consequently cannot be held accountable for every adverse event or failed intervention.¹⁷¹ The mere fact that an injury occurred does not enable one to conclude that it was necessarily due to substandard care.¹⁷² *Van Wyk v Lewis*¹⁷³ has also functioned as a “protective shield” for practitioners in this regard.¹⁷⁴ Our law has assumed a rather sheltering attitude

¹⁷⁰ Claassen and Verschoor *Medical negligence in South Africa* (1992) 26.

¹⁷¹ Giesen *International Medical Malpractice Law: A Comparative Study of Civil Responsibility Arising from Medical Care* (1988) 512.

¹⁷² *Ibid.*

¹⁷³ 1924 AD 438.

¹⁷⁴ Strauss (1994) 244.

towards the medical profession, which is nowhere more apparent than in the *Van Wyk* judgement.¹⁷⁵ The Appeal Court effectively held that the doctrine of *res ipsa loquitur* does not apply to medical situations.¹⁷⁶ The maxim thus cannot be invoked to aid the claimant plaintiff in proving his or her case. There can be no inference of negligence, except where the “negligence alleged depends on absolutes”.¹⁷⁷ This position has been widely discussed and it has been argued that the maxim should be applied in specific circumstances in the medical negligence context, especially if regard is had to principles of procedural equality and certain constitutional considerations.¹⁷⁸

The maxim has again recently come up for judicial consideration, with two differing outcomes. The court in *Ntsele* considered the case to be of an exceptional nature, thus finding that the invocation of the maxim was legally justified if regard is had to section 27 of the Constitution.¹⁷⁹ In a much more conservative judgement the court in *Goliath* indicated that it was bound by the principles set out in *Van Wyk*, and that the maxim could therefore not be applied.¹⁸⁰ Lowe J also stated that the contrary finding in *Ntsele* was incorrect.¹⁸¹ Nevertheless, the court did remark that much can be said for revisiting the applicability of the *res ipsa loquitur* maxim in the medical negligence context.¹⁸² It has since been revisited on appeal in *Goliath*, where the court steered the emphasis on the inference of negligence away from the often-obfuscatory maxim. The inference is instead described in relation to the prima facie case of negligence which arises when evidence is adduced, which may compel the defendant to provide an exculpatory

¹⁷⁵ *Ibid.*

¹⁷⁶ *Id.* 245.

¹⁷⁷ *Pringle v Administrator, Transvaal* 1990 2 SA 379 (W) 384.

¹⁷⁸ Van den Heever “The application of the doctrine of *res ipsa loquitur* to medical negligence cases: a comparative survey” (2007); Van den Heever and Carstens *Res ipsa loquitur and medical negligence : a comparative survey* (2011) 145.

¹⁷⁹ *Ntsele v MEC for Health, Gauteng Provincial Government* 2013 2 All SA 356 (GSJ) [122]-[126]. Also see Carstens “Judicial recognition of the application of the maxim *res ipsa loquitur* to a case of medical negligence Lungile Ntsele v MEC for Health, Gauteng Provincial Government (unreported as yet, Case Number: 2009/52394 (GSJ) dated 24 October 2012) : cases” *obiter Obiter* (2013) 34 548 for a discussion of the judgement.

¹⁸⁰ *Goliath v MEC for Health in the Province of Eastern Cape* (1084/2012) [2013] ZAECGHC 72 (14 June 2013) [81].

¹⁸¹ *Id.* [121].

¹⁸² *Id.* [82].

explanation (the absence of such an explanation could place the defendant at risk of an unfavourable judgement, however, the onus of proof continues to lie with the plaintiff).¹⁸³

3.1.3. EXPERT MEDICAL EVIDENCE

Medical treatment and interventions have become exceptionally sophisticated. Establishing that harm was caused due to substandard care can thus be particularly complicated. This represents another obstacle that patients would need to overcome if they are to prove their case and obtain compensation. Expert medical evidence is generally presented in support of a claim and plays a pivotal role.¹⁸⁴ This may pose a number of further problems.

Expert witnesses may be reluctant to testify due to the inconvenience it would entail.¹⁸⁵ Preparations and the trial itself are time consuming and would likely be financially detrimental to the practitioner. A practitioner called to testify would need to examine the patient, compile reports, consult with attorneys and study the pertinent literature on the aspects which may arise during the case.¹⁸⁶ The time a practitioner would need to devote to testimony during the actual trial proceedings may be more than expected, due to the nature of our adversarial system and the unpredictability thereof.¹⁸⁷ Practitioners are entitled to be reasonably remunerated for the examination of the patient and the reports they compile.¹⁸⁸ Those who have to prepare themselves to testify, are usually paid an agreed upon qualifying fee.¹⁸⁹

¹⁸³ Goliath v MEC for Health, Eastern Cape 2015 (2) SA 97 (SCA); Van den Heever provides an excellent concise explanation of the judgement “Inference of negligence – is it time to jettison the maxim res ipsa loquitur?” De Rebus (2015-06-30) <http://www.derebus.org.za/inference-of-negligence-is-it-time-to-jettison-the-maxim-res-ipsa-loquitur/>.

¹⁸⁴ Michael v Linksfeld Park Clinic (Pty) Ltd 2001 3 SA 1188 (SCA) 1200. The general applicable approach towards expert medical evidence was set out by the court. Also see Carstens and Pearmain (2007) 860.

¹⁸⁵ Strauss (1994) 433.

¹⁸⁶ *Ibid.*

¹⁸⁷ *Ibid.*

¹⁸⁸ *Id.* 434.

¹⁸⁹ *Ibid.* Now more appropriately termed ‘preparation fees’ in the Uniform Rules.

As for the trial itself, a party involved in proceedings may not enter into an agreement with a witness, whereby compensation will be paid if he or she provides evidence.¹⁹⁰ Such an agreement is *contra bonos mores* and therefor, null and void.¹⁹¹ A witness is only entitled to the fees prescribed in the official tariff of allowances as determined by the Minister.¹⁹² The new tariff was published in 2008.¹⁹³ It repealed the out-dated tariff, which had been in force since 1991.¹⁹⁴ The current tariff provides for a subsistence allowance, transport and travelling expenses, and a maximum amount of R1 500 for income forfeited as a consequence of attending the civil trial.¹⁹⁵ The maximum fee prescribed in the tariff is very low compared to what most practitioners are likely to earn during a day. It is understandable that they might not be too enthusiastic about the financial implications thereof.

The nature of the adversarial system and the rigorous cross-examination expert witnesses often have to endure may deter them from giving evidence in malpractice proceedings. The court room can be confrontational and witnesses are likely to feel that their professional and personal integrity is called into question by opposing council.¹⁹⁶ The method of enquiry applied during proceedings, may also not be analogous to the

¹⁹⁰ Van Aswegen v Lombard 1965 3 SA 613 (A).

¹⁹¹ Transnet Ltd t/a Metrorail v Witter 2008 6 SA 549 (SCA) 558. The court reiterates and confirms the position with regard to the costs of expert witnesses.

¹⁹² The tariff is prescribed by the Minister for Justice and Constitutional Development, in consultation with the Minister for Finance, under section 51bis of the Magistrates' Courts Act 32 of 1944 and section 42 of the Supreme Court Act 59 of 1959. It should be noted that the Supreme Court Act has been repealed by the Superior Courts Act 10 of 2013, which commenced on 23 August 2013. The date of commencement of section 37, which deals with witness fees, is yet to be proclaimed.

¹⁹³ "Magistrates' Courts Act (32/1944) and the Supreme Court Act (59/1959): Tariff of allowances payable to witnesses in civil cases" (GN 394 in GG 30953 of 11 April 2008).

¹⁹⁴ "Magistrates' Courts Act (32/1944): Tariff of allowances payable to witnesses in civil cases" (GN 2596 in GG 13604 of 1 November 1991). A witness who provided expert evidence was entitled to R50 and other costs incurred for accommodation, as well as subsistence expenses.

¹⁹⁵ GN 394 in GG 30953 of 11 April 2008.

¹⁹⁶ Strauss "The Physician's Liability for Malpractice: A Fair Solution to the Problem of Proof?" *S. African LJ* (1967) 84 420.

reasoning employed by members of the medical community. Explaining intricate technical details of specialised procedures and justifying complex theories in terms which the court would be able to comprehend may present its own set of unique challenges.

Patients often find it extremely difficult to obtain expert medical witnesses who are willing to testify against fellow members of the profession.¹⁹⁷ Some have even suggested that a “conspiracy of silence” exists amongst practitioners.¹⁹⁸ It is more likely that a combination of factors mentioned above, many of which relate to the intrinsic nature of our liability and compensation system, contribute to the difficulties experienced in acquiring necessary expert evidence.

3.1.4. OBTAINING COMPENSATION FROM STATE INSTITUTIONS

Patients injured in the public health sector may institute claims against the executive authority of the particular department concerned for damages incurred as a result of a breach of contract or delict, or both, committed by employees at state health facilities in terms of the State Liability Act.¹⁹⁹ The disconcerting facts in the *Nyathi* case stands to illustrate the difficulty claimants encountered when seeking to recover damages from state institutions.²⁰⁰ Section 3 of the Act, which did not allow for execution or attachment against the state, nor an accessible and simple process to secure effective satisfaction of judgement debts sounding in money, has been declared unconstitutionally invalid.²⁰¹ The inexcusable prior situation has now been alleviated by the State Liability

¹⁹⁷ *Ibid.*

¹⁹⁸ *Id.* 419. Strauss dismisses this extreme view as a gross over-simplification.

¹⁹⁹ State Liability Act 20 of 1957. Practitioners and other medical personnel are employees in public health facilities and as such the state can be held vicariously liable.

²⁰⁰ *Nyathi v MEC for Department of Health, Gauteng* 2008 5 SA 94 (CC). Also see Malherbe and Van Eck “The State’s failure to comply with its constitutional duties and its impact on democracy” *Tydskrif vir die Suid-Afrikaanse Reg* (2009) 191; Coetzee and Carstens “Medical malpractice and compensation in South Africa” *Chi.-Kent L. Rev.* (2011) 86 1274; Olivier and Williams “State liability for final court orders sounding in money : at long last alignment with the Constitution” *obiter Obiter* (2011) 32 489.

²⁰¹ *Nyathi v MEC for Department of Health, Gauteng*. Also see Neethling “State (Public Authority) Liability “ex delicto” (1)” *Tydskrif vir hedendaagse Romeins-Hollandse reg* (2012) 75 626.

Amendment Act 14 of 2011. Nevertheless, reports suggest that provincial health departments continually fail to pay their ordered judgements on time.²⁰² Recently, the sheriff of court had to attach assets (office furniture) of the Gauteng department in order to settle the R6.2m debt owed to the plaintiff.²⁰³ Not only is it morally shameful to delay payment, unnecessary interest-costs are also accrued.

4. CAUSES OF INCREASED MALPRACTICE LITIGATION

A number of factors have possibly contributed to increased malpractice litigation and the associated costs. These contributing factors will be arranged into four categories for the purposes of this discussion.

4.1. THE HEALTHCARE SYSTEM

Many adverse events can be attributed to systemic factors, rather than purely individual negligence.²⁰⁴ Errors often occur despite the best intentions and behaviour of the medical personnel involved.²⁰⁵ The environment in which these practitioners often find themselves and the medical realities they have to contend with need to be considered.²⁰⁶ The institutional weaknesses within the public health system may contribute to the rising number of claims, since the quality of care provided is compromised thereby, thus resulting in more and worse injuries. While it is true that practitioners have to perform their duties in accordance with the degree of care and skill expected from them. They are, however, often hindered by factors that are out of their control. Decisions made by administrators have a direct impact on the quality of

²⁰² "Gauteng health dept fails to meet court ordered payment deadline" Mail & Guardian (2013-06-27) <https://mg.co.za/article/2013-06-27-gauteng-health-dept-fails-to-meet-court-ordered-payment-deadline/>.

²⁰³ "Sheriff attaches Gauteng health's furniture for medical negligence debt" Business Day (2017-08-30) <https://www.businesslive.co.za/bd/national/health/2017-08-30-sheriff-attaches-gauteng-healths-furniture-for-medical-negligence-debt/>.

²⁰⁴ Kohn et al. (2000).

²⁰⁵ Reason (2000) 320 *BMJ* 768. For a more in depth discussion of the human and organisational factors that cause accidents in complex systems and the tools and techniques available for the management of the associated risks see Reason (1997) 266.

²⁰⁶ Carstens and Pearmain (2007) 638.

services practitioners can provide to their patients.²⁰⁷ The administrators are responsible for ensuring that there are adequate resources available to enable the provision of suitable health services. Liability can be incurred by these individuals, as well as health departments and hospital bodies vicariously, if negligent maladministration or mismanagement resulted in harm being suffered.²⁰⁸

4.1.1. 'PERSON' VS 'SYSTEMS' APPROACH

Adverse events occur and it may be more emotionally satisfying to blame individuals rather than institutions or organisations.²⁰⁹ The 'person approach' focuses on the unsafe acts of the practitioners and medical personnel who provide healthcare services; it attributes errors to the aberrant mental processes of these individuals and attempts to manage the occurrence of errors by attributing blame, instituting disciplinary measures, or deterring certain behaviour with the threat of litigation.²¹⁰ Human behaviour is thus the main focus and error management resources are directed at making individuals less fallible.²¹¹ This person approach may be inappropriate in the complex healthcare environment. A 'systems approach' may be better suited to medicine, as human error and fallibility are regarded as consequences rather than causes, originating not from human nature alone, but rather systemic factors.²¹² Errors are managed, not by targeting the individual, but by implementing programmes which target several different components of the system, which includes the person, the team, the task, the workplace and the institution as a whole.²¹³ Such an approach could reduce errors. However, our

²⁰⁷ Vincent (1989) 299 *BMJ* 1152.

²⁰⁸ McQuoid-Mason "Establishing liability for harm caused to patients in a resource-deficient environment" *SAMJ: South African Medical Journal* (2010) 100 573. The author discusses liability in a resource-deficient environment, indicating that a number of different parties may be held liable if harm is suffered in such circumstances. Decisions to ration services need to be reasonable and justifiable, especially where constitutional rights are affected. Also see Pieterse "Health care rights, resources and rationing" *South African Law Journal* (2007) 124 514. For an international legal perspective on the legal liability of hospitals in the USA, Canada, the United Kingdom, Australia, and South Africa see Cronje-Retief *The legal liability of hospitals* (2000).

²⁰⁹ Reason (2000) 320 *BMJ* 768.

²¹⁰ *Ibid.*

²¹¹ *Id.* 769.

²¹² *Id.* 768.

²¹³ *Id.* 769.

current liability system, which is focussed on individual accountability, may not be conducive to such an approach as it may deter individual behaviour (although there is very little evidence to support this deterrence-theory), but does little to address the systemic factors.²¹⁴

4.2. MEDICAL PROFESSION

Some have suggested that the increase in claims has been brought on by a decline in professionalism and the standard of care.²¹⁵ The HPCSA has also raised concerns about the increased number of complaints they have received.²¹⁶ Practitioners have criticised these views and have blamed the increase in litigation on other factors. However, if there was no malpractice there would be no claims.²¹⁷ Lapses in judgement do occur and even the most vigilant practitioners make mistakes.²¹⁸ The focus should perhaps rather be on putting systems in place to avoid preventable mistakes.²¹⁹ Nevertheless, practitioners need to make sure that they adhere to the standard of care expected from their particular branch of the profession. Failure to meet the expected standard may be alleviated by an increased emphasis on education and the enforcement of practice guidelines.²²⁰ Improving the detection of negligent behaviour and instituting appropriate corrective or disciplinary processes would also be constructive.²²¹

Some studies have, however, found that the quality of care provided and the technical expertise of the practitioner may not be determining factors when it comes to

²¹⁴ Leape et al. (1991) 324 *N Engl J Med* 377.

²¹⁵ "Patients 'need educating on rights, responsibilities'" Business Day (2012-08-08).

²¹⁶ "HPCSA responds to campaign criticism" Medical Chronicle (2012-06-04)

<http://www.medicalchronicle.co.za/hpcsa-responds-to-campaign-criticism/> (accessed on 30 April 2014).

²¹⁷ Coetzee (2010) 20 *Obstetrics and Gynaecology Forum* 111.

²¹⁸ Ncayiyana (2004) 94 *S Afr Med J* 303. Gallagher et al. (2007) 356 *N Engl J Med* 2713.

²¹⁹ Reason (2000) 320 *BMJ* 768.

²²⁰ Leape et al. (1991) 324 *N Engl J Med* 383.

²²¹ *Ibid.*

malpractice litigation.²²² Instead it seems that patients' dissatisfaction may be critical.²²³ A perceived lack of caring and a breakdown in communication often precedes the decision to litigate.²²⁴ Merely obtaining money may not be the only objective of injured patients; the reasons for filing suit may be due to the manner in which the practitioner subsequently managed the situation after the occurrence of the adverse event.²²⁵ Practitioners would thus be wise to adjust their behaviour accordingly. Patients need to comprehend the potential risks involved with their treatment, so that they do not harbour unrealistic expectations. As mentioned before, informed consent is crucial in this regard. It must however, be real informed consent, not those standardised forms which patients are required to sign or a brief technical explanation before the start of treatment. Communication is essential. Practitioners need to build a rapport with their patients and in the case of an adverse event they need to manage the situation sympathetically, whilst keeping in mind that patients may be immensely affected by such an unfortunate outcome.²²⁶

4.3. THE LEGAL PROFESSION

It is easy to vilify lawyers when the issue of malpractice litigation arises. As mentioned above, the Minister of Health has done so by accusing greedy lawyers of 'unmercifully' targeting doctors.²²⁷ It is likely that many members of the medical profession share his sentiments. While it may be true that lawyers are not acting entirely altruistically when taking on malpractice cases, patients who have suffered injuries as a result of a practitioner's negligence have a right to compensation and lawyers provide the only avenue for obtaining the necessary financial redress. Whether they are driven by

²²² Entman et al. "The relationship between malpractice claims history and subsequent obstetric care" *Jama* (1994) 272 1588.

²²³ Levinson et al. (1997) 277 *JAMA* 553.

²²⁴ Beckman (1994) 154 *Arch Intern Med* 1365; Hickson et al. "Patient complaints and malpractice risk" *Jama* (2002) 287 2951.

²²⁵ Hickson et al. "Factors that prompted families to file medical malpractice claims following perinatal injuries" *Jama* (1992a) 267 1359.

²²⁶ Vincent et al. (1994) 343 *Lancet* 1609; Vincent (2003) 348 *N Engl J Med* 1051.

²²⁷ "Motsoaledi wages war against lawyers" *Medical Chronicle* (2011-10-10).

sympathy or the money involved, is probably of no concern to the injured patient who requires assistance in obtaining compensation for medical and other damages incurred as a result of a practitioner's negligent care. It is in the injured patient's best interest to have an attorney who will try and get the best possible settlement or award. Again, if there was no malpractice there would be no need for malpractice litigation. The threat of an adverse order of costs does serve to deter meritless claims.²²⁸ It may be unfair to criticise attorneys, as their practices are determined by the liability and compensation system in which they function. Criticism should perhaps be directed at the system, rather than the individuals who are merely a part thereof. That being said, certain factors relating to the legal profession may contribute to the increase in medical malpractice litigation.

Some commentators have noted that medical malpractice attorneys are purposely targeting the public, often encouraging patients to seek legal assistance if they have suffered adverse consequences due to medical care.²²⁹ Others have indicated that amendments to the Road Accident Fund legislation may have driven attorneys to other types of personal injury litigation, such as medical malpractice, since it may be more financially lucrative than Road Accident Fund claims.²³⁰ The Contingency Fees Act has opened up the possibility of litigation to patients who could previously not have afforded to institute claims.²³¹ Although this "no win, no fee" arrangement allows greater access to justice, especially for indigent public sector patients, it has led to some questionable practices.²³² The incentive to inflate claims has no doubt fostered the often justified perception that lawyers are selfish and greedy.²³³ The legal profession and the public

²²⁸ Strauss (1994) 245. The author describes the threat of an adverse order of costs as the "most powerful deterrent" against litigation in South Africa.

²²⁹ Pepper and Slabbert (2011) 6 *South African Journal of Bioethics and Law* 30.

²³⁰ Road Accident Fund Amendment Act 19 of 2005; *Law Society of South Africa v Minister for Transport* 2011 1 SA 400 (CC); Malherbe (2012) 103 *S Afr Med J* 83.

²³¹ Contingency Fees Act 66 of 1997.

²³² Coetzee (2010) 20 *Obstetrics and Gynaecology Forum* 109. Howarth (2011) 4 *South African Journal of Bioethics and Law* 85.

²³³ Howarth (2013) 103 *S Afr Med J* 513.; "Health MEC attacks lawyers" *The Mercury* (2014-02-07).

should take cognisance of the fact that lawyers are bound by a range of ethical duties to both their clients and the court. These duties may well come into conflict with their own financial interest in the proceedings where contingency fee agreements are involved.²³⁴

4.4. INCREASED PATIENT AWARENESS

Stakeholders in the medical profession have indicated that the proliferation of complaints and litigation is not due to a decline in standards and care, but rather due to the fact that patients are more aware of their rights.²³⁵ This is a development that should be welcomed, as patients who have legitimate claims must be compensated.²³⁶ A number of factors may have contributed to improved patient awareness. As mentioned, lawyers may be targeting injured patients by utilising the media more deliberately than before. The HPCSA has also recently launched a patients' rights awareness campaign.²³⁷ Furthermore, the commercialisation of healthcare and the resultant change in the traditional doctor-patient relationship may also be a factor. The Consumer Protection Act broadened the scope of liability in this regard and merits discussion.

4.4.1. THE CONSUMER PROTECTION ACT

4.4.1.1. INTRODUCTION

The introduction of the Consumer Protection Act²³⁸ has also been a significant development in the healthcare context. Patients are regarded as consumers and virtually all dealings between patients and health care providers will qualify as

²³⁴ *Ronald Bobroff & Partners Inc v De La Guerre; South African Association of Personal Injury Lawyers v Minister of Justice and Constitutional Development* (CCT 122/13, CCT 123/13) 2014 ZACC 2 [10]. The appellants challenged the constitutionality of the Contingency Fees Act. In terms of the Act provision is made for fees to be charged in regulated instances and at set percentages. However, some law firms charged more than what was allowed for in the Act. The Act was found to be constitutional and leave to appeal was dismissed by the court. Common law contingency fees are unlawful.

²³⁵ "HPCSA's 'Report a doc' campaign likely to hike medical costs" *Medical Chronicle* (2012-05-07).

²³⁶ *Ncayiyana* (2004) 94 *S Afr Med J* 303.

²³⁷ Health Professions Council of South Africa (2012) Media Statement: HPCSA embarks on health and human rights awareness campaign. 19 March 2012.

²³⁸ Consumer Protection Act 68 of 2008.

transactions in terms of the Act.²³⁹ The traditional doctor-patient relationship is likely to be redefined thereby.²⁴⁰ The application of the Act is perhaps more suited to commerce and may not be entirely appropriate for the unique healthcare environment.²⁴¹ However, the expansion of patients' rights should be welcomed, especially if one considers the unequal bargaining position patients often find themselves in when dealing with healthcare providers. A potential consequence of this expanded consumer protection, may be an increase in litigation and a constraint of practitioner freedom.

EFFECT ON MEDICAL PRACTICE AND LIABILITY

4.4.1.2. QUALITY GOODS AND SERVICE

A patient has a right to demand quality service and safe, good quality goods.²⁴² The common law remedy for breach of contract is supplemented by the Act, which affirms that the patient has a right to the performance of the services in a manner and quality that persons are generally entitled to expect.²⁴³ Provision is also made for an implied warranty of quality with regard to the supply of goods to the patient.²⁴⁴ Furthermore, liability for damage caused by goods may be incurred irrespective of whether the harm resulted from any negligence on the part of the producer, importer, distributor or

²³⁹ The definitions of "consumer", "service provider", "service", "goods" and "transaction" are all broadly defined in S 1 of the Act.

²⁴⁰ Rowe and Moodley "Patients as consumers of health care in South Africa: the ethical and legal implications." *BMC Med Ethics* (2013) 14 15. The authors state that viewing patients as consumers may be detrimental to the doctor-patient relationship. The emphasis on patient autonomy may inadvertently lead to the commodification of healthcare, which would result in complex ethical considerations.

²⁴¹ Slabbert and Pepper "The Consumer Protection Act: no-fault liability of health care providers." *S Afr Med J* (2011) 101 800; "Impact of the Consumer Protection Act in the health care context" *De Rebus* (2012-03-01) <http://www.derebus.org.za/impact-consumer-protection-act-health-care-context/>.

²⁴² S 54 and 55.

²⁴³ S 54(1)(b). If there is a failure to perform a service to the standards contemplated in the Act, the patient may, in accordance with S 54(2), require the healthcare provider to either remedy the defect in the quality of the services performed or goods supplied; or refund him or her a reasonable portion of the price paid for the goods and services. Also see Dinnie "Exposure to the consumer court under the Consumer Protection Act-more litigation for the medical industry?: forum" *South African Journal of Bioethics and Law* (2009) 2 43 where the author indicates that a patient will likely have to turn to common law remedies if multiple service providers are involved or where the statutory remedy will not be able to adequately compensate all losses suffered by the patient.

²⁴⁴ S 56.

retailer.²⁴⁵ This provision will be particularly useful to patients who suffer damage as result of defective implants, prostheses, pacemakers or unsafe pharmaceuticals.²⁴⁶ Before the Act came into effect a patient who suffered damages as result of a product, would have had to either rely on contractual remedies or institute a delictual claim against the manufacturer.²⁴⁷ To be successful with the delictual claim, the patient would have needed to prove fault on the part of the manufacturer.²⁴⁸ The introduction of no-fault liability may open the litigation floodgates, as patients would only need to prove that they suffered harm as a result of the goods being unsafe, defective or hazardous; or that they were not adequately instructed or warned about a hazard which is associated with or arose from the use of the goods.²⁴⁹ Anyone in the supply chain may be held liable for harm suffered.²⁵⁰ This means that the health practitioner who administered the treatment may incur strict liability, as he or she would be the most easily identifiable person in the supply chain.²⁵¹ The harm for which one could be held liable includes: death or injury, illness, loss or damage to property, and any economic loss resulting from the harm suffered.²⁵² However, a healthcare provider who supplied the harmful goods can escape liability if it is unreasonable to expect him or her to have discovered the unsafe product characteristic, failure, defect or hazard.²⁵³ Seeing that the supplier can rely on this defence, it is unlikely that healthcare providers would experience a surge in litigation. Patients would be wise to rather institute claims against

²⁴⁵ S 61(1). Also see Slabbert and Pepper (2011) 101 *S Afr Med J* 800.

²⁴⁶ Howarth and Davidow "Don't be consumed by new Act" *Medical Protection Casebook* (2010) 18 12.

²⁴⁷ Neethling et al. *Deliktereg* (2010) 335.

²⁴⁸ *Wagener v Pharmicare Ltd; Cuttings v Pharmicare Ltd* 2003 (4) SA 285 (SCA) 298-300. The court confirmed the fault requirement, stating that if strict liability was to be imposed it would be up to the legislature to do so.

²⁴⁹ S 61(1)(a)-(c). Also see Slabbert et al. "The application of the Consumer Protection Act in the South African health care context: concerns and recommendations" *Comparative and International Law Journal of Southern Africa* (2011) 44 172.

²⁵⁰ Howarth and Davidow (2010) 18 *Medical Protection Casebook* 12.

²⁵¹ Pepper and Slabbert (2011) 6 *South African Journal of Bioethics and Law* 32.

²⁵² S 61(5).

²⁵³ S 61(4). A number of other exemptions are included in this section.

the manufacturer or producer of the harmful goods, to avoid the risk of an adverse cost order should the supplier successfully raise the aforementioned defence.²⁵⁴

4.4.1.3. MARKETING

The Consumer Protection Act will also have an impact on other areas of medical practice. The right to equality in the consumer market is protected by provisions that offer protection against discriminatory marketing.²⁵⁵ In the healthcare context these provisions would ensure that patients do not unfairly receive differential quality care on the basis that they belong to a certain category of persons or that different standards are applied when dealing with patients who belong to a particular benefit option.²⁵⁶

4.4.1.4. DISCLOSURE

The duty to disclose risks in the healthcare setting is another area of medical practice which is affected by the Act.²⁵⁷ The supplier of any activity or facility that is subject to any: a) risk of an unusual character or nature; b) risk of which a consumer could not reasonably be expected to be aware, or which an ordinarily alert consumer could not reasonably be expected to contemplate, in the circumstances; or c) risk that could result in serious injury or death, must specifically bring that risk to the attention of the patient. Patients need to be warned of the risks, the nature of the risks and the potential effects thereof.²⁵⁸ This form of disclosure differs from the conventional medico-legal one, where a doctor is not required to inform a patient of unusual or remote risks or dangers unless a patient specifically enquires about them or if they are serious and typically found to occur during the proposed intervention.²⁵⁹ Ordinarily a doctor is only obliged to disclose information to a patient where a material risk inherent to the proposed treatment exists. A risk is considered material if, in the circumstances of the particular case, a reasonable person in the patient's position, if warned of the risk, would likely attach significance to

²⁵⁴ "Impact of the Consumer Protection Act in the health care context" De Rebus (2012-03-01) <http://www.derebus.org.za/impact-consumer-protection-act-health-care-context/>.

²⁵⁵ S 8-10.

²⁵⁶ Slabbert et al. (2011) 44 *Comparative and International Law Journal of Southern Africa* 176.

²⁵⁷ *Id.* 180.

²⁵⁸ S 58(1).

²⁵⁹ Carstens and Pearmain (2007) 885.

it; or where the medical practitioner is or should reasonably be aware that the particular patient, if warned of the risk, would likely attach significance to it.²⁶⁰ Section 6 of the National Health Act, which codified the common law duty of disclosure, only requires that health care providers inform patients of the benefits, risks, costs and consequences generally associated with an intervention.²⁶¹ Patients are to be informed thereof in a language that they understand and in a manner which takes into account their level of literacy.²⁶² The Consumer Protection Act requires in addition that patients be warned of the risks in plain and understandable language in order to allow a patient with average literacy skills and minimal experience as a consumer to understand the warning.²⁶³ Healthcare providers are thus burdened with a more demanding standard of disclosure in terms of the consumer orientated statute.

Whether this more demanding standard will be adhered to in practice is another matter. Research conducted by Claassen indicates that there is a worrying trend of practitioners not adequately informing their patients with regard to their treatment.²⁶⁴ This failure to adequately inform their patients with the consequential absence of informed consent would potentially expose the practitioners to civil or criminal liability.²⁶⁵ It is also interesting to note that the patient's level of literacy and time constraints were the most frequently cited reasons for not providing the required level of disclosure.²⁶⁶ The problem is exacerbated in the public sector, where patients are often uneducated or unable to understand the practitioner due to a language barrier.²⁶⁷ Coupled with the dramatic time constraints and workloads these practitioners face it becomes almost

²⁶⁰ *Castell v De Greef* 1994 (4) SA 408 (C) at 426.

²⁶¹ S 6(1)(c) of the National Health Act 61 of 2003. Also see Carstens and Pearmain (2007) 693.

²⁶² S 6(2).

²⁶³ S 49(2) of the Consumer Protection Act 68 of 2008.

²⁶⁴ Claassen "Negotiorum gestio by geneeskundige ingrepe" (2011) 258.

²⁶⁵ *Ibid.* The author examines whether legal concept of *negotiorum gestio* could be expanded to the treatment of intellectually challenged patients, which would allow practitioners to treat such patients without first obtaining their informed consent. However, the author concludes that it would require too big of a legal leap to make *negotiorum gestio* applicable to such patients. The defence of legal impossibility would be applicable in such a situation.

²⁶⁶ *Id.* 259.

²⁶⁷ *Ibid.*

impossible to adequately inform the patients to the standard expected by the law.²⁶⁸ This expected standard of disclosure has now been elevated by the Consumer Protection Act. The healthcare realities in South Africa and the challenges faced, specifically in the public sector, will impact on the practicality of these provisions.

4.4.1.5. CONTRACTS BETWEEN PATIENTS AND HEALTHCARE PROVIDERS

Contracts between healthcare providers and patients are also affected by the Act. The patient has a right to fair, just and reasonable terms and conditions. Healthcare providers must not offer to supply, supply, or enter into an agreement to supply, any goods or services at a price or on terms that are unfair, unreasonable or unjust.²⁶⁹ A patient must also not be required to waive any rights, assume any obligation or waive any liability of the healthcare provider on terms that are unfair, unreasonable or unjust.²⁷⁰ A transaction, agreement, term or condition will be considered to be unfair, unreasonable and unjust if: a) it is excessively one-sided in the favour of the healthcare provider; b) it is adverse to the patient to a point of being inequitable; or c) the patient, to his or her detriment, relied on a false, misleading or deceptive representation or a statement of opinion by the healthcare provider.²⁷¹

A contract or notice which seeks to limit the risk or liability of a healthcare provider, or constitutes an assumption of risk or liability by the patient, or imposes an obligation on the patient to indemnify the healthcare provider or any other person for any cause must be drawn to the attention of the patient in the prescribed manner.²⁷² In addition, if the contract or notice concerns an activity or facility that is subject to any risk, the patient needs to be made specifically aware of that fact, the nature and potential effect of the

²⁶⁸ *Ibid.*

²⁶⁹ S 48(1)(a).

²⁷⁰ S 48(1)(c). Terms that are unfair, unreasonable or unjust may also not be imposed as a condition of entering into a transaction.

²⁷¹ S 48(2). Also see Slabbert et al. (2011) 44 *Comparative and International Law Journal of Southern Africa* 176.

²⁷² S 49(1). If it is not drawn to the attention of the patient as required by S 49, it would be considered unfair, unreasonable or unjust in terms of S 48(2)(d)(ii).

risk as required by the Act.²⁷³ The Act requires that the nature and effects of these provisions or notices must be brought to the patient's attention in a conspicuous manner and form that is likely to attract the attention of an ordinarily alert patient, having regard to the circumstances.²⁷⁴ It must also occur either before the patient enters into the agreement, begins to engage in the activity, enters the facility, or before consideration flowing from the agreement is required, whichever occurs first.²⁷⁵ Adequate opportunity must be provided to the patient, under the circumstances, to receive and comprehend the provision or notice, which must be written in plain understandable language.²⁷⁶ Patients are further not allowed to be subjected to contracts that limit or exempt the healthcare provider's liability for loss attributable to the gross negligence of the provider or any person acting for or controlled by the provider.²⁷⁷

Hospital admission forms and indemnification clauses are certainly affected by the above provisions.²⁷⁸ In terms of the Act contract terms that are unfair, unreasonable or unjust may be set aside by the court.²⁷⁹ Furthermore, if certain terms or conditions are not brought to the patient's attention they may also be severed from the agreement or declared to be without force or effect.²⁸⁰

²⁷³ S 49(2). The patient must assent to the provision or notice by signing or initialling the provision, or otherwise acting in a manner consistent with acknowledgement of the notice, awareness of the risk and acceptance of the provision.

²⁷⁴ S 49(4)(a).

²⁷⁵ S 49(4)(b).

²⁷⁶ S 49(5) and (3).

²⁷⁷ S 51(1)(c).

²⁷⁸ McQuoid-Mason "Hospital exclusion clauses limiting liability for medical malpractice resulting in death or physical or psychological injury: What is the effect of the Consumer Protection Act" *S Afr J BL* (2012) 5 65. The author argues that "as a result of the Act, exclusion clauses that unfairly, unreasonably or unjustly protect hospitals from liability for death or bodily or psychological injury caused by the fault of their staff, may be declared by the courts to be invalid and not binding on consumers. They may also be regarded as unconstitutional". The legal position as stated in *Afrox Healthcare Bpk v Strydom* 2002 (6) SA 21 (SCA) has now been changed by the Act. Also see Carstens and Kok "An assessment of the use of disclaimers by South African hospitals in view of constitutional demands, foreign law and medico-legal considerations" *SA Publiekreg= SA Public Law* (2003) 18 430; Naude and Lubbe "Exemption clauses-A rethink occasioned by *Afrox Healthcare Bpk v Strydom*" *S. African LJ* (2005) 122 441.

²⁷⁹ S 52(3).

²⁸⁰ S 52(4).

A number of factors are taken into account in assessing whether a contract or provision is unfair, unreasonable or unjust, including: the nature of the parties to that agreement, their relationship to each other and their relative capacity, education, experience, sophistication and bargaining position; whether there was any negotiation between the parties; and the extent to which any documents relating to the agreement satisfied the plain, understandable language requirement.²⁸¹

4.4.1.6. REMEDIES

A patient is able to enforce the rights acquired in terms of the Act by referring a complaint to the National Consumer Tribunal, the National Consumer Commission, an alternative dispute resolution agent or a court with jurisdiction if all other available remedies have been exhausted.²⁸²

5. CONCLUSION

This chapter provided a broad overview of the current malpractice situation in South Africa, with specific reference to the extent, consequences, and possible causes of malpractice.

The public health system suffers from a range of systemic weaknesses that have likely impaired the provision of quality care. These weaknesses, along with other factors, may have made the public sector especially vulnerable to malpractice litigation. The substantial amounts spent on claims, cannot be spent on improving healthcare infrastructure and services. Unfortunately, this could potentially compound the problem, and lead to more frequent and more severe harmful outcomes – with a greater number of subsequent claims. Those in the private sector have also raised concerns about the current situation. Costs of claims have reportedly contributed to escalating indemnity

²⁸¹ S 52(2).

²⁸² S 69. Also see Slabbert et al. (2011) 44 *Comparative and International Law Journal of Southern Africa* 192.

insurance premiums, which may have changed the way in which private providers practice medicine.

In the end, patients will have to contend with all the effects of malpractice and those of increased litigation – it could become more difficult to access health services and it may become more expensive, as costs are passed on to the consumer.

Unfortunately, accurate empirical information, untainted by special interests, regarding the present malpractice situation, is not readily available. The lack of transparent, verifiable information is a major concern. Without a reliable indication of the incidence of malpractice, the causes of claims, and the actual costs involved, it will remain difficult to assess the full extent of the issue and make informed decisions about the way forward. More formal independent investigation and study is needed. Unfortunately, as the next chapter will show, it seems as though stakeholders may already be considering reform in the absence of evidence. Hasty proposals based on unsound conjecture will likely lead to unsound and unhelpful ‘solutions’. The conventional malpractice system ‘solutions’ do little to address substandard care. They are instead, generally only concerned with the financial implications of malpractice, and seek to address these implications by limiting-liability.

Calls for reform may be justified, but will only be effective if the causes of malpractice and the related claims are properly identified and understood. Ideally one would want to prevent claims and costs by reducing malpractice and harm. For this to happen, patient safety must be prioritised. Policymakers should rather consider how the liability and compensation system could be better aligned with this objective.

Possible reforms more in line with patient safety concerns will be discussed at a later stage. The following chapter looks at proposals for reform that have been advanced and considers some of the latest developments surrounding the malpractice system.

CHAPTER 15. THE SOUTH AFRICAN MALPRACTICE SITUATION – RIPE FOR REFORM?

1. INTRODUCTION

1.1. A WORLDWIDE CONCERN

Many countries have in the past few decades experienced difficulties with their liability and compensation systems. Although, the systems in these countries vary significantly with regard to their respective legal processes, liability standards, sources of funding and coverage; they all have similar principal objectives and suffer from many of the same problems.¹

Two main types of mechanisms can be distinguished. A small number of countries have adopted no-fault compensation schemes.² The assessment of provider-liability as a prerequisite for indemnification is not required in these countries. Most countries, however, rely on fault-based systems.³ In these countries, damages are awarded contingent upon an assessment of liability, usually in the form of negligence. South Africa, employs a variation of the latter mechanism.

Widespread dissatisfaction with these systems, have prompted numerous stakeholder-led investigations, governmental reports, recommendations and legislative interventions.⁴

¹ OECD (2006) 82.

² Farrell et al. “No-fault compensation schemes for medical injury: a review” (2010).

³ Ken and Richard “Medical Malpractice and Compensation in Global Perspective” (2013).

⁴ See generally: Giesen *International Medical Malpractice Law: A Comparative Study of Civil Responsibility Arising from Medical Care* (1988); Gilmour “Patient Safety, Medical Error and Tort Law” (2006) 202; Koch and Bagińska *Medical liability in Europe: a comparison of selected jurisdictions* (2011); Ferrara et al. *Malpractice and medical liability* (2013); Oliphant and Wright *Medical malpractice and compensation in global perspective* (2013).

It should be noted from the outset, that many of the operational problems encountered with fault-based systems have their roots in more deep-seated flaws underlying respective civil justice systems. It just so happens that these flaws are magnified in proceedings where enquiries into alleged medical negligence are undertaken. Consequently, some reforms have targeted the civil justice system as a whole, to make it more efficient, while others have been specifically aimed at medical malpractice suits.

2. THE SOUTH AFRICAN CONTEXT

South Africa is by all accounts currently experiencing many of the same difficulties other countries have encountered with their liability and compensation systems.⁵ These shortcomings have recently received renewed attention from stakeholders. Some have called for the introduction of legislative reform, mainly as a way to address the financial implications of the system. This chapter will consider several of the more notable developments, starting with those relating to the civil justice system in the broader sense, before turning to those specifically associated with medical malpractice.

2.1. THE CIVIL JUSTICE SYSTEM

South Africa has not yet completed a thorough review of the civil justice system to assess and address its underlying problems.⁶ However, many of the concerns have long been recognised and still persist. Several of these concerns were identified by past inquiries into our justice system, in particular the Galgut and Hoexter Commissions.⁷ Although these commissions were more generally concerned with the administration of justice, they did touch on many specific problems litigants face and made

⁵ See Chapter 10.

⁶ Erasmus "Civil Procedure Reform-Modern Trends" *Stellenbosch L Rev* (1999) 10 3; Ngcobo "Delivery of justice: Agenda for change" *S. African LJ* (2003) 120 688; Vahed "Access to justice: Conference hosted by the Chief Justice 8 to 10 July 2011" *Advocate* (2011) 1; Maclons "Mandatory court based mediation as an alternative dispute resolution process in the South African civil justice system" (2014).

⁷ South et al. *Commission of Inquiry into Civil Proceedings in the Supreme Court of South Africa : chairman's report* (1980); South et al. *Commission of Inquiry into the Structure and Functioning of the Courts : fifth and final report* (1983).

recommendations for the review of various principles that underlie our civil justice system.

2.1.1. HOEXTER COMMISSION (1983)

The Hoexter Commission of Inquiry, as early as 1983, stated in its report:

‘Civil litigation in provincial and local divisions of the Supreme Court is characterised by cumbersome, complex and time-consuming pre-trial procedures; overloaded case rolls which necessitate postponements delay the actual process of trial...; protracted trials; and high costs of litigation. The abovementioned facts all conspire to create a situation in which the Supreme Court as a forum for the adjudication of contested matters is no longer accessible to the average citizen⁸

2.1.2. SOUTH AFRICAN LAW COMMISSION – PROJECT 94 (1996)

The problems encountered by ordinary citizens during legal proceedings have also garnered consideration from the South African Law Commission. On 8 July 1996, the Minister requested that the Law Commission broaden its Project 94 investigation into arbitration to include all facets of alternative dispute resolution (ADR).⁹ The Minister stressed the urgency of the project, as formalised methods of ADR could relieve the overburdened court system. This work commenced in October 1996.

In addition to lamenting the lack of access to formal justice, especially by those members of society who have been historically disadvantaged, the Commission highlighted a number of problems with the formal justice system:

‘The new Constitution of South Africa, with its Bill of Rights, is based on the principle that all people are equal before the law. The problem is that the equality thus achieved will be more of a facade than a reality if people are still *de facto* excluded because, due to past injustices, they do not have the economic, social or cultural ability to make use of those rights or to participate meaningfully in the administration of justice. What is therefore necessary is an attempt to add a social dimension to the *Rechtstaat* in terms of which even the disadvantaged and poor

⁸ South et al. (1983) 20.

⁹ South *Alternative dispute resolution* (1997).

will be entitled to representation and information. In this setting consideration may be given to alternative remedies and processes which may make justice fair and more accessible.¹⁰

‘The most common general complaint about the current justice system in South Africa is that the cost of litigation is prohibitive. This prevents meaningful access to courts and even those with access are often victims of delay. For most litigants, delay means added expense and for many people justice delayed is justice denied. Delay combined with the cost of litigation has put justice beyond the reach of the ordinary citizen. The incomprehensibility and adversarial nature of the process with a resulting lack of control (parties can only participate in an indirect manner) furthermore leads to a sense of frustration and disempowerment. Courts offering only trials are furthermore limited in their response to a legal dispute. Litigation often creates winners and losers and even winners may feel like losers given the limited nature of many legal remedies imposed from a limited range of win or lose options.’¹¹

2.1.3. NATIONAL JUDGES’ SYMPOSIUM (2003)

Chief Justice Ngcobo, addressing a National Judges’ Symposium in July 2003, echoed the earlier call of Professor Erasmus¹² for a review of the civil justice system, citing the following problems:

‘The second item that we must put on our agenda for change if we are to improve the delivery of justice, is a comprehensive review of our civil justice system together with its underlying principles. Our civil justice system suffers from a number of weaknesses: it is expensive, it is slow, it is complex, and it is fragmented and overly adversarial. These weaknesses combine to produce a

¹⁰ *Id.* 14.

¹¹ *Ibid.*

¹² “Address by the Minister of Justice and Constitutional Development Mr Jeff Radebe on the occasion of Access to Justice Conference” Department of Justice and Constitutional Development (2011-07-08) http://www.justice.gov.za/m_speeches/2011/20110708_min_ajc.html; Report by Professor HJ Erasmus to the Rules Board July 1998.

system that is gradually becoming inaccessible to the average person. In a country like South Africa, where there are gross disparities in wealth and education, the system becomes unequal for those who are wealthy and those who are poor, and the result it produces is similarly unequal. In a country where the majority is illiterate and poor, the majority suffers.¹³

2.1.4. ACCESS TO JUSTICE CONFERENCE (2011)

More recently, in 2011, Chief Justice Ngcobo spearheaded and hosted an Access to Justice Conference, where he repeated many of the same points:

‘Our civil justice system is still characterised by cumbersome, complex and time-consuming pre-trial procedures, overloaded court rolls, which necessitate postponements, delays in matters coming to trial and, at times, compels litigants to conclude settlements not acceptable to them. It is expensive, slow, complex, fragmented, and overly adversarial.’¹⁴

Looking toward the future, Chief Justice Ngcobo hoped that the conference could be the first step toward a justice system underlined by the principles identified by Lord Woolf, as essential to ensure access to justice in a civil justice system:

‘(a) be just in the results it delivers; (b) be fair in the way it treats litigants; (c) offer appropriate procedures at a reasonable cost; (d) deal with cases with reasonable speed; (e) be understandable to those who use it; (f) be responsive to the needs of those who use it; (g) provide as much certainty as the nature of particular cases allows; and (h) be effective: adequately resourced and organised.’¹⁵

Incidentally, an entire chapter of Lord Woolf’s report dealt with clinical negligence litigation, which he identified as one of the areas where the civil justice system was

¹³ Ngcobo (2003) *S. African LJ* 706.

¹⁴ Ngcobo “Enhancing Access to Justice: The Search for Better Justice” *Access to Justice Conference Towards Delivering Accessible Quality Justice for All* (2011) 1.

¹⁵ Woolf *Access to Justice: final report to the Lord Chancellor on the Civil Justice System in England and Wales* (1996) 5.

failing litigants most severely.¹⁶ Lord Woolf's 'Access to Justice' report and the subsequent reforms introduced are particularly relevant to South Africa, as our system of civil procedure 'owes its origin to and is essentially that of England'.¹⁷ The report is frequently referenced by South African jurists.¹⁸ The Woolf report and developments in the UK surrounding the issue of medical malpractice and patient safety, merits its own discussion. Such a discussion becomes all the more pertinent since, aside from the similarities between our civil justice systems, certain aspects of the South African healthcare regulatory framework have also recently been borrowed from the UK.¹⁹ The Office of Health Standards Compliance is largely based on, and was set up with help and inputs from its British equivalent, the Care Quality Commission. The Minister of Health has also on numerous occasions stated that the NHI should be thought of as South Africa's version of the NHS.²⁰

2.1.5. CIVIL JUSTICE REFORM PROJECT (2011)

In his address at the same conference, the previous Minister of Justice and Constitutional Development, Jeff Radebe, indicated that the government intends to undertake a review of the civil justice system in South Africa.²¹ The Civil Justice Reform Project seeks to overhaul the civil justice system to align it with the Constitution:

'It is inexplicable that we have taken such time to undertake this important work which is central to access to justice. The Department has provided additional capacity in terms of budget and Human Resources to fast track the Civil Justice Reform Project. This project is joint initiative of the Department and the Judiciary and both the Rules Board and the South African Law Reform Commission have

¹⁶ *Id.* 131.

¹⁷ Kahn "Is There Cause for the Popular Discontent with the Administration of Justice" *S. African LJ* (1989) 106 602; Erasmus "Historical foundations of the South African law of civil procedure" *S. African LJ* (1991) 108 265.

¹⁸ Erasmus (1999) *Stellenbosch L Rev* 10 3; Ngcobo (2003) *S. African LJ* 706; Vahed (2011) *Advocate* 1.

¹⁹ Fryatt and Matsoso "The UK and South Africa health partnership." *Lancet* (2012) 380 1970.

²⁰ The UK experience will be discussed in Chapter 16.

²¹ "Address by the Minister of Justice and Constitutional Development Mr Jeff Radebe on the occasion of Access to Justice Conference" Department of Justice and Constitutional Development (2011-07-08) http://www.justice.gov.za/m_speeches/2011/20110708_min_ajc.html.

significant roles to play. This Project includes the implementation of the court-based mediation and arbitration programmes which are essential elements of access to justice.’

The Civil Justice Reform Project will review the following:²² a) effectiveness of the courts and their capacity to deal with civil disputes; b) the alignment of the justice system with the constitution; c) affordability and cost-effectiveness; d) making court procedures and processes simpler; e) the role of information technology; f) improving case management; g) harmonisation of rules; and h) incorporation of alternative dispute resolution mechanisms.

2.1.6. REPRIORITISED PROJECT 94 - ALTERNATIVE DISPUTE RESOLUTION

On this last-mentioned point: The Law Reform Commission reprioritised project 94 at the end of 2011, following the introduction of the Civil Justice Review Project.²³ Since 10 September 2015 all the subprojects of Project 94 have been combined into one investigation, titled ‘Alternative Dispute Resolution’. The development of a Discussion Paper (including an Act on mediation) is receiving attention.²⁴

2.1.7. MEDIATION AND VOLUNTARY COURT-ANNEXED MEDIATION

Some changes, in this regard, have already begun to be effected. A pilot project of court-annexed mediation began in December 2014 and was officially launched by the Minister on 16 February 2015.²⁵ The Rules of Voluntary Court-Annexed Mediation²⁶

²² “Address by Deputy Minister Andries Nel, MP on the occasion of the 21st International Congress of the International Union of Judicial Officers (Sheriffs/Bailiffs)” Department of Justice and Constitutional Development (2012-05-02) http://www.justice.gov.za/m_speeches/2012/20120502_dmin_uihj.html.

²³ South African Law Reform Commission Annual Report 2015/2016 (2015) 32.

²⁴ South African Law Reform Commission Annual Report 2015/2016 (2015) 32.

²⁵ Department of Justice and Constitutional Development Annual Report 2015/2016 (2015) 32.

²⁶ Chapter 2 of the Magistrates’ Courts Rules.

were approved by the Minister and came into operation on 1 December 2014.²⁷ In the first phase of the pilot project, 12 magistrates' courts, 9 in Gauteng and 3 in North West, were selected to offer mediation services. More than 200 mediators were accredited by the Minister to provide mediation services. It is hoped that this initiative will reduce the high legal costs litigants usually incur. The initiative is also expected to reduce the number of cases on the court roll and make justice more accessible. Lessons learnt through the pilot will inform its roll-out to other courts, including the High Courts throughout the country.²⁸ A report of the pilot study identified a number of issues that will be considered before nation-wide implementation is undertaken.²⁹

The Department of Justice and Constitutional Development has also developed a first draft Mediation Policy for consultation with stakeholders.³⁰ This policy is intended to enable government to use mediation as a tool to lower costs of litigation, where applicable. In order to better oversee and manage all state litigation, The State Attorney Amendment Act now provides for the establishment of a Solicitor-General.³¹ Whether, this newly established post would address the quality of state legal services, remains to be seen.³² At this stage, it seems as though demographic transformation is the primary concern behind the intervention.³³

2.1.8. CONCLUSION

There are many problems with the South African civil justice system. Chief Justice Ngcobo succinctly described it as, 'expensive, slow, complex, fragmented, and overly

²⁷ Rules Board for Courts of Law Act (107/1985): amendment of rules regulating the conduct of the proceedings of the Magistrate's courts of South Africa (GN183 in GG37448 of 18 March 2014).

²⁸ Department of Justice and Constitutional Development Annual Report 2015/2016 (2015) 32.

²⁹ Department of Justice and Constitutional Development Annual Report 2016/2017 (2016) 31; See Allen "A discussion of the new mediation provisions in the South African Magistrates Courts Rules" (2014) 1 for a discussion of the new mediation provisions in the South African Magistrates Courts Rules.

³⁰ Department of Justice and Constitutional Development Annual Report 2016/2017 (2016) 32.

³¹ State Attorney Amendment Act 13 of 2014.

³² Klaaren "Civil Government Lawyers in South Africa" *NYL Sch. L. Rev.* (2015) 60 365.

³³ "Solicitor-general to head Office of the State Attorney" De Rebus (2015-06-29) <http://www.derebus.org.za/solicitor-general-to-head-office-of-the-state-attorney/>.

adversarial'.³⁴ As such, it often fails to live up to the principles identified by Lord Woolf. Many of the problems may be exacerbated in cases of medical malpractice litigation. In the report, cited by the Chief Justice, Lord Woolf singled out medical negligence, because 'it was in the area of medical negligence that the civil justice system was failing most conspicuously to meet the needs of litigants'.³⁵ This is likely true of our system as well. Therefore, it may be useful to consider Lord Woolf's recommendations for reform. These will be discussed in the following chapter. The Civil Justice Reform Programme, should similarly also review and address the challenges that litigants face in this area. It is encouraging to note that Alternative Dispute Resolution has seemingly gained traction because of this initiative.³⁶

Having considered the notable developments relating to the broader civil justice system, the focus now turns to the medical malpractice system and the proposed changes directed at this specific area of the law (with its unique challenges).

2.2. MEDICAL MALPRACTICE REFORMS

The current medical malpractice situation has led stakeholders to call for reform. Recent developments indicate that interventions aimed at limiting the costs of malpractice claims are receiving serious consideration from policymakers. This is, however, not the first time that the prospects of limiting costs associated with these types of claims have received attention. The South African Law Commission has previously investigated the need and desirability of limiting liability of medical practitioners.

³⁴ Ngcobo (2011) *Access to Justice Conference Towards Delivering Accessible Quality Justice for All* 1.

³⁵ Woolf (1996) 6.

³⁶ Walters "Mediation - an alternative to litigation in medical malpractice" *S Afr Med J* (2014) 104 717; Claassen "Mediation as an alternative solution to medical malpractice court claims" *S Afr J BL* (2016) 9 8; Dhai "Medical negligence: Alternative claims resolution an answer to the epidemic" *South African Journal of Bioethics and Law* (2016) 1.

2.2.1. SOUTH AFRICAN LAW COMMISSION - PROJECT 70: THE LIMITATION OF PROFESSIONAL LIABILITY

The South African Law Commission, as part of Project 70, has considered the desirability of limiting the liability of professional persons through legislation.³⁷ An investigation under the title 'The Limitation of Professional Liability' was included in the Commission's programme on 1 December 1989.

The Commission noted that professionals traditionally operate in spheres in which success is not always feasible.³⁸ Their success or failure can very often depend on extraneous factors. This may be the case even where important factors are within the professional's control. The Commission has observed that courts face a particular difficult task in establishing a rational approach to professional liability. They are required to strike a balance between adequate protection for the consumer, client or patient, on the one hand, and human fallibility, on the other. The solution that the courts have employed, has been to require that professionals comply with a minimum standard of skill and exercise reasonable care in the provision of professional services. This general approach has been applied almost unchanged by English courts over the past 150 years. It was also adopted in South Africa. In *Mitchell v Dixon* it was held that:

'A medical practitioner is not expected to bring to bear upon the case entrusted to him the highest possible degree of professional skill, but he is bound to employ reasonable skill and care; and he is liable for the consequences if he does not.'³⁹

The Commission's investigation was not limited to certain professions, it dealt with all professions in which liability may arise as a result of the provision of services. Some professions, including the medical profession, did indicate that they were experiencing problems and were invited to define their problems and make proposals.

The Medical Association of South Africa raised concerns about the claim situation in the United States, noting that as users become gradually more aware of their rights

³⁷ South *Limitation of professional liability* (1993).

³⁸ *Id.* 5.

³⁹ *Mitchell v Dixon*, 1914 AD 519 at 525.

they will be more inclined to resort to courts. However, they were not in favour of limiting professional liability of medical practitioners, since the public would react negatively to such a step. They did state that there could possibly be some value in investigating the potential of 'no-fault liability' schemes.⁴⁰

The Commission noted that medical practitioners have traditionally received 'soft treatment' from the court and that in the majority of cases practitioners have been absolved of blame. They indicate that this 'tradition of leniency' also prevailed in English law. In both countries, the courts have consistently disallowed the application of the *res ipsa loquitur* doctrine. The Commission took cognisance of the stricter approach taken by American courts, and the increases in litigation they have experienced, which has led to higher insurance premiums. However, the Commission stated, that unless litigation were to increase phenomenally, this effect in South Africa would be minimal. They referred to Strauss, and the fact that he considered fears of South Africa following the same course as the US to be unfounded. Particularly, since *Van Wyk v Lewis* meant that practitioners were placed in a more favourable position with regard to the proof of negligence, legal professionals were not allowed to advertise their services, adverse cost orders posed a strong deterrent, and juries are not involved. Furthermore, only four cases were reported in the courts between 1977 and 1987. Strauss characterised the legal position with regard to medical liability as balanced, and that only two matters could improve the current position. The first, would be to place a medical panel at the disposal of the courts. The second would be a 'system of extra-judicial patient compensation in which onus of proof is not required'.⁴¹

The Commission observed that there would be 'vehement public opposition' to any effort to limit liability of medical practitioners, since many felt they are already overly protected. They noted that the Patients' Rights Organisation of South Africa (PROSA) has claimed that malpractice is a common occurrence and has insisted that the Medical and Dental Council be investigated in this regard. They also claimed that the Council had not met its obligations toward patients with valid complaints of malpractice and

⁴⁰ *Id.* 74.

⁴¹ *Id.* 83.

carelessness. PROSA also raised concerns about the fairness of the complaints procedure, and the unfavourable position claimants find themselves in having to overcome the onus of proof.⁴²

The Commission indicated that a number of mechanisms were already deployed to limit professional liability. Courts have refused to extend the Aquilian action to cases based on contract, the effect of public policy considerations in cases of pure economic loss, and the legal position regarding causality and prescription. In fact, the legal position of professionals in South Africa is generally far more favourable than in most other major legal systems. The Commission was not presented with any scientific evidence that the increase in claims were disproportionate to the increase in the population or of the number of professionals. They assured members of the professions that they were insulated from factors that have adversely affected the US liability situation. Punitive damages, the jury system and unregulated contingency fees, which contributed to the astronomical amounts awarded, are not a part of our law.

With regard to the cost of indemnity insurance, the Commission, received no evidence to suggest that premiums were disproportionately high in relation to income. Therefore, they felt that compulsory insurance schemes constituted an attractive option for the spreading of risk.

Regarding the merits of the measures advocated by certain professions and other possible methods of limiting liability, the Commission came to the following conclusions:

- . 'No statutory interference in the elements of delict is desirable or necessary'.
The law of delict is based on sound principles and statutory interference may adversely affect the further development thereof by the courts.
- . 'The elimination of vicarious liability is not acceptable.'
- . 'Compulsory professional liability insurance within a profession is a sound measure to spread and reduce the risk of liability.'

⁴² *Id.* 84.

- . 'Limiting the quantum of damages is an exceptional measure, and one that is unacceptable outside the USA.' The Commission notes that even in the US, such a ceiling is only regarded as justified if there has been a crisis and the 'societal quid pro quo' established by the ceiling benefits the community.
- . 'Risk management and ethical prescriptions that keep pace with the demands of the time remain the primary means of preventing liability.' The Commission believed that South African professionals were in a good position, since statutory professional bodies impose norms and standards and enforce uniform compliance with them.

Ultimately, the Commission was not persuaded that there was justification to limit the delictual liability of any category of professionals by legislation, and in particular, that the legal rules that establish and demarcate liability do not require adaption. The Commission was of the opinion that professional groups were able to regulate the liability of their members within acceptable bounds through internal measures and by means of insurance. Therefore, the only recommendation for reform thought to be necessary, was that members of professional bodies be compelled to take out liability insurance.

This working paper was published in December 1993 for general information and comment. After the comments received had been processed, a draft report was prepared. During the course of 1996 the Commission recommended the removal of the investigation from its programme. In November 1996 the Minister, however, requested that the Commission continue with the investigation. The Commission expressed the view that limitation of liability could not be justified and that it might be unconstitutional. After further deliberations with certain professions it was resolved that the Minister should again be requested to remove the matter from the Commission's programme. On 17 December 1998, the Minister approved the request.⁴³

⁴³ South African Law Commission Annual Report 1998 (1998) 29.

2.3. REIGNITED INTEREST IN REFORM

Medical malpractice claims have once more come under the spotlight. The renewed attention and calls for intervention have mainly been driven by the Minister of Health, who perceives litigation and its costs as a threat to his National Health Insurance plans.⁴⁴ Various stakeholders in the private sector have aligned themselves with the Minister and have raised concerns about the affordability and availability of insurance. A number of developments have occurred in this regard. A summit, involving the major role-players, was held. A Ministerial Task Team was subsequently appointed and drafted a medico-legal declaration. This Task Team has been converted into a Ministerial Advisory Committee and have come up with an implementation plan. And, lastly, medical malpractice claims are again the subject of another investigation by the South African Law Reform Commission. The rest of the chapter will look at these developments.

2.3.1. THE MEDICO-LEGAL SUMMIT

The Minister of Health convened a Medico-Legal Summit in March 2015.⁴⁵ Delegates, representing the public and private health sectors, medical and legal professions, attended the two-day summit to discuss, what the Minister considers to be a medico-legal crisis facing the health system in South Africa, in order to come up with plans to address the situation.⁴⁶

⁴⁴ “Medical litigation crisis: Motsoaledi” SAPA (2015-03-09) <https://www.iol.co.za/news/crime-courts/medical-litigation-crisis-motsoaledi-1829277>; “Doctors call for lawyers to get out of hospitals” South African Medical Association (2015-03-10) <http://www.politicsweb.co.za/news-and-analysis/lawyers-must-get-out-of-hospitals--sama>; “Medical malpractice costs: Towards a solution” South African Medical Association (2016-03-04) www.samainsider.org.za/index.php/SAMAINsider/article/download/51/31;

“Why you might battle to find a doctor to deliver your baby in SA” Bhekisisa (2017-06-02) <http://bhekisisa.org/article/2017-06-02-the-real-reason-sas-doctors-wont-deliver-your-baby>; Bateman “SAMA pitches in to help victims of adverse medical events: izindaba” *South African Medical Journal* (2015) 105 337.

⁴⁵ Medico-Legal Summit, St. George’s Hotel, Pretoria 9-10 2015.

⁴⁶ Dhai (2015) 8 *S Afr J BL* 2.

2.3.2. THE MINISTER OF HEALTH'S KEYNOTE ADDRESS

The Minister of Health, Dr Aaron Motsoaledi, delivered the keynote address at the Medico-Legal Summit.⁴⁷ He employed the same tactic he used when he first introduced the NHI. In the Green Paper he blamed nearly all of the public health sector's flaws on the existence private sector, often distorting facts to fit his particular reform agenda, without regard for the consequences of ill-informed interventions that would do little to address the underlying systemic problems, effectively standing in the way of achieving the desired objective of universal coverage. The only thing standing in the way of free quality health care for all, was the 'expensive', 'unsustainable' private sector.

The Minister's approach to the medical malpractice problem has followed the same script, only the scapegoat has changed. And, one could not ask for a better, more universally despised scapegoat – greedy lawyers! Where the Minister had previously failed to convince members of the tax-paying public that – despite funding public healthcare and then paying substantial additional amounts of their own expendable income for private care in order to avoid the dysfunctional, mismanaged public sector – the NHI was the solution to the 'expensive' private sector problem. He now had the perfect target to pin all the blame on. Everyone hates 'pocket-lining' lawyers!

The following are some excerpts from his speech, with annotated points of criticism:

'Please get used to the idea that from now, henceforth, whenever we meet in this fashion, I am going to keep on reminding you that South Africa has a plan – the National Development Plan (NDP) or Vision 2030. This is because every summit, conference, plan, strategy, resolution, declaration, and debate in health, will have to align itself with the NDP.'⁴⁸

Unfortunately, the ruling party has crippled the economy to such an extent, that actual domestic economic growth has been half that of the worst case scenario envisioned by the NDP. This has rendered many of the lofty goals and targets unachievable.

⁴⁷ Motsoaledi (2015) 8 *S Afr J BL* 4.

⁴⁸ *Id.* 4.

Healthcare will almost certainly also face the dire consequences of the government's rampant corruption and devastating economic policies. Although, it is encouraging to see that the Minister seems to be committed to the NDP, references to its ideals should be tempered with realism.

'There are three main events, or should I say issues, that will be major determining factors of whether we indeed can achieve the goals of the NDP. In fact, these three issues, which are all going to happen this year – 2015, will make or break the health system in this country. The three of them are going to change the health system as we know it today. Unfortunately, the change they may bring may be either positive or negative, depending on our attitude as South Africans. These three are: the outcomes of the White Paper on the National Health Insurance (NHI); the outcome of former Chief Justice Ngcobo's public market inquiry into the cost of private health as set out by the Competition Commission; and the outcome of this very Summit on medico-legal litigation tomorrow. I repeat – these three will make or break the health system as we have come to understand it in South Africa.'⁴⁹

This statement is quite sensationalist. By presenting these important matters as a dichotomy between 'make or break' and 'positive or negative' change, the Minister overly simplifies very complex issues, leaving little space for actual engagement and debate.

'Has medico-legal litigation reached a crisis point in South Africa? The answer is definitely a big Yes. It is a crisis of large proportions.'⁵⁰

The Minister characterised the situation as the 'same crisis that engulfed Australia a decade-and-a-half ago when their general insurance collapsed' and as the 'same crisis that occurred in the United States (US) in the early 1970s'

⁴⁹ *Ibid.*

⁵⁰ *Ibid.*

If unsubstantiated and presented without proper evidence, these types of dramatic statements, could perhaps, amount to fear-mongering, which could be construed as pushing a certain agenda, especially where a conflict of interest exists.

‘Yes programme director, we are certainly headed in the direction which hit the United Kingdom (UK) in the not so distant past when a big debate in the House of Commons dubbed ‘The Big Storm’ ensued. What is the nature of this crisis in South Africa today? Are we faced with our own ‘Big Storm’?’⁵¹

The Minister seems to be referring to the debate regarding Sir Ian Kennedy’s ‘Learning from Bristol’ report. Unfortunately, the Minister does not seem to appreciate the context of that debate. It had very little to do with increases in litigation and costs, in fact Kennedy proposed a no-fault system, which would most likely cost the public sector even more.⁵²

‘The nature of the crisis is that our country is experiencing a very sharp increase – actually an explosion – in medical malpractice litigation which is not in keeping with generally known trends of negligence or malpractice. The cost of medical malpractice claims have sky-rocketed and the number of claims increased substantially.’⁵³

‘When it first started being noticed, those who have made a habit of rubbishing the Public Health system at every available opportunity jumped in without an iota of research and concluded that the reason is the rising negligence or what they call the ‘don’t care attitude’ in public healthcare in our country – and started lambasting the State about it.’⁵⁴

⁵¹ *Ibid.*

⁵² “Bristol Royal Infirmary” Hansard Volume No. 378, Part No. 82, Column: 448 (2002-01-17) https://publications.parliament.uk/pa/cm200102/cmhansrd/vo020117/debtext/20117-11.htm#20117-11_head0.

⁵³ *Ibid.*

⁵⁴ *Ibid.*

The Minister indicates that malpractice litigation 'is not in keeping with generally known trends of negligence or malpractice'. It is not clear what trends he is referring to. The Minister is also very quick to criticise those who might point to a correlation between the public system, with its known weaknesses, and the increasing litigation burden. As for his claim that these conclusions are unfounded, the National Development Plan, relied on so heavily at the onset of his speech, explicitly mentioned the poor quality of care provided by the public health system.

The Minister is correct in stating that both the public and private sectors are affected and he noted that some specialities were intrinsically more susceptible to larger claims. This has led to very high insurance premiums for those practicing in those disciplines.

Unfortunately, the Minister resorts to hyperbolic and unhelpful statements to bolster his argument:

'Just close your eyes tightly and imagine a country with many many super-rich lawyers but no obstetricians at all! That will be back to the Stone Age. It is tantamount to declaring a death sentence to women and children.'⁵⁵

The Minister again refers to the Bristol Infirmary Inquiry debate, specifically Frank Dobson's submission that the 'current inadequate, slow, unsatisfactory, grotesquely expensive and lawyers' pocket and handbag-lining system of dealing with clinical negligence' should be replaced in accordance with Kennedy's recommendation. The Minister, however, misleads when he implies that this is in response to the cost of claims. He does, however, include Dobson's (restating Kennedy's) submission that the existing system's 'main fault is that it is bad for patients' safety', but he does not mention that Kennedy proposed a no-fault system as a replacement. One gets the impression that the Minister cherry picked the quotes so that they align with his position and argument.

⁵⁵ *Id.* 5.

‘Patient safety should be our major concern and the central core of the outcomes of this Summit. I am painfully aware that this statement may lead the cynics and sceptics to conclude that the explosion of medical litigation is a direct result of patients’ safety being severely compromised. A few weeks ago, when an unauthorised report about the workshop of the stakeholders I convened to prepare for this Summit was wrongfully released, many lawyers who commented took this view – yes if they are not negligent, there will be no litigation. If patients are all safe, there will be no problem. Let us be brutally honest, many of the highly litigating lawyers care less about the concept of patient safety. They are driven by this pocket-lining phenomenon described by the British Minister. They are simply in hospitals because the platform from which they have been lining their pockets – and not that of the wronged patients – has now changed.’⁵⁶

The fact that the Minister immediately goes on the defensive, dismissing seemingly valid contentions and deflecting criticism, to instead berate lawyers who help injured patients access justice and compensation (albeit because of the financial incentive to do so), makes the Minister’s declared concern for patient safety seem mendacious. If the Minister is unwilling to at least acknowledge that there are problems with the health system, particularly the public sector, which may seriously compromise patient safety, and that litigation may be a symptom of a sick system, he cannot be as committed to safety as he proclaims. One gets the feeling that patient safety is strategically employed as a Trojan horse, to introduce liability-limiting malpractice reform. If one was to be really cynical, one might suspect that patients will find it even harder to obtain redress, whilst no real improvement in quality and safety would take place.

To his credit, the Minister, did dedicate one paragraph of his tirade against the legal profession to ‘medical solutions’. He announced that a South African counterpart to the British Quality Care Commission, the Office for Health Standards Compliance, would conduct inspections of health facilities. A Health Ombud, that ‘will examine breaches of standards and norms, for both patient redress and system improvement’ and

⁵⁶ *Ibid.*

‘complement the existing investigations of professional negligence’ would also be appointed.⁵⁷

However, after mentioning these interventions, almost as an afterthought, he goes straight back to shifting blame for the increased litigation. Without providing any proof, the Minister claimed that ‘syndicates’ were responsible. He set out his conspiracy theory, as follows:

‘People are working in syndicates – to achieve their aim which is one – to line their pockets in the name of patients who might have been victims in one way or the other. We are aware that these syndicates consist of lawyers and some within the health profession itself to make as much money from the State and other doctors as possible.

We are aware that members of these syndicates in the various State Attorney Offices are mismanaging cases deliberately, so that the State must lose at all times. We are aware that some hospital CEOs are not doing anything to safeguard the welfare of patients but instead deliberately jeopardise the welfare of patients and immediately report to the legal members of these syndicates to start litigation. We regard these people as having declared war on the health system of the country and hence will deserve no mercy when they are finally caught.’⁵⁸

If the Minister is aware of such conduct, disciplinary proceedings and criminal investigations should be instituted. I’m not aware of any further developments or media reports that have followed this accusation.

2.3.3. MINISTERIAL TASK TEAM AND DECLARATION

After the Medico-Legal Summit, the Minister appointed a Ministerial Task Team to consolidate all the submitted recommendations. They were also tasked with compiling

⁵⁷ *Id.* 6.

⁵⁸ *Ibid.*

a Declaration that would set out possible solutions to the issues raised at the summit. This Declaration was signed by the Minister on the 15th of March 2016.⁵⁹

Unfortunately, a more considered view of the situation is not to be found in the Declaration. However, at least its resolutions take a more holistic approach to the problem and simultaneously seek to address the patient safety, administration and legal concerns.

2.3.4. MEDICO LEGAL DECLARATION

The Declaration starts by ‘declaring’ that the Summit ‘noted with concern’ that:⁶⁰

1. ‘The provision of health care services is a basic human right as enshrined in section 27(1)(a) of the Constitution of the Republic of South Africa, 1996’
2. ‘That the negative impact of medico-legal litigation, due to a number of factors, has reached crisis levels in South Africa, which is compromising health service delivery in both the public and private sectors.’
3. ‘That our country is experiencing an explosion in medical malpractice litigation, which is not in keeping with generally known trends of negligence or malpractice.’
4. ‘That this crisis is having a serious impact on the current and future availability of specialists in key disciplines in the health profession – both public and private.’
5. ‘That, in view of these factors, the impact of medico-legal litigation threatens the vision of Government of achieving a long and healthy life for all South Africans.’

Possible criticism of these five declared points:

1. Allow me to be facetious and point out that, the Declaration probably did not mean to note with concern that the right to health care services is enshrined in our Constitution. It is a concern that it is not realised. (Furthermore, if one was to

⁵⁹ Team, *Declaration Medico-Legal Summit* (2016).

⁶⁰ *Id.* 1.

be pedantic, section 27(1)(a) states that everyone has ‘the right to have access to health care services’.)

2. These types of, likely, exaggerated and unsubstantiated statements are unhelpful and do nothing to engage with the substance of the issue. Words like ‘crisis levels’ are meant to evoke fear and circumvent constructive debate regarding the factors and full-extent of perceived problems. It may very well be that increases in litigation serve as a warning sign of a deteriorating public health system. It can also be argued that, instead of litigation compromising health service delivery (of which, the evidence is questionable), compromised health service delivery has led to patients seeking redress. This is just one view, it may not be accurate, but it should at the very least be considered. And in the absence of evidence, it should perhaps demand similar attention and prioritisation.
3. What are the ‘generally known trends of negligence or malpractice’? Studies have shown that injuries caused by negligence far exceed claims filed. In fact, only a fraction of harmed patients institute claims. The little evidence available seems to suggest that patients in developing countries may be more likely to face iatrogenic harm and suffer more severe consequences. If the number of valid claims has increased, it surely means that patients are more aware of their rights, which should be welcomed. It could also be an indication that they are not receiving the support they need and, therefore, turn to the courts for assistance. Whatever the case may be, to simplify the situation by employing hyperbolic language serves a narrow agenda.
4. By ‘crisis’ they, probably, imply that there is an insurance affordability problem. As studies have shown, this may not be the fault of litigation alone, and is often linked to insurance cycles and financial markets. By limiting the discussion to one possible aspect of the problem, it denies the opportunity to look at broader, more encompassing, solutions.
5. Does the ‘impact of medico-legal litigation’ threaten that vision or does the provision of substandard care, which harms a multitude of patients each year (according to numerous court verdicts), threaten it? Such an oversimplification might absolve the underlying faults highlighted by the increase in litigation.

Fortunately, despite confining the problem to one facet, the solutions proposed were not as constrained and myopic.

Some of the proposals specifically targeted patient safety.⁶¹ These included, the following: enforcement of a safety culture through the implementation of the Patients' Rights Charter; improved clinical governance; implementation of clinical audits; adoption of safety checklists; adherence to standard operating procedures and guidelines; etc. Of course, effective implementation and continual improvement counts. South Africa is unfortunately full of examples, where praiseworthy policies and idealistic promises never come to fruition. In fact, many of these proposals should already be the norm in our health system. Unfortunately, the underlying problems that prevent their realisation, although well-known, are never properly addressed.

Proposals were also made with regard to administration, including:⁶² reliable record-keeping; proper management of medical records; adequate supervision; communication and obtaining informed consent; appointment of competent management; hospital administrators fulfilling their responsibilities; and prompt institution of disciplinary proceedings. Again, these are matters that should have been addressed already and might very well explain the current 'crisis'. The most significant proposal, was for the introduction of a Uniform National Reporting System for adverse events.

Most of the proposals were aimed at the 'legal' part of the problem.⁶³ These included: the immediate implementation of mediation, with possible sanctions for failure to cooperate; requesting the Law Reform Commission to investigate the matter; appointment of an ombudsman; establishment of a tribunal or specialised court; scrapping the 'once and for all' rule; prompt intervention at the start of litigation; pursuing settlements to minimise costs; improving legal capacity of government departments; using external expertise; improving quantum assessment; reporting vexatious and

⁶¹ *Ibid.*

⁶² *Id. 2.*

⁶³ *Id. 4.*

unethical conduct to the Law Society; avoid ‘double-dipping’; appointing one expert for both parties; and strengthening the statutory councils.

A number of ‘future options to reduce claims’ were also noted. The following options would be ‘explored as part of the law reform process’: establishing a national litigation authority; comparative studies from other countries; alternatives to financial compensation; alternatives to court (i.e. no-fault compensation, Road Accident Fund model, compulsory mediation, and establishing a tribunal); capping of settlements; capping contingency fees; periodic and structured compensation; and a settlement review panel.

2.3.5. LATEST DEVELOPMENTS

The Ministerial Task Team has subsequently been converted to a Ministerial Advisory Committee on 20 June 2016. They have drafted an implementation plan, which would be communicated to provincial departments for execution.⁶⁴

The Minister touched on the issue again recently, during an address to the to the International Hospital Fellowship, in Durban on 1 November 2016.⁶⁵ Although, he still characterised litigation as ‘one of the biggest threats to the sustainable improvement in health care’, he did slightly tone down his rhetoric regarding the legal professions’ role:

‘In the light of this onslaught on litigations, I have noticed colleagues and doctors getting irritated and tempted to attacking lawyers. I will strongly advised that we rather be inward-looking and expend all our energies in fine-tuning our systems as outlined in the topics as mentioned so that the lawyers find nothing to scavenge on.’

⁶⁴ “Presentation: Medico-Legal Declaration” Carter, Deputy Director- General: Hospitals, tertiary health services and workforce development, National Department of Health (2016-10-23) https://www.samedical.org/files/conference_presentations/2016/20_Presentation.pdf.

⁶⁵ “Address to the International Hospital Fellowship, 40th World Hospital Congress” Minister of Health (2016-11-01) <http://www.kznhealth.gov.za/IHF/Minisiter-speech.pdf>.

However, the Minister has recently reiterated some of his harsher criticisms, he also wrote a rather scathing op-ed in a national newspaper.⁶⁶

3. SOUTH AFRICAN LAW REFORM COMMISSION: ISSUE PAPER 33 (PROJECT 141) MEDICO-LEGAL CLAIMS

The Minister of Health has requested that the South African Law Reform Commission include an investigation into medico-legal claims in its programme.⁶⁷ This request is predicated on the challenges posed by the apparent increase in medical malpractice claims and amounts awarded as damages, as well as the dire financial implications this escalation presents for the public health sector.⁶⁸

The Commission was also approached by the Minister of Justice and Correctional Services regarding matters raised in the Souls Cleopas case.⁶⁹ The case was brought on the basis of negligent medical treatment that the plaintiff had received from staff at Gauteng hospitals. What the Gauteng Department of Health proposed in that case would in effect amount to the abolishment of the common law 'once and for all'-rule. He believed that this should not be done without first conducting an in-depth investigation, and requested the Commission's assistance.

The investigation was approved for inclusion in the programme on 10 September 2015. In addition to these two requests, an official from the Office of the State Attorney met with the Commission regarding the increase of medical negligence claims against the

⁶⁶ "Why you might battle to find a doctor to deliver your baby in SA" Bhekisisa (2017-06-02) <http://bhekisisa.org/article/2017-06-02-the-real-reason-sas-doctors-wont-deliver-your-baby>; "SA lawyers: Motsoaledi, we're not the reason gynaes won't deliver babies" Bhekisisa (2017-06-12) <http://bhekisisa.org/article/2017-06-12-00-sa-lawyers-motsoaledi-were-not-the-reason-gynes-wont-deliver-babies>.

⁶⁷ Commission (2017) 1.

⁶⁸ *Ibid.*

⁶⁹ *Ibid.*

State.⁷⁰ It was agreed that the investigation would review the manner in which compensation for medical malpractice was determined and paid, in particular, the influence of the once-and-for-all rule and lump-sum payments.

The salient aspects of the Issue Paper will now be considered.

3.1. CHAPTER 1: EVENTS PRECEDING SALRC INVESTIGATION

The Commission's issue paper, provides some background to the current situation and the events that led up to the investigation.⁷¹ Mention is made of the Medico-Legal Summit, which the Minister of Health convened in March 2015, and a Medical Malpractice Workshop, held in March 2017.

Of concern, is the fact that under the section titled 'Need for law reform', the Commission seems to have already come to the preconceived conclusion that law reform is required.⁷² In fact, according to the Commission, law reform is a pressing matter: 'There is an urgent need to undertake reform of the law in order to regulate a system that will become paralysed if no action is taken.' It has also, evidently, already been decided that a statutory intervention would be required: 'Regardless of the nature of the changes, legislation will be required to effect such changes.'⁷³

These are drastic statements, proposing changes that would have very far-reaching consequences. One would at least expect that sound evidence and a convincing argument would be provided. Unfortunately, that is not the case. A rather, flimsy justification, based solely on a weak correlation between increasing claims (for which no evidence or context is offered) and their supposed adverse impact on the ideals of the National Development Plan, is all that is provided under this heading.

⁷⁰ *Id.* 2.

⁷¹ *Ibid.*

⁷² *Id.* 4.

⁷³ *Ibid.*

3.2. CHAPTER 2: INVESTIGATION INTO MEDICO-LEGAL CLAIMS

Chapter 2 of the Issue Paper begins by setting out the scope of the problem.⁷⁴ The objectives of the SALRC are presented and in keeping with those objectives, and contrary to above, a more reasoned course is plotted: ‘it is necessary to look into such [medico-legal] claims in more detail to determine whether the area is problematic and if so, the reasons for and extent of the problem.’⁷⁵ This is a much better starting point. However, it is unfortunate to note that reference is made to media reports and other inadequate sources in the absence of empirical evidence. Unsubstantiated claims and unfounded statements, which rely on politically influenced, misleading information presented as unassailable evidence (for instance, the Department of Health’s policy documents), could also constrain and hamper an investigation of this import, already complicated by many different stakeholders and diverging agendas. (The NHI proposals have included some disputable figures and must be approached with utmost caution. Where at all possible, other sources of data should at least be presented, to highlight possible contentious aspects and provide the fullest, objective picture of affairs.)

The Commission provides an overview of various authors’ views on the medical malpractice situation (two papers, written by Professor Carstens and myself, are also summarised).⁷⁶ The distinction made between conventional and fundamental reforms, incorrectly attributed to Van den Heever in the Issue Paper, actually forms part of one of our papers.⁷⁷ The part about capping, as discussed by the Commission, was one of the conventional reforms we considered. However, we were certainly not in favour thereof in the light of patient safety considerations, as we went on to say:

‘These reforms may reduce claims, costs and perhaps indemnity insurance premiums. However, just as more litigation under the existing system will probably not make healthcare safer, less litigation and smaller awards under a slightly

⁷⁴ *Id.* 6.

⁷⁵ *Ibid.*

⁷⁶ *Id.* 8.

⁷⁷ Oosthuizen and Carstens “Re-evaluating medical malpractice: A patient safety approach” (2015).

altered version of the existing system will also likely have no impact on patient safety.⁷⁸

The Commission turned its attention to ‘Health spending and expenditure on litigation’ next.⁷⁹ South Africa’s health expenditure as a share of GDP is below that of developed countries, but compares well to other middle-income countries. In fact, the health system appears to be under-performing with its given level of expenditure.⁸⁰ The argument is made that the money that would be spent on realising the constitutionally guaranteed right to access to healthcare, is being diverted away by to pay medico-legal claims.⁸¹ Provincial health departments have limited budgets, money spent on claims, therefore cannot be spent on providing healthcare services.⁸² The Commission notes that this amounts to a ‘vicious circle’: ‘The more damages to be paid, the less money is available for service delivery, the poorer the quality of the service rendered by the hospital, the more room for negligence and error, the more the claims.’ They submit that if this ‘vicious circle’ is not addressed ‘the entire public health system could implode’.⁸³

To emphasise the point, figures showing the principal amounts paid out for litigation and the contingent liabilities of the respective provincial health departments for medical malpractice claims, are presented.⁸⁴ As it stands, the total contingent liabilities are R40 923 535 00.

The Commission notes that the private sector is also adversely affected by the increase in claims.⁸⁵ Information provided by the Medical Protection Society (MPS) is exclusively cited (another major stakeholder, with a significant interest in the outcome of the

⁷⁸ *Ibid.*

⁷⁹ Commission (2017) 15.

⁸⁰ Africa (2009) 15.

⁸¹ Commission (2017) 15.

⁸² *Id.* 16.

⁸³ *Ibid.*

⁸⁴ The discrepancies in the publically available figures have been pointed out in Chapter 14, Paragraph 2.2.

⁸⁵ Commission (2017) 17.

investigation). The cost of indemnity insurance and the potential negative effects thereof, is the main concern in the private sector.

The Commission then provided an overview of some of the more recent cases that ended up in court (including short descriptions of the tragic facts in each).⁸⁶ They observed the long periods that often elapse before resolution is reached, noting some of the causes, such as sluggish legal processes, full court rolls, delays caused by witnesses being unavailable, trouble in obtaining evidence, etc. The Commission considered this delay in finalising cases an indication ‘that the law is unsatisfactory in this regard’.⁸⁷

3.3. CHAPTER 3: LEGAL PRINCIPLES UNDERLYING MEDICO-LEGAL CLAIMS

Chapter 3 deals with the legal principles underlying medico-legal claims.⁸⁸ The relevant constitutional rights and provisions that may come into play are briefly discussed. Mention is made of the courts’ ability to develop the common law to the extent that legislation does not give effect to a right enshrined in the Bill of Rights. However, the Commission is quick to point out that courts cannot legislate and the rest of the discussion is subsequently centred on the separation of powers doctrine.⁸⁹ This chapter superficially touched on some very significant constitutional rights, to only, presumably, imply that legislative intervention would be required.⁹⁰ The consequences or effects of such an intervention on these rights did not receive attention.

The legal processes that underlie medico-legal claims were considered next.⁹¹ Some of the hurdles potential litigants face, particularly poor previously disadvantaged patients, are highlighted. The Commission notes that ‘one can only speculate how many

⁸⁶ *Id.* 19.

⁸⁷ *Id.* 22.

⁸⁸ *Id.* 23.

⁸⁹ *Id.* 25.

⁹⁰ *Id.* 26.

⁹¹ *Ibid.*

incidents of medical negligence never proceed to litigation because of the impediments'.⁹² They conclude that this area of the law is 'unduly complex and difficult to access to the average user of public health care'.⁹³ While this is certainly true, what area of the law is not? The difficulties faced by the average citizen in accessing justice is an indictment against the entire civil justice system.

A brief overview of the law of obligations, elements of delict, test for medical negligence and the *res ipsa loquitur* doctrine was provided, before the focus shifted to the 'once and for all' rule.⁹⁴ It was noted that the rule dates back more than 300 years and although, it has its origins in the English law, it forms part of our law.⁹⁵ The Commission set out the controversies surrounding the rule as follows:

'In modern delictual claims for damages on the basis of medical negligence, the—once and for all rule is not always easy to apply. Factors such as life expectancy; future hospital, medical and therapeutic expenses; estimated amount for future care; and loss of future earnings are very difficult to determine, especially if the claim is lodged on behalf of a minor. In addition it is an unfortunate fact of life that the money awarded as damages is not always spent wisely or spent on the person that it is intended for. However, a plaintiff cannot be obliged, by law, to accept an offer to receive incremental payments for damages or to accept a certificate undertaking to make future payments in lieu of a cash payment.'⁹⁶

The Commission observed that this position was confirmed by the court in the Souls Cleopas case (mentioned above), where the judge, who was requested to deviate from the rule, stated:

'The defendant's undertaking is an invitation for this court to venture into a territory exclusively reserved for the legislature. The invitation, though tempting, is to usurp the function of Parliament. It is not for the courts to legislate but to adjudicate. If

⁹² *Id.* 27.

⁹³ *Ibid.*

⁹⁴ *Ibid.*

⁹⁵ *Id.* 32.

⁹⁶ *Id.* 33.

the time has come, such as in motor vehicle accident fund cases, it is for the legislature to intervene and embark on such an exercise for the benefits of the defendant, not courts of law. Deference must be given to the principle of separation of powers.⁹⁷

The Supreme Court was also invited to development of the common law by modifying the once and for all rule in the Zulu-case.⁹⁸ The court also considered it a matter best left to the legislature:

‘The development of the common law sought by the appellant is not an incremental change, but one of substance and more appropriately dealt with by the legislature, being an issue of policy. Any legislated change in the common law rule could only be effected after the necessary process of public participation and debate.’⁹⁹

The discussion of these case, clearly align with the Commission’s earlier assertions regarding the separation of powers doctrine, and their conclusions that legislative reform would be required to address the medico-legal claims dilemma. It may be presumptuous, but one can deduce which way they are leaning.

Next, the basis for state liability was considered.¹⁰⁰ The fact that the MEC is often held liable for the negligence of employees of the department of health, through principle of vicarious liability, was noted. The state’s constitutional and public obligations were also referred to.

⁹⁷ *Ibid.* Quoting from the unreported Souls Cleopas case, at [22].

⁹⁸ Member of the executive Council for Health and Social Development of the Gauteng Provincial Government v Zulu obo Zulu (1020/2015) [2016] ZASCA 185 (30 November 2016).

⁹⁹ Member of the executive Council for Health and Social Development of the Gauteng Provincial Government v Zulu obo Zulu (1020/2015) [2016] ZASCA 185 (30 November 2016) at [12].

¹⁰⁰ Commission (2017) 36.

3.4. CHAPTER 4: PAYMENT OF COMPENSATION

Chapter 4 considers the ‘payment of compensation’.¹⁰¹ Lump sum payments, as well as structured settlements and periodic payments are discussed. Reference is made to the Irish Law Reform Commission’s Report on Personal Injuries: Periodic Payments and Structured Settlements and the Working Group on Medical Negligence and Periodic Payments 2010 report.¹⁰²

Although, not referred to by the SALRC, in 2015 the Working Group released a report, it included the following conclusions and recommendations:¹⁰³

‘The Working Group undertook a detailed examination of the potential implications that legislation on periodic payment orders would have for claimants and defendants, including the State Claims Agency, insurers, re-insurers and medical indemnity societies. It analysed the technical issues that would have to be addressed in such legislation.

The Working Group recognised that the introduction of periodic payment orders would be of significant benefit to catastrophically injured claimants as it would enable them to have continuity of payments to cover their care and medical costs for the duration of their lives. The Working Group also recognised that the introduction of periodic payment orders would add to the liabilities of insurance companies and increase the cost of insurance, with knock-on effects for both businesses and consumers.

It recommends that the legislation should be drafted on the following basis:

- The court should have the discretion to award PPOs but should have to take account of the views of both claimants and defendants.
- The periodic payment facility should be available for those who are both catastrophically injured and requiring of long-term permanent care.

¹⁰¹ *Id.* 38.

¹⁰² *Law Report on personal injuries : periodic payments and structured settlements* (1996); Working Group on Medical Negligence and Periodic Payments Report (Module 1) 2010.

¹⁰³ Orders “Report of the Working Group on Legislation on Periodic Payment Orders 22 April, 2015” (2015) 1.

- The Irish HICP should be specified as the index to be used to track increases in costs over time. The index should be reviewed regularly, at intervals of no less than 5 years.
- The legislation should make provision for stepped periodic payments, where identified at the time of the award. These steps should include milestones such as the claimant's entry into or exit from education or the claimant's move into a paid care situation. The legislation should not provide for variation orders.
- In order to guarantee the security of payment for non-state defendants the legislation should provide for an amendment to the limits that apply under the Insurance Compensation Fund to allow for full payment of PPO liabilities in the event of insurer insolvency.¹⁰⁴

Since, financial concerns of the department of health and private practitioners seem to be the foremost concern of the Issue Paper (patients' concerns are not really raised), the working group's findings that periodic payments 'add to the liabilities of insurance companies and increase the cost of insurance, with knock-on effects for both businesses and consumers', may not be welcome news. It is also interesting to note that the Medical Defence Union and the Medical Protection Society, were quick to point out that they provide indemnity to their members on a discretionary basis and that discretionary indemnity is not insurance. As such, they are not considered by the courts as secure providers for the purposes of periodical payment orders. The Commission should take note.

The Civil Liability (Amendment) Bill 2017 is set to be enacted in Ireland to give effect to the recommendations.¹⁰⁵

¹⁰⁴ *Id.* 30.

¹⁰⁵ The Civil Liability (Amendment) Bill 2017.

The Commission provides a few examples of legislation that already provides for structured settlements or periodic payments, including the:¹⁰⁶ Occupational Diseases in Mines and Works Act; Compensation for Occupational Injuries and Diseases Act; and Road Accident Fund Act.

The Issue Paper indicates that it would be useful to look at the measures other countries have adopted to deal with increasing medical negligence claims.¹⁰⁷ The Commission notes that Canada was the first country to adopt structured settlements and periodic payments for personal injury claims. In the United Kingdom, the Damages Act, provides for these types of payments. Mention is made of Australia's Civil Liability Act, which also provides for structured settlements. As mentioned above, the Commission also noted that, in Ireland the President of the High Court established a Working Group on Medical Negligence and Periodic Payments, and one of their recommendations was that legislation be enacted to provide for such payments.

As these are the only reforms discussed, it seems that the Commission has given an indication of their preference going forward.

The advantages and disadvantages of lump sum payments, compared to the advantages and disadvantages of periodic payments are considered in the following section.¹⁰⁸ Reference is once again made to the work of the Irish Working Group on the matter.

3.5. CHAPTER 5: POSSIBLE LEGISLATIVE INTERVENTION

Chapter 5 considers the options for legislative intervention.¹⁰⁹ The Commission notes that some authors have called for legislative changes and that at the 3 March 2017 Medical Malpractice Workshop, there was a general consensus that legislation would

¹⁰⁶ Commission (2017) 39.

¹⁰⁷ *Id.* 40.

¹⁰⁸ *Id.* 43.

¹⁰⁹ *Id.* 46.

be needed to resolve the current issues.¹¹⁰ On this basis, the Commission concludes that, 'it is evident that legislative reform is urgently required'.¹¹¹ Having apparently, already decided that this course of action should be taken, the Commission considers that they only need to figure out what form the legislative intervention should take. They note that: 'A lot of work is still required in this respect.'

It is not my submission that an investigation into possible reform is not required, it may very well be. However, one would first need to conclusively establish that fact. As was done in the SALC report discussed above. The investigation, seems to have jumped the gun. A detailed empirical investigation into a number of preliminary issues should perhaps be completed first in order to fully understand the extent of the matter under consideration. It is only with this comprehensive understanding of all the underlying factors, that appropriate interventions could be proposed. The consequences of any proposed changes would be much more accurately anticipated if we possess a clearer impression of the thing we intend to change.

These are just some of the questions we should perhaps attempt to answer, if we are to make informed choices about reform:

- How many patients experience adverse events in our private and public facilities?
- How many of those adverse events are avoidable?
- How many of these patients may have valid malpractice claims?
- How many of these patients with valid claims, actually claim?
- Why do they file claims?
- How do they become aware of their claims?
- How do they navigate the system to find support (emotional and financial)?
- Is there support available to them?
- How are they impacted by their injuries and the claim process?
- Are they offered a better alternative?

- How many patients are injured, perhaps negligently, and never institute claims?
- Why do some patients with valid claims file claims and others don't?

¹¹⁰ *Id.* 47.

¹¹¹ *Ibid.*

- What happens to patients that don't file claims?
- How many patients file 'invalid' claims, and why?

- What are the administrative costs of the system?
- How long do claims take to be finalised and why?
- What are the actual costs of iatrogenic injuries?
- What are the amounts claimed?
- What are the amounts paid?
- What is the actual financial impact of medical malpractice claims?

There are many more questions, these just serve to illustrate the point. Other countries have begun to answer some of these questions, as they relate to their own systems. Unfortunately, answers mostly come from developed countries and may not translate well to our context. These are difficult questions to answer, we may not have the available resources to do so, but we should at least keep them in mind when we consider the issues shaped by them.

To their credit, the Commission does seem to be aware of the immensity of their task and the impact changes could have on stakeholders and users of healthcare services:

'An investigation of this nature, where legislation will have to be developed from scratch, would definitely require substantial long-term commitment and fundamental review. An investigation of this magnitude and complexity cannot be rushed.'¹¹²

'Various government departments, professional groups, voluntary organisations, non-profit organisations, insurers and academics all have a direct interest in this matter, and must be consulted. However, there is another substantial group of stakeholders whose views must also be solicited. Members of the public have a direct interest in the delivery of health care services and would make up the numerically largest stakeholder group in an investigation on medico-legal claims.'¹¹³

¹¹² *Id.* 48.

¹¹³ *Ibid.*

The Commission acknowledges many of the perceived problems. However, as mentioned, these need to be examined and confirmed before they are relied on to form conclusions. They may very likely be accurate, but that needs to be established as objectively as possible first.

‘The present state of this area of the law is unsatisfactory. It is clear from issues such as the inaccessibility of the law for the very people who need it most, the delays in finalising cases, the limits imposed by the nature of legal processes conducted in terms of the common law, the enormous strain placed on the fiscus by the current litigious climate and the developing crisis in the private medical sector that these concerns should be addressed as soon as possible.’¹¹⁴

The Commission’s discussion and overview of the current perceived medico-legal landscape ends here. As indicated above, there are some concerns regarding the manner in which the issues were presented. The Issue Paper is severely tainted by various preconceived notions. One would expect that the Commission would be as objective and neutral as possible, at this early stage in the investigation. Unsubstantiated information is often uncritically presented to support predetermined conclusions, which could now form the basis of the entire exercise.

3.6. CHAPTER 6: QUESTIONS FOR CONSIDERATION

Chapter 6 of the Issue Paper, calls for comments on the matter under investigation.¹¹⁵ Although, the manner in which the matter was presented could predispose the responses to follow the particular frame of reference provided. Thereby, unduly influencing the process. Nevertheless, respondents are requested to consider a number of concerns about the current system, the merits of existing measures and short-term solutions, amendment of the State Liability Act to include periodic payments, proposals for legislation that have been put forth, and general concerns.

¹¹⁴ *Id.* 50.

¹¹⁵ *Id.* 51.

4. CONCLUSION

South Africa is by all accounts currently facing many of the same challenges other countries have faced with their compensation and liability systems. Although concerns regarding the costs of the system have mainly been the catalyst for increased lobbying from stakeholders and attention from policymakers, the system also suffers from a number of other problems (which often receives less consideration).

Many of these problems have their roots in the functioning of the civil justice system. Litigants often find the system expensive, slow, complex and overly adversarial. Access to justice is impeded by these negative aspects of the system. The deficiencies may be amplified in cases involving alleged medical malpractice. The enduring problems of our civil justice system, have long been known and acknowledged. Steps have begun to be taken to remedy the situation. The Civil Justice Reform Project seeks to address some of litigants' most urgent concerns. It seems as though alternative dispute resolution mechanisms may be a large part of the CJRP's strategy in this regard. We are still in the very early stages of an enormous undertaking. Nevertheless, it is important to be mindful of the civil justice system's effect on issues specifically related to cases of alleged medical malpractice. The following chapter, which discusses the United Kingdom's experience, serves to illustrate this point (among others).

As mentioned, the costs of medical malpractice claims generally receive the most consideration. Proposals for possible reform, targeting these costs, usually follow. This chapter highlighted some of the developments in this regard.

In the early 90's, the South African Law Commission investigated the desirability of limiting professional liability (medical professionals included). They were not persuaded that such a limitation would be justifiable and suggested that it may be unconstitutional. Two decades later medical malpractice claims are again receiving attention.

The Minister of Health has lashed out at attorneys and attributed, what is perhaps, a disproportionate amount of blame to the legal profession for the current malpractice situation. While it may be true that some attorneys act unethically, attorneys are often

the only recourse patients have to obtain desperately-needed compensation. These injured patients are frequently left with no option, but to turn to the inefficient legal system for financial redress.

Unfortunately, without any empirical information, the Minister has continually sought to deflect responsibility for the substandard outcomes caused by a compromised public healthcare system and poor after-event support, to 'greedy' lawyers and 'frivolous' litigation. He has also blamed attorneys for problems related to the affordability and availability of insurance in the private sector. Thereby, disregarding or ignoring the other contributory factors. For instance, there is no indication that he is looking at the role that insurance markets and insurers play, or that he is considering calling for better regulation of the sector. In fact, indemnity insurers have aligned themselves with the Minister and will likely lobby for liability-limiting reforms.

The Medico-Legal Summit brought together various stakeholders to consider and address some of the perceived problems surrounding malpractice claims. This culminated in a Declaration, which narrowly defined and confined the problem to 'an explosion in medical malpractice litigation, which is not in keeping with generally known trends of negligence or malpractice'. One of the recommendations of the Declaration was that the South African Law Reform Commission investigate medico-legal claims. This investigation has begun and is still at an early stage.

However, there are already concerns, chief of which being that, unsubstantiated information has been uncritically presented to support predetermined conclusions, which could now form the basis of the entire investigation. The immensity and complexity of the task, potentially far-reaching consequences, special interest agendas and political pressures, high-financial stakes, and the interests of patients (above all) demand that this investigation be conducted as comprehensively, objectively and cautiously as possible.

We have now considered the legal and policy interventions that have been introduced to improve the quality and safety of care provided in the South African healthcare

system. We also turned our attention to the current state of the South African medical malpractice system. The broad overview of the extent, consequences and possible causes of the existing medical malpractice situation, served to contextualise the developments that have been discussed in this chapter.

Reform seems to be firmly on the agenda – for both the healthcare system and the civil justice system, with medical malpractice claims receiving special attention.

South Africa is at the start of this journey. Other countries have already made significant progress and may hold important lessons on the way forward. As mentioned, the United Kingdom's experience with their civil justice and health systems, may be particularly relevant to our context and provide an illuminative example of the arduous journey ahead. The UK experience is presented as an illustrative case study in the following chapter, with patient safety considerations receiving special attention.

CHAPTER 16. THE UK EXPERIENCE – AN ILLUSTRATIVE CASE STUDY

1. INTRODUCTION

Having considered the confluence of patient safety and medical malpractice law, as well as the existing South African situation and the challenges presented, it may be useful to consider how similar challenges have been addressed in other jurisdictions. If for no other reason than to better understand and appreciate the challenges involved in implementing and aligning systems designed to ensure safer care.

Why has the United Kingdom been chosen as an illustrative case study? (Instead of, for instance, a country that utilises a ‘no fault’ system).

Firstly, Lord Woolf’s ‘Access to Justice’ report and the subsequent reforms introduced in their civil justice system are particularly relevant to South Africa, as our system of civil procedure ‘owes its origin to and is essentially that of England’.¹ The report is frequently referenced by South African jurists.² As such, the Woolf report and developments in the UK surrounding the issue of medical malpractice and patient safety, merit discussion.

Secondly, such a discussion becomes all the more pertinent since, aside from the similarities between our civil justice systems, certain aspects of the South African healthcare regulatory framework have also recently been borrowed from the UK. The Office of Health Standards Compliance is largely based on and was set up with help and input from its British equivalent, the Care Quality Commission.³

¹ Kahn (1989) 106 *S. African LJ* 602; Erasmus (1991) *S. African LJ*

² Ngcobo (2003) *S. African LJ* 706; Ngcobo (2011) *Access to Justice Conference Towards Delivering Accessible Quality Justice for All* 1.

³ Fryatt and Matsoso (2012) 380 *Lancet* 1970.

Lastly, the Minister of Health has also on numerous occasions stated his admiration for the NHS and has indicated that the NHI should be thought of as South Africa's version of the NHS. If one analyses the government's proposals for health reform, it does appear as though the NHI is modelled on the UK's NHS.

This chapter will consider and highlight initiatives undertaken in the United Kingdom to address aspects of its civil justice- and healthcare system, that have failed to meet the needs of patients. Efforts aimed at improving patient safety will receive specific consideration.

2. THE CIVIL JUSTICE SYSTEM AND MEDICAL MALPRACTICE

Since the weaknesses underlying civil justice systems that ultimately impact on medical negligence claims have garnered considerable attention in other jurisdictions, it would be pertinent to examine one such example—the UK, which has been more comprehensive in their analysis, to further the discussion. The Woolf report, often referred to by South African jurists, and which dealt specifically with medical negligence litigation, would provide an ideal illustration and starting point. The issues raised in Woolf's and subsequent reports, and interventions that have followed, are particularly relevant to South Africa, as our civil justice system is, to a great extent, essentially based on the English system.⁴

2.1. THE WOOLF REPORT

Lord Woolf identified several flaws in his review of the civil justice system in England and Wales.⁵ He enunciated the shortcomings in his 1996 'Access to Justice' report, as follows:

⁴ Erasmus (1991) *S. African LJ* 265; Theophilopoulos "Constitutional transformation and fundamental reform of civil procedure" *Journal of South African Law/Tydskrif vir die Suid-Afrikaanse Reg* (2016) 2016 68; Van Loggerenberg "Civil Justice in South Africa" *BRICS law journal* (2016) 3 125.

⁵ Woolf (1996).

‘The defects I identified in our present system were that it is too expensive in that the costs often exceed the value of the claim; too slow in bringing cases to a conclusion and too unequal: there is a lack of equality between the powerful, wealthy litigant and the under resourced litigant. It is too uncertain: the difficulty of forecasting what litigation will cost and how long it will last induces the fear of the unknown; and it is incomprehensible to many litigants. Above all it is too fragmented in the way it is organised since there is no one with clear overall responsibility for the administration of civil justice; and too adversarial as cases are run by the parties, not by the courts and the rules of court, all too often, are ignored by the parties and not enforced by the court.’⁶

2.1.1. MEDICAL NEGLIGENCE LITIGATION

Although, they had no special procedures or rules of court, medical negligence cases were singled out by Lord Woolf due to the fact that, as he explains: ‘early in the Inquiry it became increasingly obvious that it was in the area of medical negligence that the civil justice system was failing most conspicuously to meet the needs of litigants in a number of respects.’⁷ He noted some of these concerns:

‘(a) The disproportion between costs and damages in medical negligence is particularly excessive, especially in lower value cases; (b) The delay in resolving claims is more often unacceptable; (c) Unmeritorious cases are often pursued, and clear-cut claims defended, for too long; (d) The success rate is lower than in other personal injury litigation; (e) The suspicion between the parties is more intense and the lack of co-operation frequently greater than in many other areas of litigation.’⁸

This specific area of tort law can certainly be substantively complex, however many of the issues Lord Woolf identified stem from structural factors related to these types of claims. This is also reflected in his recommendations.

⁶ *Id.* 5.

⁷ *Id.* 131.

⁸ *Ibid.*

2.1.2. A CHANGE OF CULTURE

One such recommendation called for a change of culture.⁹ He noted that the mistrust which accompanies injuries and claims for compensation should be eradicated. According to Lord Woolf, this could be done if healthcare providers 'demonstrate their commitment to patients' well-being by adopting a constructive approach to claims handling'. He recommended that the prevailing reluctance to investigate complaints, owing to a fear of finding negligence and attracting liability, should be discarded. Instead, it must be accepted that 'injured patients are entitled to redress, and that professional solidarity or individual self-esteem are not sufficient reasons for resisting or obstructing valid claims.'

Lord Woolf suggested that patients often only institute proceedings because they have been stonewalled. Somehow, in the existing litigation system, it is possible for a case to go to trial 'several years after the event, in which there has at no stage been any personal contact between the healthcare professionals involved and the injured patient or his family'. As Lord Woolf indicated, this surely should not happen. Furthermore, it goes against his fundamental approach to civil litigation, in that generally 'legal proceedings should be treated as a last resort, to be used only when other means of resolving a dispute are inappropriate or have failed'. All stakeholders have a role to play in limiting litigation. Accordingly, Lord Woolf was convinced that affected parties should adopt a proactive approach to claims-handling: 'In some cases, an explanation from the doctor of what went wrong, coupled with a personal apology, would resolve the matter without any further action'. Claims managers, who act as the hospital's first point of contact with aggrieved patients, should at least try to achieve this, or some other amicable resolution in suitable cases. As Lord Woolf pointed out, 'it is far better for patients and hospitals to resolve their disputes through other channels wherever possible'.

Calling for more openness and effective communication, Lord Woolf stated:

⁹ *Id.* 135.

‘The best way of dealing with the problem of delay before claims are started would be a policy of more open communication on the part of hospital staff. Effective communication of course needs to start before things go wrong. All patients who are about to undergo treatment should understand that the outcome of medical treatment can be uncertain, and should be told about the range of possible outcomes in their particular case. Wherever practicable, the advice should be confirmed in writing. Doctors and hospitals should encourage patients to report any unsatisfactory outcome as soon as possible, and to seek an explanation direct from the individual doctor or hospital before going to a solicitor.’¹⁰

He also called for the implementation of ‘communication and resolution programmes’ in appropriate cases:

‘Every patient who has suffered an adverse outcome is entitled to an explanation, and, where appropriate, an apology. In appropriate cases, there is no reason why an offer of compensation should not be made before any legal claim is notified, provided the patient is encouraged to seek independent advice on the offer. I understand that some hospitals offer to pay for such advice, to ensure that patients are not deterred from seeking it through fear of the cost.

I can understand why this approach is unwelcome to many doctors, in particular. There is a natural reluctance to admit that one has been at fault, and sometimes a fear that any form of apology will amount to an admission of legal liability. Such an admission could have implications for the doctor's professional reputation and career prospects. A face to face meeting with an injured patient may be a very daunting prospect for the doctor concerned. From the trust's point of view, an immediate offer of compensation may not appear to be an effective or prudent use of resources.

There are, nevertheless, good reasons for adopting such an approach. Most importantly, unless the patient himself opts to go elsewhere, the hospital and the

¹⁰ *Id.* 136.

individual doctor have a continuing obligation to care for a patient who has been injured by negligent treatment. In some cases, at least, that obligation includes the provision of financial compensation to pay for rehabilitation. Secondly, from the hospital's point of view it will be easier to trace the relevant records and carry out an investigation if a potential claim is identified as early as possible. Finally, an open approach is also in the interest of the doctor because an explanation or apology will resolve some cases without the need for litigation.¹¹

Furthermore, as part of this open approach, it was suggested 'that there should be an obligation on doctors, as part of their ethical code, to inform their patients if they discover an act or omission in their care and treatment which may have caused injury, and that doctors who fail to comply with such a duty should be subject to disciplinary action'. There is some debate as to whether such a 'duty of candour' may already be expected.

To achieve this change in culture, as proposed by Lord Woolf, in particular, the changes relating to openness and communication, one would have to address the apprehensiveness of healthcare providers. Lord Woolf found that the 'fear of litigation among so many doctors is often based on ignorance of the legal system.' He, therefore, proposed that 'all doctors should be given, as part of their basic medical training, an introduction to the legal context of their work, including an indication of what is involved in a claim for negligence.' The professional bodies and associations would have a significant role to play in such a cultural change.

2.1.3. PRE-LITIGATION ISSUES

Lord Woolf also identified several issues that arise during the pre-litigation stage as major sources of costs and delays:¹²

'(a) Inadequate incident reporting and record keeping in hospitals, and mobility of staff, make it difficult to establish facts, often several years after the event. (b) Claimants must incur the cost of an expert investigation in order to establish

¹¹ *Id.* 135.

¹² *Id.* 137.

whether they have a viable claim. (c) There is often a long delay before a claim is made. (d) Defendants do not have sufficient resources to carry out a full investigation of every incident, and do not consider it worthwhile to start an investigation as soon as they receive a request for records, because many cases do not proceed beyond that stage. (e) Patients often give the defendant little or no notice of a firm intention to sue. Consequently, many incidents are not investigated by the defendant until after proceedings have started. (f) Doctors and hospital staff in general are traditionally reluctant to admit negligence or apologise to or negotiate with claimants, for fear of damage to their professional reputation or career prospects.’¹³

This is in contrast to, what Lord Woolf believes, would be an effective pre-action procedure in medical negligence cases. It was pointed out that an effectual procedure would need to:

‘(a) encourage early communication between claimants and defendants, and ensure that any appropriate apology or explanation is always offered to the claimant; (b) set a challenging but realistic target for disclosure of medical records by defendants; (c) ensure that the claimant knows what options are available (including ADR) and what each will involve; (d) require the parties to consider whether joint instructions to an expert would be possible, at least on some of the issues in the case; and (e) provide an early opportunity for defendants to identify cases where a full investigation is required.’¹⁴

Lord Woolf noted the numerous practical problems litigants currently face during the early stages of a dispute. For instance, difficulties arise when hospitals need to locate patients’ records and former staff, especially where a claim is only instituted after a number of years have passed, or where a hospital has failed to document an adverse event. It is understandable that patients may not become aware of a possible claim until after they have undergone a protracted course of treatment or consultations. This late

¹³ *Ibid.*

¹⁴ *Id.* 138.

notification of a claim often makes it more difficult to establish liability or to launch a proper investigation into the incident.

Lord Woolf highlighted the need for improved record keeping and incident reporting in hospitals. This would make it easier to access the necessary patient information, either for purposes of claim investigation or to decide whether claims have merit. Attorneys should also adopt a less adversarial attitude and find out at an early stage what their clients want. As Lord Woolf suggested: ‘Solicitors should not automatically advise litigation, but should explore and provide information about any available alternatives such as mediation or the Ombudsman service’. If patients do decide to litigate, timely notice should be given, with the ‘fullest available information about the basis of the intended claim, in the light of the expert evidence obtained by the patient, and, whenever possible, include an offer to settle’. Defendants would at this stage, fully investigate the claim and offer a well-reasoned response, or settle. The case management reforms, proposed by Lord Woolf, would ensure that cases are resolved much quicker, by defining the issues in dispute at an earlier stage and using protocols to avoid delays.¹⁵

2.1.4. ALTERNATIVE DISPUTE RESOLUTION

Lord Woolf suggested that alternative dispute resolution mechanisms may be better suited to these types of claims, as well as the needs of the parties involved.¹⁶ Wider adoption of these mechanisms could result in a significant number of medical negligence claims being resolved without litigation. ADR could be particularly fitting for smaller claims and instances where financial compensation is not the patient's main or only requirement. Hospitals with professional claims managers could develop in-house resolution programmes to settle relatively small and simple claims.

¹⁵ *Id.* 140.

¹⁶ *Ibid.*

However, as Lord Woolf noted, it is ‘important to ensure that informal procedures do not put claimants at a disadvantage because of the inevitable imbalance of knowledge and power between patients and hospitals’.¹⁷

Larger, more complex cases, could benefit from pre-litigation mediation, which might help to achieve out of court resolutions. It may be possible, at the outset, to mediate cases successfully, provided that claims can be properly valued. The valuation would, of course, require an exchange of experts’ reports, valuations and medical records. Guidelines could be developed to streamline such a process and could be incorporated into pre-action protocols. Lord Woolf believed that ADR should be encouraged, rather than compelled. However, the refusal to follow protocol in this regard could be taken into account by the court in subsequent proceedings.

2.1.5. SPECIAL TREATMENT FOR MEDICAL NEGLIGENCE CASES

Lord Woolf did not go as far as to suggest that ‘health courts’ should be established to deal with cases of medical negligence, but he did feel that a special arrangement would be advantageous. He stated that: ‘Medical negligence work is significantly different from, and in many cases more complex than, ordinary personal injury cases, and effective case management (including trial management) requires a degree of familiarity with standard medical practices and procedures which is unlikely to be acquired by judges who only occasionally deal with medical negligence cases.’¹⁸

To this end, Lord Woolf suggested that certain divisions of court that have special lists should include a separate medical negligence list. He believed that such an arrangement would help ‘foster the appropriate degree of special experience and expertise among the judiciary which is needed for the efficient and effective disposal of these cases’. Specially designated court centres, where both the judiciary and staff would have the opportunity to build up experience and expertise in medical negligence, were also proposed.

¹⁷ *Ibid.*

¹⁸ *Id.* 141.

Specialist procedural and trial judges would add considerable value and help to reduce delays. Lord Woolf also suggested that these specialist judges would benefit greatly if they were to receive additional training. Training would allow the judges to better understand the substantive issues and to play a more active role in the management of cases. It was recommended that medical schools and experts be brought in to assist therewith.¹⁹

2.1.6. EXPERT EVIDENCE

The unique nature of medical negligence claims, often means that expert evidence is more heavily relied on; as Lord Woolf explained in his report:²⁰

'Medical negligence differs from other personal injury litigation in the parties' greater reliance on expert medical evidence for issues of causation and liability as well as quantum. Causation is more difficult to establish than in other personal injury cases. This is because the effects of the allegedly negligent treatment must be distinguished from those of the patient's underlying condition which gave rise to the need for treatment. Liability is often very difficult to establish.'²¹

Expert evidence is generally required with respect to causation, liability and quantum of damages. This can be a very expensive undertaking, especially where experts from several specialities are used by each side. It could also be a significant source of delay since time is taken by experts to produce their reports. That is if you were fortunate enough to find an expert that was willing to criticise one of his peers or go to the stand to face attorneys from a medical protection society (to which he or she might belong). Claimants, certainly, face an immense challenge in obtaining critical information. Issues surrounding expert evidence and the polarisation of experts have been identified as a fundamental problem. To alleviate the problem, Lord Woolf recommended that expert evidence should fall under the control of the court, that a single expert is used wherever possible, and that if opposing experts had to be used, they narrow down and define the

¹⁹ *Id.* 142.

²⁰ *Id.* 143.

²¹ *Ibid.*

issues in dispute as early as possible.

2.1.7. QUANTIFICATION OF MEDICAL NEGLIGENCE CLAIMS

An enormous amount of time and money is spent on quantification of medical negligence claims. Experts in a number of different fields are usually required to calculate the damages. Lord Woolf recommended that standard tables be adopted, and used wherever possible, to reduce the need for separate quantification in individual cases.²²

2.1.8. SMALLER CLAIMS RESOLUTION

Lord Woolf identified that the problem of disproportionate cost and use of resources was particularly acute in smaller medical negligence cases.²³ To address this issue, he proposed a number of options. The options could be piloted and be applicable to claims falling under a set amount (e.g. £10 000). One option would be a ‘fast-track’ procedure with spending limits. Another would be a more streamlined efficient version of the existing system with pre-set budgets and cost-caps. Still, alternatives to litigation may provide the best solution for smaller medical negligence cases.²⁴

2.1.9. RECOMMENDATIONS

Lord Woolf’s final ‘Access to Justice’ report included a total of 303 recommendations, twelve of which dealt specifically with medical negligence cases.²⁵ Lord Woolf’s proposals culminated in the enactment of the Civil Procedure Act 1997²⁶ that conferred the power to make the Civil Procedure Rules 1998,²⁷ which came into force on 26 April 1999. Part 1 of the CPR includes the ‘overriding objective’, which states:

‘1.1—(1) These Rules are a new procedural code with the overriding objective of enabling the court to deal with cases justly.

²² *Id.* 146.

²³ *Ibid.*

²⁴ *Id.* 148.

²⁵ *Id.* 149.

²⁶ Civil Procedure Act 1997 (1997 c. 12).

²⁷ The Civil Procedure Rules 1998 (1998 No. 3132 (L. 17)).

(2) Dealing with a case justly includes, so far as is practicable—

(a) ensuring that the parties are on an equal footing;

(b) saving expense;

(c) dealing with the case in ways which are proportionate—

(i) to the amount of money involved;

(ii) to the importance of the case;

(iii) to the complexity of the issues; and

(iv) to the financial position of each party;

(d) ensuring that it is dealt with expeditiously and fairly; and

(e) allotting to it an appropriate share of the court's resources, while taking into account the need to allot resources to other cases.'

Furthermore, the CPR provides for a 'Pre-Action Protocol for the Resolution of Clinical Disputes'. The general aims of the Protocol are: '(a) to maintain and/or restore the patient/healthcare provider relationship in an open and transparent way; (b) to reduce delay and ensure that costs are proportionate; and (c) to resolve as many disputes as possible without litigation'.

2.2. NHS LITIGATION AUTHORITY/RESOLUTION

The NHS Litigation Authority (NHSLA) was established in November 1995, as a Special Health Authority, to administer the 'Clinical Negligence Scheme for Trusts', a risk-pooling scheme that indemnifies healthcare providers in respect of clinical claims.²⁸ The NHSLA also took over the management of other schemes, including the Existing Liabilities Scheme.²⁹ Due to a lack of capacity, claims-handling was initially outsourced and overseen by the Medical Protection Society. However, since April 1998 everything has been managed in-house by the NHSLA. Consolidation followed, and by April 2002

²⁸ Mead "National Health Service Litigation Authority: 10 years on." *Clin Med (Lond)* (2006) 6 57.

²⁹ Great *Handling clinical negligence claims in England* (2001).

the NHSLA was able to control all clinical negligence claims against NHS trusts and health authorities in England.³⁰

The NHSLA framework document sets out its aims and objectives as follows:³¹

‘The Secretary of State’s overall aims for the Authority in administering the schemes are to promote the highest possible standards of patient care and to minimise the suffering resulting from any adverse incidents which do nevertheless occur. In particular, the Authority will contribute to these aims by its efficient, effective and impartial administration of the schemes, and by advising the Secretary of State on any changes that may be needed in the light of experience in running the schemes and of changing circumstances.’

In pursuit of this overriding aim, the NHSLA seeks to:

- Maximise the resources available for patient care, by defending unjustified actions robustly, settling justified actions efficiently, and contributing to the incentives for reducing the number of negligent or preventable incidents.
- Ensure that, where liability has been established, patients have appropriate access to remedies including, where proper, financial compensation.
- Contribute to the improvement of the quality of patient care by providing incentives within the schemes for NHS bodies to improve cost-effective clinical and non-clinical risk management.
- Provide mechanisms for the proper, prompt and cost-effective resolution of disputes between NHS primary care organisations and the practitioners and organisations that provide or seek to provide services for patients.

The NHSLA exercises a risk management and claims handling function, with the added objective of contributing to the improvement of the quality of care patients receive.³²

³⁰ Authority “About the NHS Litigation Authority (2004)” (2006).

³¹ Executive “The National Health Service Litigation Authority Framework Document (96FP0046)” *Department of Health* (1996).

³² Tingle and Bark “Patient Safety, Law Policy and Practice” (2011) 12.

With regards to claims management, it played a key role in the development and implementation of the Pre-Action Protocol for the Resolution of Clinical Disputes, introduced in April 1999, which encourages a constructive ‘cards-on-the-table’ approach to litigation, so as to facilitate early resolutions and reduce legal fees.³³ The NHSLA was also quick to adopt structured settlements or periodic payments and has pioneered the use of alternative dispute resolution in clinical negligence cases.³⁴

Risk management is a major aspect of the NHSLA. They have developed and monitored various standards. These standards not only reduce the risk of claims but also serve as an incentive, since compliant providers qualify for discounts on their contributions. ‘An organisation with a memory’ noted that the claims information held by the NHSLA could be a very valuable source of learning opportunities and safety lessons.³⁵

The NHSLA has become more involved with efforts to improve patient safety. They support the NHS in England in its attempts to reduce harm by learning from claims. They have published an analysis of ‘Ten Years of Maternity Claims’, ‘Five years of cerebral palsy claims’ and a report on ‘Stillbirth Claims’, to assist the NHS, and in particular health professionals responsible for the care of women and their babies, to improve safety.³⁶ Other similar reports and safety materials are also made available to providers. A Safety and Learning Service has also been established.³⁷

The NHSLA also supports efforts to build a safety and learning culture.³⁸ They have provided information on how to apologise to patients for incidents and have developed

³³ Woolf “Clinical Negligence: What is the Solution? How Can We Provide Justice for Doctors and Patients” *Medical Law International* (2000) 4 133.

³⁴ Great (2001).

³⁵ Health (2000) 58.

³⁶ Authority “Study of stillbirth claims” *London: NHS Litigation Authority* (2009); Authority “Ten years of maternity claims: an analysis of NHS Litigation Authority data” *London: NHS Litigation Authority* (2012).

³⁷ Great et al. *NHS Litigation Authority Report and Accounts 2015/16* (2016).

³⁸ <http://www.nhsla.com/Safety/Pages/Home.aspx>.

guidance surrounding the Duty of Candour.³⁹ The NHSLA is also part of ‘Sign up for safety’ and have signed the 5 Pledges.⁴⁰

In April 2017, the NHSLA brought together all their functions under the umbrella of a new name, NHS Resolution.⁴¹ With the new name, comes a new focus – ‘delivering fair resolution and learning from harm to improve safety’.⁴²

The change signals a move to an organisation which is now more focused than before on prevention, learning and early intervention to address the rising costs of harm in the NHS. NHS Resolution plans to be more involved in incidents at an earlier stage. They aim to become more effective at preventing situations from escalating into unnecessary court action and will also try to resolve concerns in ways other than litigation. NHS Resolution hopes that earlier intervention will improve the experience for those who are injured and ultimately address the level and cost of negligent harm.

A new website sets out their strategic direction and will go live in 2018.

2.3. LEARNING FROM BRISTOL

The Bristol Royal Infirmary Inquiry was established to investigate the deaths of 29 babies who had undergone cardiac surgery over the period between 1984 and 1995.⁴³ The Inquiry, which began in October 1998, was led by Sir Ian Kennedy. The final report, ‘Learning from Bristol’, was published in July 2001.⁴⁴ Its publication followed one of the most comprehensive inquiries ever undertaken into the NHS, confronting issues of

³⁹ Authority “NHS Litigation Authority Guidance on Candour” (2014).

⁴⁰ <http://www.nhsla.com/Safety/Learning/Pages/Home.aspx>.

⁴¹ Dyer “New negligence claims service aims to resolve cases more quickly” *BMJ: British Medical Journal (Online)* (2017) 356; Dyer “New settlement procedures: changing the way the NHS resolves negligence claims” *BMJ* (2017) 358 j4134; Tingle “Making the NHS Litigation Authority more effective as NHS Resolution.” *British journal of nursing (Mark Allen Publishing)* (2017) 26 634.

⁴² <http://resolution.nhs.uk/about/>.

⁴³ Dyer “Bristol doctors found guilty of serious professional misconduct” *BMJ* (1998) 316 1924; Smith “All changed, changed utterly. British medicine will be transformed by the Bristol case.” *BMJ* (1998) 316 1917.

⁴⁴ *Health Learning from Bristol: The Report of the Public Inquiry into Children’s Heart Surgery at the Bristol Royal Infirmary 1984-1995 (Command Paper)* (2001).

clinical safety, accountability, organisational culture and patient rights, through the adoption of a systems approach.⁴⁵ The findings and nearly 200 recommendations included in the 529-page report have had a significant, far-reaching impact on healthcare provision in the UK.⁴⁶

The safety of care received significant attention.⁴⁷ One of the overriding messages from the inquiry was that the absence of a culture of safety and a culture of openness meant that concerns and incidents were not routinely or systematically discussed and addressed.⁴⁸ As a result, unsafe practices were allowed to continue unabated. When things did go wrong, the lack of a systematic approach to learning, prevented effective remedial action from being taken.⁴⁹

2.3.1. A COUNTERPRODUCTIVE SYSTEM

To overcome the barriers to openness, with patient safety as the principal rationale, substantial changes would need to be effected. The medical malpractice system was singled out as a major obstacle, which stood squarely in the path of the attainment of a more open and safe culture:

‘It is our view, therefore, that the culture and the practice of clinical negligence litigation work against the interests of patients’ safety. The system is positively counter-productive, in that it provides a clear incentive not to report, or to cover up, an error or incident. And, once covered up, no one can learn from it and the next patient is exposed to the same or a similar risk.’⁵⁰

⁴⁵ Walshe and Offen “A very public failure: lessons for quality improvement in healthcare organisations from the Bristol Royal Infirmary” *Quality and Safety in Health Care* (2001) 10 250; Walshe “The rise of regulation in the NHS” *BMJ: British Medical Journal* (2002) 324 967; Walshe and Higgins “The use and impact of inquiries in the NHS” *BMJ: British Medical Journal* (2002) 325 895.

⁴⁶ Keogh et al. “The legacy of Bristol: public disclosure of individual surgeons’ results” *BMJ: British Medical Journal* (2004) 329 450.

⁴⁷ Vincent (2011) 20.

⁴⁸ Weick and Sutcliffe “Hospitals as cultures of entrapment: a re-analysis of the Bristol Royal Infirmary” *California Management Review* (2003) 45 73.

⁴⁹ Health (2001) 341.

⁵⁰ *Id.* 366.

In fact, the system was considered to be so outdated and ill-suited to the clinical context, that Sir Ian Kennedy's inquiry recommended a comprehensive review thereof, whilst also making it abundantly clear that they believed it should be abolished:

'The system is now out of alignment with other policy initiatives on quality and safety: in fact it serves to undermine those policies and inhibits improvements in the safety of the care received by patients. Ultimately, we take the view that it will not be possible to achieve an environment of full, open reporting within the NHS when, outside it, there exists a litigation system the incentives of which press in the opposite direction. We believe that the way forward lies in the abolition of clinical negligence litigation, taking clinical error out of the courts and the tort system. It should be replaced by effective systems for identifying, analysing, learning from and preventing errors along with all other sentinel events. There must also be a new approach to compensating those patients harmed through such events. The abolition of recourse to clinical negligence litigation would be a major step in changing the climate and the incentive for reporting when things go wrong and, we believe, encourage the openness essential for improving safety. Although our view on what needs to happen is clear, we recognise that such a radical change is likely to have wide implications, not least in terms of any new system of compensation. We recognise, therefore, that the way forward lies in a review by an expert group of the entire system of clinical negligence litigation, with clear terms of reference to consider alternatives to the current arrangements. The review must also address needs arising from harm, both financial and emotional, and how they should be compensated.'⁵¹

2.3.2. AN ADMINISTRATIVE NO-FAULT ALTERNATIVE

The authors favoured the introduction of an administrative system, that would promptly provide support and compensation to those who suffer harm arising out of medical care.⁵² Contrary to the existing malpractice system, it was suggested that such an administrative scheme could foster the open and non-punitive environment required to

⁵¹ *Id.* 367.

⁵² *Id.* 442.

enable the reporting of errors and other relevant safety information. This would form a crucial part of a broader drive to incentivise reporting at the organisational level. Another key recommendation was, that all the information should be collected by a single, unified, accessible reporting system. The reporting system's database should then be systematically monitored and analysed in order to generate frequent reports and remedial actions that would assist in the promotion of safer care.⁵³

The UK government responded positively to the report, stating that: 'Bristol was a turning point in the history of the NHS. We are determined that some good can come from the tragedy that took place there.'⁵⁴ Indeed, around the time of the report's publication, a number of encouraging interventions occurred, including: the enactment of novel health legislation to address some of the concerns raised; establishment of the National Patient Safety Agency; and an inquiry into the reform of medical negligence was undertaken.⁵⁵

2.4. MAKING AMENDS

The Department of Health under the stewardship of the Chief Medical Officer, Sir Liam Donaldson, published 'Making Amends' on the 1st of July 2003.⁵⁶ The consultation paper set out proposals for reforming the approach to clinical negligence in the NHS. Although, the civil justice system reforms introduced following Lord Woolf's report are generally regarded as having had a positive impact, many of the problems that plagued the medical negligence system persisted. The key issues, which gave rise to Health Departments investigation, were highlighted by the Chief Medical Officer. Despite the reforms, Sir Liam Donaldson indicated that the system still warranted further action since:

‘— it is complex;

⁵³ *Id.* 450.

⁵⁴ Britain *Learning from Bristol: The Department of Health's response to the report of the public inquiry into children's heart surgery at the Bristol Royal Infirmary, 1984-1995* (2002)

⁵⁵ National Health Service Reform and Health Care Professions Act 2002; <http://www.npsa.nhs.uk/corporate/about-us/>.

⁵⁶ Donaldson (2003).

- it is unfair – apparently similar cases may reach different outcomes;
- it is slow – cases can take up to four years from the time of claim to settlement – though timescales have decreased in recent years;
- it is costly in legal fees; diversion of clinical staff time from clinical care; staff morale; and public confidence;
- patients are dissatisfied with the lack of explanations and apologies or reassurance that action has been taken to prevent repetition;
- it encourages defensiveness and secrecy and stands in the way of learning and improvement in the health service.⁵⁷

The Chief Medical Officer had hoped to see the existing system replaced with a successful alternative, one which would create an environment where:

- ‘– risks of care are reduced and patient safety improves because medical errors and near misses are readily reported, successfully analysed and effective corrective action takes place and is sustained;
- remedial treatment, care and rehabilitation are available to redress harm and injuries arising from healthcare;
- any financial compensation is provided fairly and efficiently;
- payments of compensation act as financial incentives on healthcare organisations and their staff to improve quality and patient safety;
- the process of compensation does not undermine the strength of the relationship between patient and healthcare professional;
- different entry points to expressing complaints and concerns about standards of care are well co-ordinated and well understood by the public and healthcare professionals;
- the system of compensation is affordable and reasonably predictable in the way it operates.⁵⁸

⁵⁷ *Id.* 13.

⁵⁸ *Ibid.*

Several alternative approaches were comprehensively reviewed in the consultation paper. The introduction of a no-fault system, as advocated in the Bristol report, received serious consideration.⁵⁹ However, despite the multitude of potential benefits offered by such a scheme, it was ultimately rejected. Concerns about such a scheme's affordability and issues surrounding causation could not be overcome.⁶⁰ The establishment of a tribunal system based on a prescribed structured tariff mechanism was also rejected as it was considered to be too blunt of an instrument and may end up replicating the court system.⁶¹

2.4.1. NHS REDRESS SCHEME

In the end, 19 recommendations for reform of the existing system were made.⁶² The principal reform proposal was the establishment of a new system for providing redress to patients who have been harmed as a result of seriously substandard NHS hospital care. The new NHS Redress Scheme⁶³ would consist of four main elements: an investigation of the incident which is alleged to have caused harm; provision of an explanation to the patient and of the action proposed to prevent repetition; development and delivery of a package of care providing remedial treatment, therapy and arrangements for continuing care where needed; and payments for pain and suffering, out of pocket expenses and care or treatment which the NHS could not provide. It was hoped that such a scheme would address many of the existing system's flaws, whilst signalling a clear commitment to patient safety. Not just to ensure that the court rolls were less congested, but for the sake of safety above all.

The new NHS Redress Scheme would not take away a person's right to sue through the Courts, but, except for cases of children with cerebral palsy, there would be a presumption that they had first applied to the scheme. Furthermore, those accepting packages of care and compensation under the NHS Redress Scheme would be

⁵⁹ *Id.* 97.

⁶⁰ *Id.* 110.

⁶¹ *Id.* 113.

⁶² *Id.* 117.

⁶³ *Id.* 119.

required to waive their right to go to court on the same case. As for cases that did not fall within the criteria of the scheme, there would be an expectation that mediation would be used as a first step, periodical payments would be strongly encouraged, costs of future care would no longer reflect the cost of private treatment, and the judges handling these cases would be specially trained.

Additional changes would ensure that the scheme was more closely aligned to a complaints procedure. Provision would be made for after-event and after-complaint management by the NHS so that there is a full investigation of each case, a clear explanation is provided to victims and any necessary remedial action taken. The current fragmented processes would be reorganised to see to it that respective organisations rigorously investigate and learn effectively from complaints, adverse events and claims. Investigation of complaints and incidents would instead be co-ordinated under a single senior manager.

Steps would be taken to encourage openness in the reporting of adverse events, including the introduction of a duty of candour and exemptions from disciplinary action for those who report adverse events or medical errors. These reports would be provided legal privilege. Arrangement would also be made for the care and support of victims.

2.5. NHS REDRESS ACT 2006

Sir Liam Donaldson report was certainly encouraging and was widely welcomed by patient groups and other stakeholders. Patient safety was finally at the heart of reform efforts. What is more, many of the report's recommendations actually received legislative expression, being enacted in the NHS Redress Act 2006, which gained Royal Assent on the 8th of November 2006.⁶⁴

The Act empowered the Secretary of State to promulgate regulations so as to 'establish a scheme for the purpose of enabling redress...without recourse to civil proceedings'. The four main elements of the Chief Medical Officer's proposal, including matters

⁶⁴ NHS Redress Act 2006 (2006 c. 44).

relating to compensation, are to be found in section 3 of the Act and form the basis of the scheme. Patient safety concerns feature prominently, with the prevention of similar adverse events at the forefront.

'Redress under scheme

(1) Subject to subsections (2) and (5), a scheme may make such provision as the Secretary of State thinks fit about redress under the scheme.

(2) A scheme must provide for redress ordinarily to comprise—

(a) the making of an offer of compensation in satisfaction of any right to bring civil proceedings in respect of the liability concerned,

(b) the giving of an explanation,

(c) the giving of an apology, and

(d) the giving of a report on the action which has been, or will be, taken to prevent similar cases arising, but may specify circumstances in which one or more of those forms of redress is not required.

(3) A scheme may, in particular—

(a) make provision for the compensation that may be offered to take the form of entry into a contract to provide care or treatment or of financial compensation, or both;

(b) make provision about the circumstances in which different forms of compensation may be offered.

(4) A scheme that provides for financial compensation to be offered may, in particular—

(a) make provision about the matters in respect of which financial compensation may be offered;

(b) make provision with respect to the assessment of the amount of any financial compensation.

(5) A scheme that provides for financial compensation to be offered—

(a) may specify an upper limit on the amount of financial compensation that may be included in an offer under the scheme;

- (b) if it does not specify a limit under paragraph (a), must specify an upper limit on the amount of financial compensation that may be included in such an offer in respect of pain and suffering;
- (c) may not specify any other limit on what may be included in such an offer by way of financial compensation.’

In order to contain administrative costs, the scheme would make provision for assistance and the furnishing of legal advice without charge in respect to certain proceedings, as well as access to jointly appointed medical experts. The Act also provides for the handling and consideration of complaints about maladministration, which would potentially deal with minor cases.

Unfortunately, the Act has been buried. As yet, the regulations required to establish the NHS Redress Scheme have not been promulgated.⁶⁵ It is really a shame, as such a scheme could have gone a long way to address the concerns that Lord Woolf raised in his report. It could have enabled medical negligence cases to be resolved much more efficiently and away from the clogged adversarial court system. It might have also been a significant step towards the realisation of a system where patient safety considerations were at the forefront, as Sir Liam Donaldson had hoped. In the absence of such a system, the current adversarial, punitive arrangement would ensure that errors are concealed until it is too late. Safety lessons will remain unlearned.⁶⁶

2.6. LORD JUSTICE JACKSON’S REVIEW OF CIVIL LITIGATION COSTS

The Jackson report is the most comprehensive review of civil litigation costs since the Woolf report.⁶⁷ The review was conducted in response to concerns that the

⁶⁵ Tingle and Bark (2011) 34.

⁶⁶ Dyer “Scotland considers no fault compensation for medical injuries” *BMJ: British Medical Journal (Online)* (2012) 345; Dyer “Fault lines: resolving clinical negligence claims” *BMJ: British Medical Journal (Online)* (2013) 347; Ken and Richard (2013) 448.

⁶⁷ Jackson *Review of civil litigation costs: final report* (2009).

disproportionate costs of civil litigation were impeding access to justice. The report set out a package of interlocking reforms, designed to control costs and promote access to justice.

2.6.1. CLINICAL NEGLIGENCE LITIGATION

An entire chapter was dedicated to the issue of clinical negligence litigation.⁶⁸ Lord Jackson highlighted two objectives relating to this area of his review: First, negligently injured patients must have access to justice in order to receive proper compensation. Secondly, it is an area of massive public expenditure that should be kept under control to prevent resources from being unnecessary squandered on litigation costs.

Various stakeholders were consulted, including defendant lawyers, claimant lawyers, the Medical Defence Union, the Medical Protection Society, NHS Litigation Authority, and patient groups. The stakeholder consultations make for interesting reading. If only to glimpse the different, often conflicting, agendas at play.⁶⁹

2.6.2. CONDITIONAL FEE AGREEMENTS

Lord Jackson indicated that Conditional Fee Agreements, ‘no win, no fee’ agreements being the most commonly used variant, have been the major contributor to disproportionate costs in civil litigation in England and Wales.⁷⁰ According to the report, the success fee that lawyers negotiate and the after-event insurance premium, are the two key drivers of costs under these agreements – both of which are recoverable from the unsuccessful defendant. One of Lord Jackson’s more controversial proposals was that these success fees and insurance premiums should cease to be recoverable from unsuccessful opponents in civil litigation. This would supposedly lead to significant cost savings. Instead, these costs would be recovered from successful claimants who have entered into ‘no win no fee’ agreements. In other words, the success fee will be payable by the client, which would likely mean that the success fee comes out of the damages awarded. Furthermore, it was recommended that provision be made for a new type of

⁶⁸ *Id.* 231.

⁶⁹ *Id.* 473.

⁷⁰ *Id.* 240.

'no win no fee' arrangement between clients and their legal representatives, so-called Damages-Based Agreements (DBAs), where the client agrees to pay a percentage of sums recovered in a successful claim to the attorney.

To ensure that claimants are properly compensated and that legal fees do not disproportionately subtract from their compensation, it was also recommended that general damages for pain, suffering and loss of amenity be increased by 10%, and that the maximum amount of damages that lawyers may deduct for success fees be capped at 25% of damages (excluding any damages referable to future care or future losses).

2.6.3. COST SHIFTING

Another controversial proposal was for the implementation of 'qualified one-way costs shifting' in clinical negligence litigation, whereby, subject to certain qualifications, a claimant will not be required to pay the defendant's costs if the claim is unsuccessful, but the defendant will be required to pay the claimant's costs if it is successful.

2.6.4. ALTERNATIVE DISPUTE RESOLUTION AND EARLY SETTLEMENT

It was acknowledged that Alternative Dispute Resolution, which encourages the early settlement of cases, has a vital role to play in reducing the costs of civil disputes. It was noted that it is, unfortunately, under-utilised and that the benefits thereof are not as widely known as they should be. The report emphasised that all available options that may induce earlier settlements should be explored (including incentivising Part 36 settlement offers).

2.6.5. RECOMMENDATIONS

The report made a number of recommendations specifically aimed at clinical negligence cases.⁷¹ These include: financial penalties for any health authority that fails to provide copies of medical records requested in accordance with the pre-action protocol; defendants should be granted more time to respond to claims (four months); where the NHSLA is proposing to deny liability, it should obtain independent expert evidence on

⁷¹ *Id.* 246.

liability and causation; a process that allows claimant attorneys to report egregious cases of defendant lawyers failing to address the issues; the protocol should provide a limited period for settlement negotiations where the defendant offers to settle without formal admission of liability; case management directions for clinical negligence cases should be harmonised; and costs management for clinical negligence cases should be piloted.

The report's final recommendation on the subject was that regulations should be drawn up in order to implement the NHS Redress Act 2006. Lord Jackson noted that he believes the redress scheme 'will promote access to justice at proportionate cost'. He called for the matter to be taken forward immediately 'both in the interests of patients and (no less important) in the interests of saving the NHS from paying out unnecessary litigation costs'.⁷²

The government welcomed the report and agreed that the right way forward was to abolish the recoverability of Conditional Fee Arrangement success fees and after the event insurance premiums, as well as other changes Lord Jackson recommended.⁷³

2.7. LEGAL AID, SENTENCING AND PUNISHMENT OF OFFENDERS ACT 2012

Many of the proposed changes were legislatively effected by the Legal Aid, Sentencing and Punishment of Offenders Act 2012.⁷⁴ Most of the relevant provisions came into force on the 1st of April 2013.

The Act has come under severe criticism, as in its quest for cost savings, it has had the effect of also ceasing legal aid for several categories of claims, including clinical

⁷² *Ibid.*

⁷³ Justice "Reforming Civil Litigation Funding and Costs in England and Wales" (2011) 75; Jackson *The Reform of Civil Litigation* (2016).

⁷⁴ Legal Aid, Sentencing and Punishment of Offenders Act 2012 (2012 c. 10).

negligence cases (except certain cases involving neurological injury to infants).⁷⁵ This has meant that these cases would have to be almost exclusively funded through ‘no win no fee’ agreements. However, it is feared that this could seriously impede access to justice, especially for borderline or high-risk cases where negligence may not be clearly established.⁷⁶ The House of Commons Justice Committee has also come out strongly against the Act and the impact it has had in their report, stating:

‘Our overall conclusion was that, while it had made significant savings in the cost of the [legal aid] scheme, the Ministry had harmed access to justice for some litigants and had not achieved the other three out of four of its stated objectives for the reforms.’

‘It was clear to us that the urgency attached by the Government to the programme of savings militated against having a research-based and well-structured programme of change to the provision of civil legal aid.’⁷⁷

More than 100 judges, peers, lawyers and doctors wrote an open letter to one of the UK’s leading newspapers, calling on the new government to prevent ‘widespread miscarriages of justice’. They noted that many would be denied redress, and the figures seem to confirm this, for instance from 2012-13 to 2013-14, clinical negligence cases fell from 2859 to 114.⁷⁸

⁷⁵ Lee “New Rules to Control Compensation Claims: Which Will Cut Off Access to Lawyers for Many” *Medico-Legal Journal* (2013) 81 95; Bermingham and Brennan *Tort law directions* (2016) 10; Palmer et al. *Access to Justice: Beyond the Policies and Politics of Austerity* (2016) 15; Flynn and Hodgson *Access to Justice and Legal Aid: Comparative Perspectives on Unmet Legal Need* (2017) 222.

⁷⁶ Walsh “The future for Medico-Legal disputes - a patient perspective.” *Med Leg J* (2014) 82 18.

⁷⁷ Committee *Impact of Changes to Civil Legal Aid Under Part 1 of the Legal Aid, Sentencing and Punishment of Offenders Act 2012: Report. Together with Formal. of Session 2014-15 (House of Commons Papers)* (2015) 4.

⁷⁸ “Open letter condemns legal aid cuts, calls on new government to restore justice” *The Guardian* (2015-05-01) <https://www.theguardian.com/law/2015/may/01/open-letter-judges-peers-restore-legal-aid-incoming-government-justice>

2.8. LATEST DEVELOPMENTS

Despite the fact that negligence claims reported by the NHSLA (now NHS Resolution) have steadily declined over 10% from 2013-14 to 2016-17, the damages paid out continued to rise. In 2016/17 total payments stood at £1,707.2 million.⁷⁹ To counter these rising the costs, the current UK government has proposed the introduction of a mandatory Fixed Recoverable Costs scheme for clinical negligence claims above £1 000 and up to £25 000 (there are, however, indications that the upper limit may be as high as £250 000), which will be implemented through revised Civil Procedure Rules.⁸⁰

The establishment of a Rapid Resolution and Redress scheme, a voluntary administrative compensation scheme for families affected by severe avoidable birth injury is being considered, as current expenditure on maternity claims is nearly £500m per year.⁸¹ The government is also planning to develop a state-backed indemnity scheme for GPs, to protect them from the costs of clinical negligence claims.⁸²

These interventions are in addition to those undertaken by NHS Resolution (discussed above).

⁷⁹ Resolution “Annual report and accounts 2016/17” (2017).

⁸⁰ Jackson “Review of Civil Litigation Costs: Supplemental Report Fixed Recoverable Cost” *Judiciary of England and Wales* (2017); Rimmer “Cap on legal fees for clinical negligence work does not go far enough, defence organisations warn” *BMJ: British Medical Journal (Online)* (2017) 358.

⁸¹ Tingle “Managing clinical negligence litigation and costs in the NHS.” *Br J Nurs* (2016) 25 1218; Health “A Rapid Resolution and Redress Scheme for Severe Avoidable Birth Injury: a Consultation.” (2017); Dyer (2017) 358 *Bmj* j4134; Tingle (2017) 26 *Br J Nurs* 474; Dyer “Indemnity provider calls for urgent reform of negligence payouts.” *BMJ* (2017) 357 j3025; Dyer “Government unveils plan to speed up payments for birth injuries.” *BMJ* (2017) 356 j1181; Tingle “The high cost of clinical negligence litigation in the NHS.” *Br J Nurs* (2017) 26 296; Dyer “New negligence claims service aims to resolve cases more quickly.” *BMJ* (2017) 356 j1503.

⁸² “GP indemnity: development of state-backed scheme for England” Department of Health (2017-10-12) <https://www.gov.uk/government/news/gp-indemnity-development-of-state-backed-scheme-for-england>; Rimmer “A new indemnity scheme for GPs” (2017).

3. THE HEALTH SYSTEM

3.1. INTRODUCTION

A number of reports and interventions have highlighted the importance of patient safety in the UK health system. A few of the more notable developments will be discussed. An overview of the changes that occurred immediately after the publication of 'An organisation with a memory' is provided. The discussion then turns to the events and interventions which followed in the aftermath of the Mid Staffordshire inquiry.⁸³

3.2. AN ORGANISATION WITH A MEMORY

Following the Institute of Medicine's report, various governments and organisations launched investigations into the scale of harm and errors in their own systems. The British equivalent of 'To err is human', was prepared by an expert group under the leadership of the Chief Medical Officer, Professor Liam Donaldson. 'An Organisation with a Memory' helped to define and popularise the field of patient safety and remains relevant to this day.⁸⁴

The report looked at how adverse events are caused in the NHS and examined how organisations and the healthcare system can make sense of the failures, using what was learnt to ultimately minimise future risks and improve safety. It considered the extent to which the NHS had the systems and capacity to learn from failures. The analysis was informed by evidence and experience from not only healthcare, but a range of sectors including industry, aviation and academic research. The findings and recommendations of the report have been used to modernise the NHS's approach to learning from failure. The key interventions that were identified included: establishing a unified reporting mechanism; supporting an open learning culture; ensuring that the lessons learned are put into practice; and fostering a wider appreciation of the value of the system approach to reduce failure.

⁸³ Exworthy et al. *Dismantling the NHS?: Evaluating the Impact of Health Reforms* (2016) 323.

⁸⁴ Health (2000).

‘Building a Safer NHS for Patients’ set out the Government’s plans for promoting patient safety and the commitment to implement it in ‘The NHS Plan’.⁸⁵ The report also announced the establishment of the National Patient Safety Agency.

The National Patient Safety Agency (NPSA) was created in April 2001 as an arm’s-length body of the Department of Health, to oversee the implementation of the Report’s recommendations. Most notably, the NPSA developed and established the world’s first comprehensive adverse incident reporting system, the National Reporting and Learning System.⁸⁶ Since April 2010 all NHS Trusts have been required to report serious patient safety incidents to the NPSA.⁸⁷

The National Audit Office published ‘A Safer Place for Patients: Learning to improve patient safety’ in November 2005.⁸⁸ The report followed the Office’s review on the implementation of the Government’s policy on patient safety. It considered the progress that had been made and the challenges that remained.

‘Safety First’ was published on 15 December 2006, it reviewed the organisational arrangements that were put in place following ‘An Organisation with a memory’ and the challenges that were highlighted in the later reports.⁸⁹ The review highlighted the need to build on the progress that has been achieved in addressing the patient safety agenda to refocus efforts to enable clinicians and healthcare organisations to deliver safe healthcare.

In June 2008, Lord Darzi published his review, ‘High quality care for all’, which set out the government’s plans for NHS reform with a focus on improving standards of quality

⁸⁵ NHS *NHS plan* (2000); Great and Department “Building a safer NHS for patients: implementing an organisation with a memory” (2001).

⁸⁶ National *The National Patient Safety Agency annual report and accounts. 2004-2005.* (2005).

⁸⁷ Since 1 June 2012 the key functions and expertise for patient safety developed by the National Patient Safety Agency (NPSA) transferred to the NHS Commissioning Board Special Health Authority.

⁸⁸ National *A safer place for patients : learning to improve patient safety* (2005).

⁸⁹ Carruthers et al. *Safety first : a report for patients, clinicians and healthcare managers* (2006).

and safety.⁹⁰ The report led to the introduction of local quality indicators measuring mortality, complications and survival rates, as well as patient perceptions, allowing providers to measure and improve their performance.

3.3. CARE QUALITY COMMISSION

The Care Quality Commission is a non-departmental public body, overseen by the Department of Health.⁹¹ The CQC was established under the Health and Social Care Act 2008 and is accountable to the Secretary of State for Health for discharging their functions, duties and powers effectively, efficiently and economically.⁹² It replaced the Commission for Healthcare, Audit and Inspection (known as the Healthcare Commission), the Commission for Social Care Inspection and The Mental Health Act Commission.

The Care Quality Commission began operating on 1 April 2009 as the independent regulator of health and adult social care in England.⁹³ The Commission ensures that care provided by hospitals, dentists, ambulances, care homes and home-care agencies adheres to government standards of quality and safety. The CQC uses National Institute for Health and Care Excellence (NICE) guidelines and quality standards as evidence for inspections.⁹⁴

The CQC registers health and adult social care services across England and inspects them to ascertain whether or not set standards are being met. They are legally empowered to enforce the standards, by issuing fines and warnings, stopping admissions and cancelling or suspending registrations.

⁹⁰ Great et al. "High quality care for all : NHS next stage review final report" (2008).

⁹¹ Care et al. *Care Quality Commission annual report and accounts for the period 1 October 2008 to 31 March 2009* (2009).

⁹² Health and Social Care Act 2008 (2008 c. 14).

⁹³ "CQC – About Us" Care Quality Commission <https://www.cqc.org.uk/about-us>.

⁹⁴ "Memorandum of Understanding between NICE and CQC" Care Quality Commission <https://www.cqc.org.uk/sites/default/files/201410-NICE-MOU.pdf>.

The Francis Report, discussed below, considered many of the challenges faced by the CQC and made a number of recommendations to ensure that it fulfils its purpose. The government and CQC have responded positively to these recommendations and introduced a number of changes, including a more stringent inspection regime.⁹⁵

The Secretary of State for Health stated the following in ‘Culture change in the NHS’:

‘The Public Inquiry was scathing about the failure of the Healthcare Commission to notice or act on the appalling standard of care which persisted at Mid Staffordshire, and the regulatory system operated by the Healthcare Commission and its successor the Care Quality Commission. Sir Robert Francis QC found that the Commission’s culture needed to be transformed if it was to be an effective regulator that commanded confidence.

Re-establishing the credibility and effectiveness of the Care Quality Commission has therefore been a critical component of the Government response to the Inquiry, seeking to establish the regulator as a trusted, authoritative and independent agency that can quickly identify poor care so that effective action can be taken. The Care Quality Commission has a new Chair, a new Chief Executive and a new board. Three powerful and independent Chief Inspectors have been appointed, covering hospitals, general practice and adult social care. The organisation’s independence has been strengthened in legislation. The Care Quality Commission’s inspection model has been completely overhauled, moving from a generalist light-touch and tick-box model to a thorough approach, informed by experts, patients and staff, and drawing on a rich set of data to provide assurance that the care provided is safe, effective, well led, caring and responsive.’⁹⁶

South Africa’s Office of Health Standards Compliance, which is essentially modelled after the CQC, should heed these warnings.

⁹⁵ Great and Department *Culture change in the NHS : applying the lessons of the Francis inquiries* (2015).

⁹⁶ *Ibid.*

3.4. ROBERT FRANCIS QC'S REPORT OF THE MID STAFFORDSHIRE NHS FOUNDATION TRUST PUBLIC INQUIRY.

Robert Francis QC led two inquiries into the shocking standards of care which prevailed at the Mid Staffordshire NHS Trust from 2005 to 2009 and the circumstances that allowed such an appalling situation to persist.⁹⁷ As many as 400-1200 patients died of neglect, misdiagnosis and 'horrific abuse' during this period.⁹⁸ His first inquiry, published as an independent report under the NHS Act in 2010, was more limited in scope and only examined the quality of care at Stafford hospital.⁹⁹ The second inquiry, a full-scale public inquiry conducted over a period of 31 months, investigated the extent of the failure of the broader system (the operation of the commissioning, supervisory and regulatory organisations and other agencies) in order to determine why the problems were not detected and remedied sooner.¹⁰⁰

It was emphasised in both of the reports that it should be patients – not numbers – that count. The responsibility to ensure that patients are always placed first falls on the people working in the health service and those charged with developing healthcare policy.¹⁰¹ A key message of the report was that the safety of patients should 'transcend particular policies and to permeate all considerations within the system'. The extent of the complete system failure that emerged from the investigation, led the Inquiry to conclude that a fundamental change of culture was needed if patients were to be re-established as the foremost consideration.

The report identified a number of warning signs that should have been heeded. Many of these signs were overlooked or ignored due to the absence of a caring culture which placed patients and their safety first. The nursing and medical professions failed to promote such a positive culture. Furthermore, poor standards were tolerated. Concerns

⁹⁷ Francis "Report of the Mid Staffordshire NHS Foundation Trust public inquiry" (2013).

⁹⁸ Coombes "Francis interview: what doctors must learn from my report" *BMJ: British Medical Journal (Online)* (2013) 346.

⁹⁹ Francis "Independent Inquiry into care provided by Mid Staffordshire NHS Foundation Trust January 2005 - March 2009." (2010).

¹⁰⁰ Martin and Dixon-Woods "After Mid Staffordshire: from acknowledgement, through learning, to improvement." *BMJ Qual Saf* (2014) 23 706.

¹⁰¹ Francis (2013) 83.

were either not raised, or not communicated properly between the various agencies that were tasked with responding to them. Assumptions about responsibilities in regard to monitoring, performance management and interventions led to widespread inaction. And there was also a failure to foresee that repeated, multi-level reorganisation, would lead to a disruptive loss of corporate memory and focus. In essence, there was an overall drift into organisational failure.¹⁰²

3.4.1. PROPOSALS

To address the many concerns identified during the inquiry, Francis outlined 290 proposals in his extensive three-volume report. The essential aims were to: Foster a common culture shared by all in the service of putting the patient first. Develop a set of fundamental standards. Provide a professionally endorsed and evidence-based means of compliance with these fundamental standards. Ensure that openness, transparency and candour prevail throughout the system. Ensure that the relentless focus of the healthcare regulator is on policing compliance with these standards. Make all those who provide care for patients – individuals and organisations – properly accountable for what they do and ensure that the public is protected from those not fit to provide such a service. Provide for a proper degree of accountability for senior managers and leaders to place all with responsibility for protecting the interests of patients on a level playing field. Enhance the recruitment, education, training and support of all the key contributors to the provision of healthcare, but in particular, those in nursing and leadership positions, to integrate the essential shared values of the common culture into everything they do. Develop and share ever improving means of measuring and understanding the performance of individual professionals, teams, units and provider organisations for the patients, the public, and all other stakeholders in the system.

Evidence submitted to the Inquiry showed that the NHS had ‘still not managed to move successfully away from the culture of blame which Professor Sir Liam Donaldson, in *Organisation with a Memory*, and Professor Sir Ian Kennedy, in the report of the Bristol Inquiry, were so keen to banish.’¹⁰³ That in a system failure, such as the one at Mid

¹⁰² Dekker (2012b).

¹⁰³ Francis (2013) 35.

Staffs, ascribing blame to individuals would almost become a futile exercise, since ‘so many are in one sense accountable, it is far more effective to learn rather than to punish.’¹⁰⁴ Whilst analysing complex system failures ‘the temptation of offering up scapegoats is a dangerous one which must be resisted’.¹⁰⁵ To do so, one might lose sight of the bigger picture, ‘create the fiction that the behaviour of one person, or a small group of people, would have made all the difference and conclude that the easy answer to the problem is to appoint better performing individuals’.¹⁰⁶ The report cautions that it was not ‘a single rogue healthcare professional who delivered poor care in Stafford, or a single manager who ignored patient safety, who caused the extensive failure which has been identified’.¹⁰⁷ The report refutes the ‘bad apple’ theory, instead, it indicates that there was ‘a combination of factors, of deficiencies throughout the complexity that is the NHS, which produced the vacuum in which the running of the Trust was allowed to deteriorate’.¹⁰⁸ Francis contextualises it well in the following words: ‘To focus, therefore, on blame will perpetuate the cycle of defensiveness, concealment, lessons not being identified and further harm.’¹⁰⁹

Rather than a culture of blame, the report envisioned a common, shared culture built upon three pillars:

1. Openness: enabling concerns to be raised and disclosed freely without fear, and for questions to be answered;
2. Transparency: allowing true information about performance and outcomes to be shared with staff, patients and the public;
3. Candour: ensuring that patients harmed by a healthcare service are informed of the fact and that an appropriate remedy is offered, whether or not a complaint

¹⁰⁴ *Ibid.*

¹⁰⁵ *Id.* 36.

¹⁰⁶ *Ibid.*

¹⁰⁷ *Ibid.*

¹⁰⁸ Dekker and Leveson “The bad apple theory won’t work: response to ‘Challenging the systems approach: why adverse event rates are not improving’ by Dr Levitt.” *BMJ Qual Saf* (2014) 23 1050; Dekker and Hugh “A just culture after Mid Staffordshire” *BMJ Qual Saf* (2014) 23 356.

¹⁰⁹ Francis (2013) 35.

has been made or a question asked about it.

This 'common culture of caring', as the report puts it, calls for: 'a displacement of a culture of fear with a culture of openness, honesty and transparency, where the only fear is the failure to uphold the fundamental standards and the caring culture'.¹¹⁰

The BMJ Quality & Safety commissioned a number of perspective papers, which formed part of a series devoted to the aftermath of the Mid Staffordshire disaster.¹¹¹ It also included contributions by Sidney Dekker (just culture) and Carl Macrae (incubation and independent accident investigation), whose work is discussed in an earlier chapter.¹¹²

3.5. A PROMISE TO LEARN - A COMMITMENT TO ACT: IMPROVING THE SAFETY OF PATIENTS IN ENGLAN

Donald Berwick, an American patient safety expert, led a decidedly forward-looking independent Advisory Group in the aftermath of Mid Staffordshire.¹¹³ They examined the findings of the Francis report and others, distilled the lessons learned and specified what changes were needed.

3.5.1. FOREMOST PROBLEMS

The most important problems were identified as follows:¹¹⁴

1. Patient safety problems exist throughout the NHS, Mid Staffordshire was not unique and all healthcare systems, including the whole NHS should strengthen patient safety now and into the future.
2. NHS staff are not to blame, and it is unjustified to label them as uncaring, unskilled, or culpable. The vast majority of staff want the best for their patients, but may fall short when their working conditions are not conducive to success.
3. Incorrect priorities do damage, especially when the focus is diverted from the

¹¹⁰ *Id.* 75.

¹¹¹ Martin and Dixon-Woods (2014) 23 *BMJ Qual Saf* 706.

¹¹² Dixon-Woods et al. "Culture and behaviour in the English National Health Service: overview of lessons from a large multimethod study." *BMJ Qual Saf* (2014) 23 106; Macrae (2014) 23 *BMJ Qual Saf* 440; Dekker and Hugh (2014) 23 *BMJ Qual Saf* 356.

¹¹³ Berwick *A promise to learn—a commitment to act: improving the safety of patients in England* (2013).

¹¹⁴ *Id.* 8.

needs of the patient to hitting targets or reducing costs.

4. Warning signals abounded and were not heeded. Urgent warning signs, including complaints and quantitative metrics were muffled or explained away.
5. Responsibility for oversight of quality and safety concerns is diffused and therefore not clearly owned. This divided responsibility often meant that no one was responsible.
6. Improvement requires a system of support. 'The most important single change in the NHS in response to this report would be for it to become, more than ever before, a system devoted to continual learning and improvement of patient care, top to bottom and end to end.'
7. Fear is toxic to both safety and improvement. Fear hampers improvement, since problems are concealed and the truth buried.

3.5.2. SOLUTIONS

The Berwick report makes it abundantly clear that these problems are not unique to the NHS and are most likely present in almost all healthcare systems around the world. Recognition provides the first opportunity to repair and the principles of action which guided the recommendations, set out as follows, reflected this:¹¹⁵

1. Recognise with clarity and courage the need for wide systemic change. Everyone involved must recognise and acknowledge the need to improve.
2. Abandon blame as a tool. Misconduct does occur and deserves sanction; however, errors are not misconduct and do not warrant punishment.
3. Reassert the primacy of working with patients and carers to set and achieve health care goals.
4. Use quantitative targets with caution, as patient care and healing remain the overriding priority.
5. Recognise that transparency is essential and expect and insist on it at all levels and with regard to all types of information. 'The most valuable information of all is information on risks and on things that have gone wrong'. Everyone should be free to voice their concerns about patient safety without

¹¹⁵ *Id.* 10.

reprisal.

6. Ensure that responsibility for functions related to safety and improvement are vested clearly and simply.
7. Give the people of the NHS – top to bottom – career-long help to learn, master and apply modern methods for quality control, quality improvement and quality planning.
8. Make sure pride and joy in work, not fear, infuse the NHS.

The primacy of the patient and their safety is clearly emphasised by the following passage:

‘In sum, the recommendations...reflect our view that the quality of patient care should come before all other considerations in the leadership and conduct of the NHS, and that patient safety is the keystone dimension of quality. The pursuit of continually improving safety should permeate every action and level in the NHS.’¹¹⁶

3.5.3. CULTURE TRUMPS REGULATION

Francis recommended various types of new regulation to achieve this. The Berwick report, notes the importance of regulation, but also points to its limitations:

‘However, regulation alone cannot solve the problems highlighted by Mid Staffordshire. Neither quality assurance nor continual improvement can be achieved through regulation based purely on technically specific standards, particularly where a blunt assertion is made that any breach in them is unacceptable.

In the end, culture will trump rules, standards and control strategies every single time, and achieving a vastly safer NHS will depend far more on major cultural change than on a new regulatory regime.’¹¹⁷

¹¹⁶ *Id.* 11.

¹¹⁷ *Ibid.* The text is highlighted in the report.

3.5.4. APPROACHES TO HARM

The Berwick report includes a note on the nature of quality and patient safety.¹¹⁸ It reasserts that safety ('first do no harm') is the central aim in healthcare. Yet, the authors acknowledge that risks of harm are concomitant with health care, that there is often an 'inescapable tension between the pursuit of safety and the pursuit of other healthcare priorities'. This tension comes under even more strain when the reality of finite resources inevitably interposes.

The approach taken towards these risks of harm is set out as follows and should by now be familiar to the reader (from earlier discussions on the system approach to human error and the concept of just culture)

'Even though hazards in care cannot be eliminated, harms to patients can be and should be reduced continually, everywhere and forever. The fight for safety is a never-ending struggle against entropy, engaged tirelessly and with focus against an enemy that continually emerges and re-emerges.

We distinguish three types of unnecessary risk of harm: risk of harm due to neglect or wilful misconduct; risk of harm due to failures in the system; and risk of harm from error. They are not the same. As Robert Francis has unequivocally shown, some harm is, indeed, due to neglect or to wilful misconduct. These rare sources of harm should be distinguished from the far more common kind: errors made by well-intentioned people or arising from failures in the system. Improving the reliability and safety of healthcare systems is a critical task for leaders. They need to differentiate carefully between error and neglect or wilful misconduct.

Error and neglect or wilful misconduct warrant different responses. Even apparently simple human errors almost always have multiple causes, many beyond the control of the individual who makes the mistake. Therefore, it makes no sense at all to punish a person who makes an error, still less to criminalise it. The same is true of system failures that derive from the same kind of multiple unintentional mistakes. Because human error is normal and, by definition, is

¹¹⁸ *Ibid.*

unintended, well-intentioned people who make errors or are involved in systems that have failed around them need to be supported, not punished, so they will report their mistakes and the system defects they observe, such that all can learn from them. On the other hand, harm caused by neglect or wilful misconduct does warrant sanctions in health care, just as it does in other settings.¹¹⁹

3.5.5. RECOMMENDATIONS

It is evident from the report that the adoption of a safety culture was the most important change required, such a cultural shift would also underlie, inform and be required if the recommendations were to be successfully effected. The specific recommendations were as follows:

1. An ethic of learning should be embraced to continually and forever reduce patient harm.¹²⁰
2. All leaders concerned with healthcare should place quality of care in general, and patient safety in particular, at the top of their priorities for investment, inquiry, improvement, regular reporting, encouragement and support.¹²¹
3. Patients and the public should be present, powerful and involved at all levels of healthcare.¹²²
4. Government should assure that sufficient staff are available to meet the needs of the healthcare system. Staff must be well-supported and present in appropriate numbers to provide safe care at all times.¹²³
5. Mastery of quality and patient safety sciences and practices should be part of initial preparation and lifelong education of all health care professionals, including managers and executives.¹²⁴
6. The entire healthcare industry should become a learning organisation. Its leaders should create and support the capability for learning, and therefore

¹¹⁹ *Id.* 12.

¹²⁰ *Id.* 14.

¹²¹ *Id.* 15.

¹²² *Id.* 18.

¹²³ *Id.* 21.

¹²⁴ *Id.* 24.

change, at scale, within the system.¹²⁵

7. Transparency should be complete, timely and unequivocal. All non-personal data on quality and safety, whether assembled by government, organisations, or professional societies, should be shared in a timely fashion with all parties who want it, including, in accessible form, with the public.¹²⁶
8. The patient and carer voice should be sought out as an essential asset in monitoring the safety and quality of care.¹²⁷
9. Supervisory and regulatory systems should be simple and clear. They should avoid diffusion of responsibility. They should be respectful of the goodwill and sound intention of the vast majority of staff. All incentives should point in the same direction.¹²⁸
10. Regulation of organisations should be responsive, with a hierarchy of responses. Recourse to criminal sanctions should be extremely rare, and should function primarily as a deterrent to wilful or reckless neglect or mistreatment. A correct balance should be struck between learning and accountability.¹²⁹

As the authors indicate, some of their recommendations have the hard edge of requirement and enforcement:¹³⁰

- Providers should act on patient safety alerts, and regulators should ensure that they do.
- Transparency ought not to be optional.
- Staffing levels should be adequate, based on evidence.
- Sanctions should apply to reckless and wilful neglect or mistreatment of patients.

However, it is clear from their most important recommendations, that they want to see

¹²⁵ *Ibid.*

¹²⁶ *Id.* 27.

¹²⁷ *Ibid.*

¹²⁸ *Id.* 30.

¹²⁹ *Id.* 33.

¹³⁰ *Id.* 36.

that the NHS becomes a learning organisation by:¹³¹

- Placing the quality of patient care, especially patient safety, above all other aims.
- Engaging, empowering, and hearing patients and carers throughout the entire system and at all times.
- Fostering whole-heartedly the growth and development of all staff, including their ability and support to improve the processes in which they work.
- Embracing transparency unequivocally and everywhere, in the service of accountability, trust, and the growth of knowledge.

The report concluded by calling for a concerted effort from all stakeholders to commit themselves to the objective of continual improvement. It once again stressed the imperative of cultural change in this respect, asserting that: 'Rules, standards, regulations and enforcement have a place in the pursuit of quality, but they pale in potential compared to the power of pervasive and constant learning.'¹³²

3.6. SIGN UP TO SAFETY

As part of the response to the Berwick report, the Secretary of State for Health, on 24 June 2014, launched the 'Sign up to Safety' campaign with the mission to strengthen patient safety in the NHS and make it the safest healthcare system in the world.¹³³

'I want today to mark the start of a new movement within the NHS in which each and every part of our remarkable healthcare system signs up to safety, heart and soul, board to ward.

Professor Berwick said the heart of safe care is a culture of learning.

So the engine room of this new movement will be a new national network housed in NHS England, a collaboration of all NHS organisations and local patients, who

¹³¹ *Ibid.*

¹³² *Id.* 38.

¹³³ Woodward "Sign up to safety" *NICC Nursing in Critical Care* (2015) 20 172.

share, learn and improve ideas for reducing harm and saving lives.¹³⁴

The campaign has a three-year objective to save 6,000 lives, halve avoidable harm and the costs of harm. Organisations and individuals can sign up to safety and make pledges to improve patient safety. Organisations are being asked to set out how they will take action to improve safety and reduce harm. Those who sign up are also encouraged to take the five Sign up to Safety Pledges:

1. Putting safety first – Committing to reduce avoidable harm in the NHS by half through taking a systematic approach to safety and making public your locally developed goals, plans and progress. Instilling a preoccupation with failure so that systems are designed to prevent error and avoidable harm.
2. Continually learn – Review your incident reporting and investigation processes to make sure that you are truly learning from them and using these lessons to make your organisation more resilient to risks. Listen, learn and act on the feedback from patients and staff and by constantly measuring and monitoring how safe your services are.
3. Be honest – Being open and transparent with people about your progress to tackle patient safety issues and supporting staff to be candid with patients and their families if something goes wrong.
4. Collaborate – Stepping up and actively collaborating with other organisations and teams; sharing your work, your ideas and your learning to create a truly national approach to safety. Working together with others, joining forces and creating partnerships that ensure a sustained approach to sharing and learning across the system.
5. Be supportive – Being kind to your staff, helping them bring joy and pride to their work. Being thoughtful when things go wrong; helping staff cope and creating a positive just culture that asks why things go wrong in order to put them right. Giving staff the time, resources and support to work safely and to work on improvements. Thanking your staff, rewarding and recognising their

¹³⁴ “Sign Up To Safety - The path to saving 6,000 lives” Department of Health (2014-03-24)
<https://www.gov.uk/government/speeches/sign-up-to-safety-the-path-to-saving-6000-lives>.

efforts and celebrating your progress towards safer care.

A number of entities and organisations have joined the campaign, including the NHS England, Department of Health, CQC and the NHS Litigation Authority/Resolution. They have all committed to aligning their organisations' work with the initiative.

Sign up to Safety is led by Dr Suzette Woodward as Campaign Director.¹³⁵

3.7. HARD TRUTHS

The UK government has responded positively to the inquiries occasioned by the Mid Staffordshire tragedy. Their initial response, following the Francis report, *Patients First and Foremost*, set out a sweeping plan to prioritise care, improve transparency and ensure that where poor care is detected, there is clear action and clear accountability.¹³⁶ The initial response has been expatiated on in *Hard Truths*, which also considered a number of independent reviews, including that of Berwick.¹³⁷ In it, the UK government noted the changes which will be made in order to 'improve inspection, increase transparency, put a clear emphasis on compassion, standards and safety, increase accountability for failure, and build capability'.¹³⁸

Some of the more significant changes include: strengthening the Care Quality Commission and overhauling its inspection regime, facilitating the reporting of safety information, introducing a new statutory duty of candour, criminalising wilful neglect, establishing Patient Safety initiatives and programmes (including Sign Up to Safety), developing an effective complaints system, and enhancing organisational accountability.

'Culture Change in the NHS', published on 11 February 2015, sets out the steps that the government has taken since Robert Francis' public inquiry into the challenges facing

¹³⁵ "About Sign Up to Safety" NHS England <https://www.england.nhs.uk/signuptosafety/about/>.

¹³⁶ Great et al. *Patients first and foremost : the initial Government response to the Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry* (2013).

¹³⁷ Health *Hard Truths: The Journey to Putting Patients First, Government Response to the Mid Staffordshire NHS Foundation Trust Public Inquiry (Cm.)* (2013).

¹³⁸ *Id.* 9.

Mid-Staffordshire in 2010.¹³⁹

3.8. FREEDOM TO SPEAK UP

Following his Mid Staffordshire NHS Foundation Trust Public Inquiry, where recommendations were made to address the culture of the NHS in order to make it more patient-focused, open and transparent, Sir Robert Francis conducted a review into the challenges faced when voicing safety concerns.¹⁴⁰

In his Freedom to Speak up report, published in February 2015, Sir Robert Francis set out 20 Principles and Actions to rectify the situation. His predominant suggestion was similar to that of the Berwick report, in that a strong emphasis was placed on attaining a safety culture:

‘The overarching Principle is that every organisation needs to foster a culture of safety and learning in which all staff feel safe to raise a concern. This is something to which everyone...can and should contribute. We need to get away from the culture of blame, and the fear that it generates, to one which celebrates openness and commitment to safety and improvement. That is the way to ensure that staff can make the valuable contribution they want to offer towards protecting patients and the integrity of the NHS. Most importantly the risks to patients' lives and well-being will be reduced, and confidence in the NHS protected.’¹⁴¹

3.9. LEARNING NOT BLAMING

‘Learning not Blaming’ sets out the UK government’s response to the Freedom to Speak Up consultation, the Public Administration Select Committee report 'Investigating Clinical Incidents in the NHS', and the Morecambe Bay Investigation.¹⁴²

In its response, the government considered: Sir Francis’ revelations regarding evasive and hostile responses staff face when speaking up about quality and safety concerns;

¹³⁹ Great and Department (2015).

¹⁴⁰ Francis (2015).

¹⁴¹ *Id.* 6.

¹⁴² Health (2015) 102.

The challenges that need to be overcome in order to effectively learn from mistakes and failures in care, as identified by the Public Administration Select Committee; and, in the case of Morecambe Bay, the repercussions of a lack of honesty on the part of the system.

The interventions following Mid Staffordshire were noted, but it was emphasised that they were insufficient on their own. As the Department of Health affirmed: ‘The remaining critical component is culture’.¹⁴³ Although, progress had been made, much more remains to be done. Some common themes emerged from the three reports, and these were to be the focus of future efforts: openness, honesty and candour; listening to patients, families and staff; finding and facing the truth; learning from errors and failures in care; people and professionalism; and the right culture from top to bottom.¹⁴⁴

Some of the new changes that will be introduced, are as follows: The Duty of Candour, which places a clear obligation on providers to be honest with patients and their families when they experience significant harm, has now come into force and is one of the ‘Fundamental Standards’ taken into account by the Care Quality Commission.¹⁴⁵ It is hoped that a culture of openness and honesty will be stimulated thereby. The reform of the Ombudsman system will be undertaken, to capture complaints and ensure that patients are heard.¹⁴⁶ An independent patient safety investigation function will be established to promote a culture of learning.¹⁴⁷ A commitment was given to make the NHS the most transparent health service in the world, starting with the publication of outcomes data.¹⁴⁸ Legislation will be enacted, which makes wilful neglect a criminal offence and a review of the professional codes of both doctors and nurses will be conducted to ensure that the right incentives are in place to prevent cover-ups and to promote learning.¹⁴⁹ It is considered crucial that the system ‘must embrace a culture of

¹⁴³ *Id.* 6.

¹⁴⁴ *Id.* 7.

¹⁴⁵ *Ibid.*

¹⁴⁶ *Id.* 8.

¹⁴⁷ *Id.* 9.

¹⁴⁸ *Id.* 10.

¹⁴⁹ *Id.* 11.

learning rooted in the truth, a culture that listens to patients, families and staff and which takes responsibility for problems rather than seeking to avoid blame.¹⁵⁰ The need was highlighted for organisations to be less defensive and more welcoming of feedback in all of its forms, whether that is a complaint or an informal query since it is only by listening to users and carers that services can improve.¹⁵¹ Early warning signs, which were abundant in all three reports, should be harnessed to help prevent issues from becoming crises.¹⁵²

3.10. HEALTH SAFETY INVESTIGATION BRANCH

The Health Safety Investigation Branch (HSIB) was established as part of the NHS's plan to develop a more open, learning culture.¹⁵³ It draws on lessons from the airline industry to conduct thorough, independent and impartial investigations into patient safety accidents in the health system. The HSIB then produces clearly written, thorough and concise reports with well-founded analysis and conclusions to explain the circumstances and causes of clinical incidents without attributing blame. Safety recommendations are made accordingly and the lessons learned are shared as widely as possible throughout the entire healthcare system.

The HSIB came into operation in April 2017 as a division of NHS Improvement. A Health Service Safety Investigations Bill was recently published.¹⁵⁴ This new Bill will establish and enshrine in law the powers of the Health Service Safety Investigations Body (HSSIB). The HSSIB will take forward the work of the current HSIB.

The HSSIB will be independent of the NHS and at arm's length from government. It will have far-reaching access to investigate serious safety incidents or risks to patient safety. After each investigation is completed, the HSSIB will publish detailed reports which will: make recommendations for system-wide learning across the NHS; help develop national standards on investigations; and provide advice, guidance and training

¹⁵⁰ *Id.* 12.

¹⁵¹ *Id.* 13.

¹⁵² *Ibid.*

¹⁵³ "HSIB – About Us" Health and Safety Investigation Branch <https://www.hsib.org.uk/about-us/>.

¹⁵⁴ Great and Department "Draft Health Service Safety Investigations Bill" (2017).

to improve investigative practice across the health service.

A key feature of the HSSIB would be its new approach to investigations, which will protect the information it holds from disclosure.

The aim is to create a ‘safe space’ in which participants, including patients, families and staff, can share information in the knowledge that it will not be disclosed except in limited circumstances, or by order of the High Court.

It is hoped that the safe space model will encourage more participants in investigations to speak out about safety concerns to help identify and address risks across the NHS. This approach is already used in the safety-critical rail, aviation and marine industries – all of which have achieved dramatic improvements in industry safety.

The draft bill also proposes to give the HSSIB the power to establish an accreditation system across the NHS – supporting trusts who receive accreditation to conduct safe space investigations. This will further reduce unsafe and costly practice, improve investigations, and embed a culture of learning and improvement throughout the health service.¹⁵⁵

4. CONCLUSION

As mentioned before, South Africa is at the start of its patient safety journey. The United Kingdom was one of the first countries to prioritise safety and has made significant progress toward putting systems in place to achieve safer care. The UK’s experience with both the civil justice and healthcare system provides an illustrative example of the

¹⁵⁵ “Health Service Safety Investigations Bill” Department of Health (2017-09-14) <https://www.gov.uk/government/publications/health-service-safety-investigations-bill>; “New Bill to improve patient safety” Department of Health (2017-09-14) <https://www.gov.uk/government/news/new-bill-to-improve-patient-safety>; “Learning from post-accident investigations to ensure patient safety” Department of Health (2017-09-28) <https://www.gov.uk/government/speeches/learning-from-post-accident-investigations-to-ensure-patient-safety>.

arduous journey ahead. Unlikely as it might seem at first, aspects of their journey may be particularly relevant to our context.

As a previous colony, we inherited many of the same procedural idiosyncrasies and difficulties of the UK civil justice system. Therefore, in the absence of our own civil justice review, Lord Woolf's report and subsequent developments could be of interest. Similar to South Africa, healthcare providers and their indemnifiers in the UK have also recently been forced to reconsider their approach to medical negligence claims. Importantly, they have reconsidered their approach by taking patient safety into account. Reports have scrutinised the existing malpractice system and have proposed less adversarial, patient-friendly compensation schemes. Even the NHS Litigation Authority has in recent years changed its focus to be more supportive of patient safety. In April 2017, they changed their name to NHS Resolution, they also changed the way they respond to claims. Their new stated purpose is, to deliver fair resolution and to learn from harm to improve safety. These are definitely interventions worth considering.

Our healthcare regulatory landscape also changed recently and has begun to emulate some of the structures found in the British system. South Africa has introduced our equivalent of the Care Quality Commission, the Office of Health Standards Compliance, with the help of the British regulator. The CQC has been operating since 2009, it has gained experience and encountered difficulties, which have been subject to review. This has led to alterations and improvements in its operations. These reviews and the changes adopted may provide insight into potential future problems that may arise for our OHSC and help it to minimise and avoid known stumbling blocks which may curtail its effectiveness. It could also be useful to examine the surrounding regulatory framework in the UK and how these entities and organisations integrate or support the functions of one another, in order to improve safety. A recent development in this regard has been the establishment of the Health Service Safety Investigations Body, which fulfils a safety function akin to those of independent investigator entities in aviation.

There are, of course, immense differences between our two countries. South Africa faces a number of unique challenges, owing to its devastating history, the persisting

legacy of apartheid, a quadruple burden of disease, and policy, leadership and stewardship failures. These challenges and our specific context complicate any comparisons and the effective translation of interventions that may have worked elsewhere.

However, patient safety is a challenge every country shares. The solutions might not be the same, but the objective certainly is – keeping patients from harm. In this regard, the mere fact that the UK has grappled with this problem for two decades means that there are many lessons to be learned. Incidentally, one of the first lessons would probably emphasise the importance of establishing a learning culture. Unfortunately, the next lesson will likely be that patient safety is difficult and complex. There are no easy solutions (even seemingly simple checklists are hard).

CONCLUSION

1. 'FIRST, DO NO HARM'

1.1. HISTORY OF HARM

Primum non nocere. The injunction to 'first, do no harm', and the bioethics principle of non-maleficence derived from the maxim, have been one of the enduring and core precepts of medicine for centuries.¹ Despite the best intentions of those who have taken the Hippocratic Oath and promised 'to abstain from doing harm', the history of medicine is unfortunately beset with iatrogenesis.² At first, it was accepted as the price that had to be paid for progress, a known side-effect of advancement.³ A lack of oversight and accountability had meant that the outcomes of care were often not fully considered. This began to change and some practitioners, such as Ernest Codman, believed that they should establish the 'end result' of their care, to see if it had the desired effect, and improve it if it didn't.⁴ Investigations into the outcomes of care uncovered what many had privately suspected, modern medicine was inundated with hazards.⁵ Some questioned whether the benefits justified the risks, it was even possible, as Illich had done, to legitimately argue that the medical establishment had become a major threat to health.⁶ Although such an argument may have been

¹ Smith (2005) 45 *J Clin Pharmacol* 371.

² Sharpe and Faden (1998).

³ Barr (1955) 159 *Journal of the American Medical Association* 1452; Moser (1956) 255 *New England Journal of Medicine* 606; Seckler and Spritzer (1966) 117 *Arch Intern Med* 447.

⁴ Codman (1914) 18 *Surgery, Gynecology Obstetrics* 491; Codman (1917); Codman (1934); Donabedian (1989) 67 *Milbank Q* 233; Mallon (2000); Neuhauser "Ernest Amory Codman MD" *Quality and Safety in Health Care* (2002) 11 104.

⁵ Schimmel (1964) 60 *Annals of internal medicine* 100; Lembcke (1967) *JAMA* ; Ogilvie and Ruedy (1967) 97 *Can Med Assoc J* 1445; McLamb and Huntley (1967) 60 *South Med J* 469; Harrison (1968a) *South African Medical Journal*; Harrison (1968b) *South African Medical Journal*; Smith "Iatrogenesis--a medico-legal problem" *S Afr Med J* (1973) 47 2194; Harrison (1974) *South African Medical Journal*; Association (1977); Harrison "Death attributable to anaesthesia: A 10-year survey (1967-1976)" *BJA: British Journal of Anaesthesia* (1978) 50 1041; Cooper et al. (1978) 49 *Anesthesiology* 399; Steel et al. (1981) 304 *N Engl J Med* 638.

⁶ Illich (1975) 1 *J Med Ethics* 78; Illich (1976); Illich (1995) 311 *BMJ* 1652.

dismissed as rather excessive at the time, the scale of iatrogenic illness revealed by the Institute of Medicine's groundbreaking report gave it some credence.⁷

1.2. TO ERR IS HUMAN AND THE BURDEN OF UNSAFE CARE

To Err is Human garnered widespread attention and reframed medical incidents and harm as a public health problem.⁸ It galvanized extensive stakeholder support and launched the patient safety movement.⁹ Similar investigations and reports were conducted by other countries. Patient safety was placed firmly on the international agenda.¹⁰ Mounting global concern about the incidence of adverse events, the significant avoidable human suffering caused thereby, and the financial burden these preventable injuries placed on countries' health systems, led to the adoption of Resolution WHA55.18 by the World Health Assembly in May 2002.¹¹

⁷ Leape et al. (1993) 19 *QRB. Quality review bulletin* 144; Kohn et al. (2000).

⁸ Leape and Berwick (2005) 293 *JAMA* 2384; Stelfox et al. (2006) 15 *Qual Saf Health Care* 174; Donaldson (2008); Leape "Errors in medicine." *Clin Chim Acta* (2009) 404 2; Clancy (2009) 24 *Am J Med Qual* 525; Van Den Bos et al. (2011) 30 *Health Aff (Millwood)* 596; Andel et al. "The economics of health care quality and medical errors." *Journal of health care finance* (2012b) 39 39; James (2013) 9 *J Patient Saf* 122; Makary and Daniel (2016) 353 *BMJ* i2139; Abbasi (2016) 316 *JAMA* 698; Panesar et al. "How safe is primary care? A systematic review." *BMJ Qual Saf* (2016) 25 544; Pronovost et al. (2016) 25 *BMJ Qual Saf* 396; Gandhi et al. "Patient Safety at the Crossroads." *JAMA* (2016) 315 1829; Jha and Pronovost "Toward a Safer Health Care System: The Critical Need to Improve Measurement." *JAMA* (2016) 315 1831; Howell et al. "International recommendations for national patient safety incident reporting systems: an expert Delphi consensus-building process." *BMJ Qual Saf* (2017) 26 150; Jeffrey et al. "Health Systems Improvement Across the Globe" (2017).

⁹ Organization (2009a); Organization (2017); Organization (2017) 1.

¹⁰ Donaldson and Philip (2004) 82 *Bulletin of the World Health Organization* 892; Donaldson (2004) 13 *Quality and Safety in Health Care* 86; Organization (2009a); Bates et al. (2009) 338 *BMJ* b1775; Jha et al. (2010) 19 *Qual Saf Health Care* 42; Cresswell et al. (2013) 10 *PLoS medicine* e1001554; Larizgoitia et al. "WHO Efforts to Promote Reporting of Adverse Events and Global Learning." *J Public Health Res* (2013) 2 e29; Adhikari (2013) 22 *BMJ Qual Saf* 798; Jha et al. (2013) 22 *BMJ Qual Saf* 809; Office "Addressing the Global Health Crisis" (2014) 50; Scott and Jha (2014) 371 *N Engl J Med* 3; Pronovost et al. (2017) *Bulletin of the World ...* ; Flott et al. (2017) 389 *Lancet* 1279; Kruk et al. "Introducing The Lancet Global Health Commission on High-Quality Health Systems in the SDG Era." *Lancet Glob Health* (2017) 5 e480; Jeffrey et al. "Healthcare Reform, Quality and Safety" (2017).

¹¹ Organization "Quality of care: patient safety" *Report by the Secretariat* (2002).

A number of important studies have shed light on the extent and burden of unsafe care.¹² Some of the most significant sources of harm have been identified and studied.¹³ Most of this research has thus far focused on developed countries, however, the available evidence suggests that developing countries may face severe safety problems and an even greater burden of harm.¹⁴ This added burden would hamper efforts to expand access to care.¹⁵

Efforts to expand healthcare coverage must, therefore, consist of efforts to expand safe coverage.¹⁶ As many developing countries, including South Africa, take steps toward realizing the goal of universal coverage, safety becomes paramount.¹⁷ Unsafe

¹² Brennan et al. (1991) 324 *N Engl J Med* 370; Wilson et al. (1995) 163 *Med J Aust* 458; Gawande et al. (1999) 126 *Surgery* 66; Thomas et al. (2000) 12 *Int J Qual Health Care* 371; Vincent et al. (2001) 322 *BMJ* 517; Davis et al. (2002) 115 *N Z Med J* U271; Runciman et al. (2003) 15 Suppl 1 *Int J Qual Health Care* i49; Baker et al. (2004) 170 *CMAJ* 1678; Sari et al. "Extent, nature and consequences of adverse events: results of a retrospective casenote review in a large NHS hospital." *Qual Saf Health Care* (2007) 16 434; Michel et al. (2007) 16 *Qual Saf Health Care* 369; Aranaz-Andrés et al. (2008) 62 *J Epidemiol Community Health* 1022; de Vries et al. (2008) 17 *Qual Saf Health Care* 216; Williams et al. (2008) 53 *Scott Med J* 26; Mendes et al. (2009) 21 *Int J Qual Health Care* 279; Soop et al. (2009) 21 *Int J Qual Health Care* 285; Zegers et al. (2009) 18 *Qual Saf Health Care* 297; Letaief et al. (2010) 22 *Int J Qual Health Care* 380; Classen et al. (2011) 30 *Health Aff (Millwood)* 581; Aranaz-Andres et al. (2011) *BMJ Qual Saf* ; Tartaglia et al. (2012) 36 *Epidemiol Prev* 151; Anderson et al. (2013) 206 *American journal of surgery* 253; Najjar et al. "The Global Trigger Tool shows that one out of seven patients suffers harm in Palestinian hospitals: challenges for launching a strategic safety plan." *Int J Qual Health Care* (2013) 25 640; Larizgoitia et al. (2013) 2 *J Public Health Res* e29; Merten et al. (2013) 42 *Age Ageing* 87; Adhikari (2013) 22 *BMJ Qual Saf* 798; Jha et al. (2013) 22 *BMJ Qual Saf* 809; Sousa et al. (2014) 14 *BMC Health Serv Res* 311; Vermeulen et al. (2014) 15 *Pediatr Crit Care Med* 464; Deilkas et al. "Monitoring adverse events in Norwegian hospitals from 2010 to 2013." *BMJ open* (2015) 5 e008576; Kurutkan et al. "Application of the IHI Global Trigger Tool in measuring the adverse event rate in a Turkish healthcare setting." *Int J Risk Saf Med* (2015) 27 11; Xu et al. "Adverse Events at Baseline in a Chinese General Hospital: A Pilot Study of the Global Trigger Tool." *J Patient Saf* (2016); Rafter et al. (2017) 26 *BMJ Qual Saf* 111.

¹³ Organization (2017) 1.

¹⁴ Jha et al. (2013) 22 *BMJ Qual Saf* 809. Kruk and Freedman (2008) 85 *Health Policy* 263; Carpenter et al. (2010) 19 *Qual Saf Health Care* 48; Jha et al. (2010) 19 *Qual Saf Health Care* 42; Hussein et al. (2011) 7 *Globalization and health* 14; Organization (2011) 57 *Geneva: World Health Organization* 203; Allegranzi et al. (2011) 377 *Lancet* 228; Rosenthal (2011b) 377 *The Lancet* 186; Wilson et al. (2012) 344 *BMJ* e832.

¹⁵ Jha et al. (2016) 353 *BMJ* i2216; A et al. (2016) 1; Flott et al. (2017) 389 *Lancet* 1279.

¹⁶ Jha et al. (2016) 353 *BMJ* i2216.

¹⁷ McIntyre et al. "Beyond fragmentation and towards universal coverage: insights from Ghana, South Africa and the United Republic of Tanzania" *Bulletin of the World Health Organization* (2008) 86 871; Lagomarsino et al.

care not only compromises health outcomes,¹⁸ it can have a devastating effect on patients and their families¹⁹ and weaken trust in the health system.²⁰ Furthermore, unsafe care provokes dire economic implications these countries can ill-afford, in terms of both lost workforce productivity and wasted resources due to extended hospitalization and compensation claims.²¹

“Moving towards universal health coverage: health insurance reforms in nine developing countries in Africa and Asia” *The Lancet* (2012) 380 933; Mills et al. “Equity in financing and use of health care in Ghana, South Africa, and Tanzania: implications for paths to universal coverage” *The Lancet* (2012) 380 126; Rodin and de Ferranti “Universal health coverage: the third global health transition” *The Lancet* (2012) 380 861; Sachs “Achieving universal health coverage in low-income settings” *The Lancet* (2012) 380 944; Mayosi et al. (2012) 380 *Lancet* 2029; Dye et al. “Research for universal health coverage” (2013); Giedion et al. “The impact of universal coverage schemes in the developing world: a review of the existing evidence” (2013); Kutzin “Health financing for universal coverage and health system performance: concepts and implications for policy” *Bulletin of the World Health Organization* (2013) 91 602; McIntyre et al. “Universal Health Coverage Assessment South Africa” (2014); Maeda et al. *Universal Health Coverage for Inclusive and Sustainable Development* (2014); World *Tracking universal health coverage: first global monitoring report* (2015); Honda et al. (2015) 30 *Health Policy Plan* 600; Reich et al. “Moving towards universal health coverage: lessons from 11 country studies” *The Lancet* (2016) 387 811; Wagstaff et al. “Measuring progress towards universal health coverage: with an application to 24 developing countries” *Oxford Review of Economic Policy* (2016) 32 147.

¹⁸ Mate et al. “Improving health system quality in low-and middle-income countries that are expanding health coverage: a framework for insurance” *International Journal for Quality in Health Care* (2013) 25 497; World “Policy and technical topics: Patient safety contributing to sustainable universal health coverage-SE” (2015); Braithwaite et al. “How to do better health reform: a snapshot of change and improvement initiatives in the health systems of 30 countries” *International Journal for Quality in Health Care* (2016) 28 843; Kutzin and Sparkes “Health systems strengthening, universal health coverage, health security and resilience” *Bulletin of the World Health Organization* (2016) 94 2; Storr et al. “Redefining infection prevention and control in the new era of quality universal health coverage” *Journal of Research in Nursing* (2016) 21 39; Akachi and Kruk “Quality of care: measuring a neglected driver of improved health” *Bulletin of the World Health Organization* (2017) 95 465; Kieny et al. “Strengthening health systems for universal health coverage and sustainable development” *Bulletin of the World Health Organization* (2017); Flott et al. (2017) 389 *Lancet* 1279.

¹⁹ Vincent “Caring for patients harmed by treatment.” *Quality in Health Care* (1995) 4 144; Vincent and Coulter (2002) 11 *Qual Saf Health Care* 76; Vincent (2003) 348 *N Engl J Med* 1051; Vincent and Saunders “Managing the aftermath of iatrogenic injury” *International Journal of Risk & Safety in Medicine* (2005) 17 5.

²⁰ Guijarro et al. “Adverse events in hospitals: the patient’s point of view.” *Quality & safety in health care* (2010) 19 144; Flott et al. (2017) 389 *Lancet* 1279.

²¹ Classen et al. “Adverse drug events in hospitalized patients: excess length of stay, extra costs, and attributable mortality” *Jama* (1997) 277 301; Waters et al. (2011) 26 *Am J Med Qual* 333; Andel et al. (2012b) 39 *Journal of health care finance* 39; Andel et al. (2012a) 39 *Journal of health care finance* 39; Economics *Exploring the costs of unsafe care in the NHS: a report prepared for the department of health* (2014); Slawomirski et al. (2017); “Towards Universal Health Care in Emerging Economies” (2017) 421.

2. CONFRONTING THE PROBLEM OF MEDICAL HARM

2.1. INTRODUCTION

These concerns highlight the importance of confronting the problem of medical harm. Some progress has been made.²² Leape showed how healthcare might benefit from moving away from a ‘blame and shame’ person approach to error, toward a ‘systems approach’.²³ Medicine was slow to acknowledge the prevalence of error, and in instances where mistakes have been acknowledged, erring individuals were generally confronted and sanctioned, which has had an insignificant effect on prevention.²⁴ Much of our knowledge of error has come from other disciplines, including human factors and cognitive psychology.²⁵

2.2. MINDFUL ORGANISATION

More recently, we have learned how to better manage error by turning to High-Reliability Organisations that function within hazardous industries, for guidance.²⁶ Their reliance on ‘mindful organisation’ and especially their preoccupation with

²² Shekelle et al. (2013) *Evid Rep Technol Assess (Full Rep)* 1; Wachter et al. (2013) 158 *Ann Intern Med* 350; Jeffrey et al. (2017).

²³ Leape (1994) 272 *JAMA* 1851.

²⁴ Vincent (1989) 299 *BMJ* 1150.

²⁵ Rasmussen “Information processing and human-machine interaction. An approach to cognitive engineering” *citeulike.org* (1986); Reason (1990) 302; Reason (1995) 4 *Quality and Safety in Health Care* 80; Reason (1995) 38 *Ergonomics* 1708; Reason (1997) 266; Reason (1998b) 12 *Work & Stress* 293; Rasmussen and Suedung *Proactive risk management in a dynamic society* (2000); Reason (2000) 320 *BMJ* 768; Amalberti et al. “Violations and migrations in health care: a framework for understanding and management.” *Qual Saf Health Care* (2006) 15 Suppl 1 i66.

²⁶ Weick et al. (1999) 21 *Research in organizational behavior* 23; Flin et al. “Crew resource management: improving team work in high reliability industries” *Team performance management: an international journal* (2002) 8 68; Hudson (2003) 12 Suppl 1 *Qual Saf Health Care* i7; Leonard et al. (2004) 13 Suppl 1 *Quality and Safety in Health Care* i85; Tamuz and Harrison “Improving patient safety in hospitals: contributions of high-reliability theory and normal accident theory” *Health services research* (2006) 41 1654; Pronovost et al. (2006) 41 *Health Services Research* 1599; Chassin and Loeb (2011) 30 *Health Aff (Millwood)* 559; Chassin and Loeb (2013) 91 *Milbank Q* 459; Oster and Braaten (2016); Morrow “Leading High-Reliability Organizations in Healthcare” (2016) 235; Sutcliffe et al. “Re-examining high reliability: actively organising for safety” *BMJ Qual Saf* (2017) 26 248.

fostering a Safety Culture, holds vital lessons.²⁷ Although seemingly far removed from medicine, these organisations embrace specific cultural attributes that could be of great value in healthcare settings.²⁸ Weick and Sutcliffe identified five characteristics that high-reliability organisations share, which enable them to withstand demanding conditions and persistently have fewer than their fair share of failures.²⁹ These five characteristics, which make up what they have termed, ‘mindful organising’, are as follows: Preoccupation with failure; Reluctance to simplify; Sensitivity to operations; Commitment to resilience; Deference to expertise; and Organisational culture.³⁰

2.3. SHIFTING TO A SAFETY CULTURE

This last characteristic of Organizational culture is perhaps the one overriding factor that can predispose all systems and processes to either failure or success.³¹ A facet

²⁷ Weick et al. “Organizing for high reliability: Processes of collective mindfulness” *Crisis management* (2008b) 3 81; Weick and Sutcliffe (2015) 224.

²⁸ Dekker and Woods “The high reliability organization perspective” *Human factors in aviation* (2010) 2 123; Sutcliffe (2011) 25 *Best Practice & Research Clinical Anaesthesiology* 133; Leveson (2012); Chassin and Loeb (2013) 91 *Milbank Q* 459.

²⁹ Weick et al. (2008b) 3 *Crisis management* 81; Sutcliffe (2011) 25 *Best Practice & Research Clinical Anaesthesiology* 133; Sutcliffe et al. (2017) 26 *BMJ Qual Saf* 248.

³⁰ Weick and Sutcliffe (2015) 224.

³¹ Guldenmund (2000) 34 *Safety Science* 215; Reason “Safety paradoxes and safety culture” *Injury Control and Safety Promotion* (2000a) 7 3; Hudson (2003) 12 *Suppl 1 Qual Saf Health Care* i7; Medicine et al. *Patient Safety: Achieving a New Standard for Care (Quality Chasm)* (2003); Leonard *Achieving Safe and Reliable Healthcare: Strategies and Solutions (ACHE Management)* (2004); Pronovost and Sexton (2005) 14 *Qual Saf Health Care* 231; Sammer et al. “What is patient safety culture? A review of the literature.” *J Nurs Scholarsh* (2010) 42 156; Leonard and Frankel (2010) 80 *Patient Educ Couns* 288; Halligan and Zecevic (2011) 20 *BMJ Qual Saf* 338; Patankar (2012); Morello et al. (2013) 22 *BMJ Qual Saf* 11; Weaver et al. (2013) 158 *Ann Intern Med* 369; Chassin and Loeb (2013) 91 *Milbank Q* 459; Dixon-Woods et al. (2014) 23 *BMJ Qual Saf* 106; Waterson *Patient Safety Culture: Theory, Methods and Application* (2014); Foundation (2015) 1; Mayeng and Wolvaardt “Patient safety culture in a district hospital in South Africa: An issue of quality.” *Curationis* (2015) 38 7 pages; Glendon and Clarke (2015) 474; DiCuccio “The Relationship Between Patient Safety Culture and Patient Outcomes: A Systematic Review.” *J Patient Saf* (2015) 11 135; Govender “An Evaluation of the Culture of Patient Safety as a Critical Element of Healthcare in a Public Hospital in Durban, KwaZulu-Natal” (2016) 242; Oster and Braaten (2016); Richter and McAlearney (2016) *Health Care Manage Rev* ; Berry et al. (2016) *J Patient Saf* ; Commission “Sentinel Event Alert: The essential role of leadership in developing a safety culture” *jointcommission.org* (2017).

of this organizational culture, safety culture, is particularly important. All high-reliability organisations strive to maintain a safety culture. It has been defined as follows:

‘The safety culture of an organization is the product of individual and group values, attitudes, perceptions, competencies, and patterns of behaviour that determine the commitment to, and the style and proficiency of, an organization’s health and safety management. Organizations with a positive safety culture are characterized by communications founded on mutual trust, by shared perceptions of the importance of safety and by confidence in the efficacy of preventive measures.’³²

For a similar culture shift to be achieved in medicine, an environment in which teamwork, clear communication, and openness about errors, both with other health care professionals and with patients, would have to become the norm.³³ As ‘safety culture’ is such a broad concept, strategies to foster a positive culture of safety have focused on developing teamwork and communication among medical personnel.³⁴ Other important dimensions of a safety culture, that are most often cited in the literature, include: leadership commitment to safety; organisational learning; a non-punitive approach to adverse event reporting and analysis; and shared belief in the importance of safety.³⁵ The impact of a safety culture cannot be understated, it

³² Commission (1993).

³³ Reason (1998b) 12 *Work & Stress* 293; Reason (2000) 320 *BMJ* 768.

³⁴ Helmreich et al. (2001) 305331 *Improving teamwork in organizations: Applications of resource management training*; Grogan et al. (2004) 199 *J Am Coll Surg* 843; Leonard et al. (2004) 13 *Suppl 1 Quality and Safety in Health Care* i85; Clancy and Tornberg (2007) 22 *American Journal of Medical Quality* 214; Pronovost et al. (2008) 23 *Journal of critical care* 207; Blegen et al. (2010) 19 *Qual Saf Health Care* 346; Thomas (2011) 20 *BMJ Qual Saf* 647; Salas et al. “Improving teamwork and safety: toward a practical systems approach, a commentary on Deneckere et al.” *Soc Sci Med* (2012) 75 986; Salas and Rosen (2013) 22 *BMJ Qual Saf* 369; Pettker et al. (2014) 211 *Am J Obstet Gynecol* 319; Richter and McAlearney (2016) *Health Care Manage Rev*; Berry et al. (2016) *J Patient Saf*.

³⁵ Patankar (2012); Weaver et al. (2013) 158 *Ann Intern Med* 369; Waterson (2014); DiCuccio (2015) 11 *J Patient Saf* 135.

underlies many of the proposed interventions and will, to a great extent, be pivotal to their successful implementation.³⁶

2.4. LEARNING FROM ERROR – THE SYSTEMS APPROACH

A fundamental principle of a safety culture is that mistakes present learning opportunities.³⁷ Errors are openly discussed, without fear of censure, in a non-punitive environment, so as to encourage reporting, thereby allowing organisations to learn from their mistakes, and translate those lessons into preventative measures. As Leape so succinctly put it: ‘The paradox is that the single greatest impediment to error prevention is that we punish people for making them.’³⁸ This harkens back to the systems approach, which Reason described as follows:

‘The basic premise in the system approach is that humans are fallible and errors are to be expected, even in the best organisations. Errors are seen as consequences rather than causes, having their origins not so much in the perversity of human nature as in “upstream” systemic factors. These include recurrent error traps in the workplace and the organisational processes that give rise to them. Countermeasures are based on the assumption that though we cannot change the human condition, we can change the conditions under which humans work. A central idea is that of system defences. All hazardous technologies possess barriers and safeguards. When an adverse event occurs, the important issue is not who blundered, but how and why the defences failed.’³⁹

These layered system defences, and the active failures and latent conditions which might one day coalesce, and align to permit a breach are simply, yet profoundly, illustrated by the ‘Swiss Cheese’ model of accident causation.⁴⁰ It captures the

³⁶ Berwick (2013).

³⁷ Health (2000); Health (2001); National (2005); Larizgoitia et al. (2013) 2 *J Public Health Res* e29; Macrae and Vincent (2014) 107 *J R Soc Med* 439; Health (2015) 102.

³⁸ Leape (1997).

³⁹ Reason (2000) 320 *BMJ* 768.

⁴⁰ Reason (1997) 266.

importance of effective, successive layers of defences, barriers, and safeguards and the crucial role they play in the system approach. Defences consist of engineered safety features (alarms, physical barriers, automatic shutdowns, etc.), protocols, standardised procedures, administrative controls and people.⁴¹ Their function is to protect potential victims (patients) from local harm.

An unfortunate reality, particularly in healthcare, is that little slips can cause immense tragedies.⁴² Patients are vulnerable, and medicine is an inherently, highly error-provoking, undertaking. This calls for an even greater effort to identify the holes (or systemic weaknesses), shrink their size and create enough overlap, so as to prevent them from ever lining up in the future.

The system approach advocated by the patient safety movement, views the question, 'who is at fault?' as a distraction.⁴³ This has, perhaps misleadingly, been called a 'no blame' model. In that, it is considered more constructive to identify error-conducive situations and settings, and to implement systems that prevent healthcare professionals from committing errors, than merely blaming 'culpable' individuals; Intercepting errors before they cause harm, or mitigating harm if errors do reach the patient.⁴⁴ This 'no blame' model has undoubtedly been vindicated, for instance, rather than trying to perfect doctors' penmanship and memories, computerised order-entry systems catch and alert practitioners to medication errors before they are able to cause patient harm. The implementation of simple checklists, that aid evidence-based best practices, has also been responsible for remarkable improvements in rates of surgical complications and central line-associated bloodstream infections.⁴⁵

⁴¹ Rasmussen (1986); Wickens et al. (1998); Newton et al. "Making existing technology safer in healthcare." *Qual Saf Health Care* (2010) 19 Suppl 2 i15; Leveson (2012).

⁴² Reason (2016) 160.

⁴³ Wachter and Pronovost (2009) 361 *N Engl J Med* 1401.

⁴⁴ Reason (1990) 302; Reason (1995) 4 *Quality and Safety in Health Care* 80; Reason (1995) 38 *Ergonomics* 1708.

⁴⁵ Pronovost et al. (2005) 1 *Journal of patient safety* 33; Hales and Pronovost (2006) 21 *J Crit Care* 231; Dziekan (2008) 86 *Bulletin of the World Health Organization*; Pronovost et al. (2008) 23 *Journal of critical care* 207; Safety (2008); Organization (2008) 1; Organization (2009d); Haynes et al. (2009) 360 *N Engl J Med* 491; Weiser

The 'no blame' model has served a valuable purpose.⁴⁶ Besides the numerous safety improvements (including: computerised order entry and bar coding systems, electronic medical records, standardisation, simplified processes, error-resistant equipment design, etc.) it has been instrumental in engaging healthcare professionals in safety efforts. It is doubtful whether progress in the early stages of the patient safety movement would have been as rapid if the 'no blame' aspect had not been as prominent.⁴⁷ One can imagine that it would be quite difficult to get doctors to acknowledge and discuss the prevalence of 'medical error', in an exceedingly antagonistic malpractice climate. Errors were hardly ever discussed before, and if they were, it would involve the pointing of fingers or even possibly adversarial plaintiffs' attorneys. The 'no blame' model changed this error landscape. Doctors were finally able to admit that they sometimes make mistakes—not as an admission of guilt, rather an admission that they are human and all humans err.⁴⁸ It was, thus, crucial to emphasise the 'no blame' systems approach in order to advance the patient safety movement and garner widespread support.⁴⁹ Unfortunately, non-punitive environments, that encourage systematic approaches to safety are still habitually not

et al. (2010) 251 *Annals of surgery* 976; Gawande (2010) 224; Pronovost et al. (2010) 340 *BMJ* c309; de Vries et al. "Effect of a comprehensive surgical safety system on patient outcomes." *N Engl J Med* (2010) 363 1928; Semel et al. "Adopting a surgical safety checklist could save money and improve the quality of care in U.S. hospitals." *Health Aff (Millwood)* (2010) 29 1593; de Vries et al. (2011) 253 *Ann Surg* 624; Pronovost and Bollinn "Preventing patient harms through systems of care." *JAMA* (2012) 308 769; Berenholtz et al. (2014) 35 *Infect Control Hosp Epidemiol* 56; Leape (2014) 370 *N Engl J Med* 1063; Haugen et al. (2015) 261 *Ann Surg* 821; Haynes et al. "What Do We Know About the Safe Surgery Checklist Now?" *Annals of surgery* (2015) 261 829; Biccard et al. (2016) 106 *SAMJ: South African Medical Journal* 592; Mayer et al. (2016) 263 *Ann Surg* 58; Moodley and Ngene "Severe hypertension in pregnancy: Using dynamic checklists to save lives." *S Afr Med J* (2016) 106 767; Pronovost et al. (2016) 25 *BMJ Qual Saf* 396; Naidoo et al. "The impact of a modified World Health Organization surgical safety checklist on maternal outcomes in a South African setting: A stratified cluster-randomised controlled trial" *SAMJ: South African Medical Journal* (2017a) 107 248. Moodley et al. have shown how checklists can be successfully implemented in South African healthcare facilities to reduce errors and adverse events.

⁴⁶ Wachter (2013) 22 *Quality in health care : QHC* 176.

⁴⁷ *Ibid.*

⁴⁸ Wachter and Pronovost (2009) 361 *N Engl J Med* 1401.

⁴⁹ Leape and Berwick (2000) 320 *BMJ* 725; Leape and Fromson (2006) 144 *Ann Intern Med* 107.

observed, to the detriment of local safety cultures. Some have again leaned too far toward the other end of the non-punitive spectrum, and have misinterpreted the ‘no blame’ model, assuming that individuals could never be at fault or be answerable for their conduct.⁵⁰

3. BALANCING ‘NO BLAME’ AND ACCOUNTABILITY

The ‘no blame’ culture that has been championed since the publication of ‘To Err is Human’, has recently come to be reconsidered.⁵¹ A few prominent healthcare figures have called for a more nuanced balance between an outright blame-free approach and individual accountability.⁵² There is some concern that a shift back to individual accountability for certain types of unsafe acts would undo much of the progress made towards achieving a safety culture and impede further improvement, causing healthcare professionals to revert to unforthcoming behaviour and detract from more beneficial system-based safety interventions.⁵³ The concept of a just culture, which first appeared in the aviation safety literature and has gained prominence in other hazardous industries, has been put forward as a response to these concerns. It aims to rebalance the system approach with accountability.⁵⁴

3.1. JUST CULTURE

It should be emphasized that the pioneers and supporters of the system approach, never intended for there to be zero accountability for unacceptable behaviour.

⁵⁰ Leape (2001) 27 *Am. J. L. & Med.* 145; Leape “Ethical issues in patient safety.” *Thorac Surg Clin* (2005) 15 493.

⁵¹ Wachter, *The ‘Must Do’ List: Certain Patient Safety Rules Should Not Be Elective*, 2015, <<http://healthaffairs.org/blog/2015/08/20/the-must-do-list-certain-patient-safety-rules-should-not-be-elective/>>; Wachter and Pronovost (2009) 361 *N Engl J Med* 1401; Wachter (2013) 22 *Quality in health care : QHC* 176; McTiernan et al. (2015) 24 *BMJ Qual Saf* 162.

⁵² Wachter, *The ‘Must Do’ List: Certain Patient Safety Rules Should Not Be Elective*; Wachter and Pronovost (2009) 361 *N Engl J Med* 1401; Wachter (2013) 22 *Quality in health care : QHC* 176; McTiernan et al. (2015) 24 *BMJ Qual Saf* 162.

⁵³ Dekker and Hugh (2010) 362 *N Engl J Med* 275; author reply 275.

⁵⁴ Marx (2001) *Trustees of Columbia University*; International (2003) 22 *Eleventh Air Navigation Conference Montreal*; Dekker (2007) 978-0-7546-7267-8 1; Woodward “Rethinking Patient Safety” (2017) 208.

Although the concept of a just culture is often attributed to Marx and frequently mistakenly regarded as a counterpoint to Reason’s model, it was first described in the latter author’s seminal book:

‘A ‘no-blame’ culture is neither feasible nor desirable. A small proportion of human unsafe acts are egregious...and warrant sanctions, severe ones in some cases. A blanket amnesty on all unsafe acts would lack credibility in the eyes of the workforce. More importantly, it would be seen to oppose natural justice. What is needed is a just culture, an atmosphere of trust in which people are encouraged, even rewarded, for providing essential safety-related information—but in which they are also clear about where the line must be drawn between acceptable and unacceptable behaviour.’⁵⁵

3.2. ALGORITHMS AND DECISION TREES

Marx’s construction of a just culture is similar to that of Reason, however, he structures his discussion around three key behavioural concepts, and tailors it to the disciplinary challenges facing healthcare organisations.⁵⁶ It specifically grapples with the implementation of a disciplinary approach that would encourage individuals to report information that would previously have been regarded as self-compromising.

High-risk industries have realised that a safety culture requires, above all, the promotion of trust, reporting and continuous improvement.⁵⁷ The existence of a safety culture, which incorporates just culture principles, is often cited as a cornerstone of high-reliability and patient safety efforts.⁵⁸ High-reliability organisations balance accountability and learning by cultivating a just culture, making sure that discipline is

⁵⁵ Reason (1990) 302.

⁵⁶ Marx (2001) *Trustees of Columbia University*; Marx (2003) 19 *OR manager* 1; Marx (2008) *Outcome Engineering*; Marx (2012) *Outcome Engenuity* 1.

⁵⁷ Reason (1998b) 12 *Work & Stress* 293.

⁵⁸ Frankel et al. (2006) 41 *Health Serv Res* 1690; Chassin and Loeb (2011) 30 *Health Aff (Millwood)* 559; Chassin “Improving the quality of health care: where law, accreditation, and professionalism collide.” *Health Matrix Clevel* (2013) 23 395; Chassin and Loeb (2013) 91 *Milbank Q* 459; A et al. “A Framework for Safe, Reliable, and Effective Care. White Paper” *Institute for Healthcare Improvement and Safe Reliable Healthcare* (2017) 1.

equitably applied throughout the system.⁵⁹ They distinguish between blameless errors, that create learning opportunities, and blameworthy errors, that are met with equitably applied, sanction.⁶⁰ This ensures that they are able to learn and improve by openly identifying and examining their own weaknesses.

3.3. DRAWING A LINE

Healthcare organisations have begun to introduce explanatory documents and policies, that articulate the principles espoused by a just culture. Some have also adopted algorithms and incident decision trees to assist in the application of the policies.⁶¹ These tools depend on the uniform application of accountability standards. Arbitrary enforcement by uncommitted leadership will defeat the purpose and would instead be severely detrimental to the establishment of a just culture.⁶²

3.4. WHO DRAWS THE LINE?

As Dekker cautions, ‘the critical question is not where to draw the line, but who gets to draw it’.⁶³ By relying on an *a priori* cut-off point to distinguish between acceptable and unacceptable behaviour, it is easy to lose sight of the fact that culpability is conferred upon an act by our own assumptions and interpretation, it does not inhere in it.⁶⁴ Decision trees are useful guides; however, they remain just that – guides. In attempting to categorise conduct, concrete lines can very easily become vague, as any classification invites new deliberations and judgements. One thus has to caution against ‘Just-culture-by-algorithm’ approaches, as justice cannot be separated from

⁵⁹ Oster and Braaten (2016) 11.

⁶⁰ Chassin and Loeb (2013) 91 *Milbank Q* 459.

⁶¹ Agency (2003); Meadows et al. (2005).

⁶² Wachter and Pronovost (2009) 361 *N Engl J Med* 1401.

⁶³ Dekker (2009) 11 *Cogn Tech Work* 177.

⁶⁴ Dekker and Woods (2010) 2 *Human factors in aviation* 123; Dekker (2010) 36 *Joint Commission Journal on Quality and Patient Safety* 147; Dekker et al. “The complexity of failure: Implications of complexity theory for safety investigations” *Safety Science* (2011) 49 939.

clinical and social interpretation.⁶⁵ Power, perception and perspective play a large role.⁶⁶ What management perceives as at-risk behaviour, may be entirely logical and efficient to employees at the 'sharp end'.⁶⁷

If we accept that the line cannot be drawn in isolation, that factors such as hierarchy and perspective may influence our clinical and social interpretation of events, and sway seemingly 'objective' decisions regarding accountability.⁶⁸ And we are cognisant of the role that perception and power play in our formation of culpability categories and constructs. The question then arises: who draws the line between unacceptable and acceptable behaviour?

The Organisation, Professional Boards, Regulators, and the Judiciary all have the authority to draw the line, and therefore have the capacity to influence conceptions of a just culture. It is crucially important that the line is drawn in a procedurally fair and substantively just manner.⁶⁹ Those drawing the line should also guard against following a retributive approach to just culture.

3.4.1. ORGANISATIONS

Organisations that are truly concerned with fostering a just culture, and providing safer care, do not just leave the rules to the lawyers and risk managers. Yet, some organisations may cynically, do just that, in order to limit legal exposure and absolve the organisation and managers of liability. Safety standards and the façade of a just

⁶⁵ Dekker "Illusions of explanation: A critical essay on error classification" *The International Journal of Aviation Psychology* (2003) 13 95; Hugh and Dekker (2009) 16 *J Law Med* 846; Dekker (2010) 36 *Joint Commission Journal on Quality and Patient Safety* 147.

⁶⁶ Dekker and Nyce (2013) 2 *JHA* p73; Dekker and Nyce (2014) 67 *Safety Science* 44.

⁶⁷ Professor (2014); Dekker *Safety Differently: Human Factors for a New Era, Second Edition* (2014a); Braithwaite et al. (2015) 27 *Int J Qual Health Care* 418; Braithwaite et al. (2016) 236.

⁶⁸ Hugh and Dekker (2009) 16 *J Law Med* 846; Dekker (2010) 36 *Joint Commission Journal on Quality and Patient Safety* 147.

⁶⁹ Dekker and Breakey (2016) 85 *Safety science* 187.

culture program might conveniently allow for the identification of an individual scapegoat to shift blame to.⁷⁰

3.4.2. PROFESSIONAL BOARDS

Professional Boards should be hesitant to label human error as unprofessional conduct or neglect systemic factors in their appraisals. If the profession distances itself from scrutiny by merely blaming a few ‘bad apples’ for unsafe care, overall safety is unlikely to improve.⁷¹ There will, of course, be practitioners that should not treat patients, but the system should identify them long before they are given the opportunity to harm.⁷² It must be determined how they were let in, how they were trained, mentored, promoted, supervised, and how they managed to stay. If the system missed them, it has already failed in one of its most important tasks. Nevertheless, reckless conduct must be promptly reported and dealt with to prevent harm. High-risk practitioners must be identified as soon as possible so that targeted improvement efforts can be adopted.

3.4.3. REGULATORS

Regulators should be safeguarded from undue influence and must function independently and impartially. They must be enabled to take an all-embracing view of the systems they regulate. Regulators must be authoritative, experienced, respected and trusted by those whose oversight is exercised over.⁷³

⁷⁰ Cromie and Bott “Just culture’s “line in the sand” is a shifting one; an empirical investigation of culpability determination” *Safety Science* (2016a) 86 258; McCall and Pruchnicki (2017b) 94 *Safety science* 143.

⁷¹ Berwick “Continuous improvement as an ideal in health care.” *N Engl J Med* (1989) 320 53; Shojania and Dixon-Woods (2013); Dekker and Leveson (2014) 23 *BMJ Qual Saf* 1050; Hamedani et al. “Patient Experience Must Move Beyond Bad Apples.” *Ann Intern Med* (2016) 165 869.

⁷² Spittal et al. “The PRONE score: an algorithm for predicting doctors’ risks of formal patient complaints using routinely collected administrative data.” *BMJ Qual Saf* (2015) 24 360; Studdert et al. “Prevalence and Characteristics of Physicians Prone to Malpractice Claims.” *N Engl J Med* (2016) 374 354.

⁷³ Dekker and Breakey (2016) 85 *Safety science* 187.

3.4.4. JUSTICE SYSTEM

The justice system may also be called on to draw the line. Rather paradoxically, when the justice system gets involved, things do not necessarily get any safer or more just. In fact, it might have the opposite effect. This is, in part, due to the difficulties involved with the retrospective evaluation of adverse events.⁷⁴ The legal classification of conduct as negligent is actually quite complex. It relies on a number of judgement calls regarding what is, essentially, an after-the-fact social construction.⁷⁵ To complicate matters further, compensation is tied to this determination. It is often the only recourse injured patients have when seeking financial assistance. The legal response tends to be proportionate to the actual consequences of the error, rather than to potential consequences or the moral culpability involved.⁷⁶ Moreover, those called upon to evaluate the behaviour are invariably subject to ubiquitous bias, often unwittingly. Particularly, outcome and hindsight-bias.⁷⁷

Besides the inherent and implicit biases that may be prevalent in retroactive determinations of negligence, medical malpractice litigation, as it exists today, may very well be inimical to patient safety.⁷⁸ The way in which the legal system functions, deterrence through the attribution of blame and damage awards, is at odds with our

⁷⁴ *Ibid.*; Dekker (2012b); Dekker et al. (2011) 49 *Safety Science* 939; Dekker (2010) 36 *Joint Commission Journal on Quality and Patient Safety* 147; Hugh and Dekker (2009) 16 *J Law Med* 846.

⁷⁵ Hugh and Dekker (2009) 16 *J Law Med* 846.

⁷⁶ Merry and Smith *Errors, Medicine and the Law* (2001); Merry "How does the law recognize and deal with medical errors" *J R Soc Med* (2009) 102 265.

⁷⁷ Fischhoff (1975) 1 *Journal of Experimental Psychology: Human perception and performance* 288; LaBine and LaBine (1996) 20 *Law and Human Behavior* 501; Berlin "Hindsight bias." *AJR Am J Roentgenol* (2000) 175 597; Henriksen and Kaplan "Hindsight bias, outcome knowledge and adaptive learning." *Qual Saf Health Care* (2003) 12 Suppl 2 ii46; Harley (2007) 25 *Social Cognition* 48; Hugh and Dekker (2009) 16 *J Law Med* 846.

⁷⁸ Studdert et al. (2004) 350 *N Engl J Med* 283; Mello et al. (2005) 30 *J Health Polit Policy Law* 375; Waring "Beyond blame: cultural barriers to medical incident reporting." *Soc Sci Med* (2005) 60 1927; Bovbjerg "Reform of Medical Liability and Patient Safety: Are Health Courts and Medicare the Keys to Effective Change" *J. Health Care L. & Pol'y* (2006); Hyman and Silver "Medical Malpractice Litigation and Tort Reform: It's the Incentives, Stupid" *Vand. L. Rev.* (2006); Mello et al. (2006) 84 *Milbank Q* 459; Mello and Studdert "Deconstructing negligence: the role of individual and system factors in causing medical injuries" *Geo LJ* (2007) 96 599; Mello et al. (2007) 4 *Journal of Empirical Legal Studies* 835.

current understanding of human error and effective prevention strategies.⁷⁹ One can argue that two seemingly irreconcilable cultures collide when practitioners and their errors are subjected to medical malpractice suits.

The malpractice litigation system also follows an adversarial, individualistic and punitive approach, which is entirely inconsistent with the approach recommended by safety experts. Experts advocate for the adoption of a just culture, within the broader framework of a safety culture, whereby responses to errors are non-punitive, systems-orientated, cooperative, based on trust and accountability (as opposed to blame).⁸⁰ Transparency is also emphasised. Practitioners are encouraged to be forthright and open regarding their mistakes. Errors are seen as learning opportunities, and thus candidly reported. Practitioners who report honest errors are met with appreciation and support, rather than condemnation and sanction. Everyone in the organisation understands that most errors arise from the faulty systems, not from practitioners' incompetence or carelessness.⁸¹ This is in stark contrast to the medical malpractice system.

In the retrospective determination of negligence, individual practitioners are the focus, blame is assigned, and compensation is awarded on that basis, related to the damage suffered. Damages awarded, usually reflect the severity of the outcome, not the magnitude of the error. The threat of litigation and the adverse consequences thereof for the practitioner involved ensures that errors are only reported if they cannot be concealed. Information regarding the error is then only shared with a defence attorney, and only for purposes of managing liability. Patients might not even get an explanation or apology, for fear that it may be interpreted as an admission of guilt or used as evidence in a potential trial. The medical malpractice system, which retrospectively imputes blame to individuals, therefore engenders a climate of fear and silence,

⁷⁹ Mello and Studdert (2007) *Geo LJ* 96 599.

⁸⁰ Dekker and Hugh (2014) 23 *BMJ Qual Saf* 356; McCall and Pruchnicki (2017b) 94 *Safety science* 143.

⁸¹ Leape "Patient safety in the era of healthcare reform." *Clin Orthop Relat Res* (2015) 473 1568; Pronovost et al. (2017) *Bulletin of the World ...* 95 476.

negatively impacting the establishment of a safety culture (encompassing just culture) in the healthcare system.⁸²

4. BLAME VS. ACCOUNTABILITY

There is a chasm between accountability and blame. Accountability plays a key role in patient safety, blame inhibits it.⁸³ If we are to achieve a safe and just culture, we need to rethink our conventional notion of accountability. What information do we adjudge to be relevant and what is it that we wish to accomplish by ascribing accountability?

Sharpe makes a distinction between two types of accountability ascription:⁸⁴ accountability in the backwards-looking or retrospective sense, and accountability in the forward-looking or prospective sense. Retrospective accountability is retributive, it focusses on outcomes; errors are met with blame and sanction. Prospective accountability is restorative, it focusses on processes; errors are viewed as lessons, and represent opportunities for improvement.

The medical malpractice system (or an overly rigid organisational just culture algorithm) ascribes accountability in the backward-looking sense. Errors are only actionable or relevant when they cause harm, near-misses or reckless conduct sans damage, are not addressed. It seeks to deter further individual malpractice by imposing culpability and punishment.

4.1. PROSPECTIVE ACCOUNTABILITY

Accountability can become forward-looking if, instead, a systems approach to error is followed.⁸⁵ Errors are bound to occur in an environment as dynamic, complex, and

⁸² Studdert and Brennan “No-fault compensation for medical injuries: the prospect for error prevention.” *JAMA* (2001) 286 217; Health (2001); Donaldson (2003); Quick “Regulating and legislating safety: the case for candour.” *BMJ Qual Saf* (2014) 23 614.

⁸³ Sharpe (2003) 33 *The Hastings Center report* S3.

⁸⁴ *Id.* 5.

⁸⁵ *Id.* 5; McCall and Pruchnicki (2017b) 94 *Safety science* 143.

high-risk as healthcare. Every participant in the system is cognisant of that fact, and subsequently constantly vigilant, practitioners and the organisation have an interdependent shared responsibility towards patients and their safety. Prospective accountability involves proactive preventative measures, that include: designing safety and safeguards into the system to catch errors before they can cause harm, improving poor organisational or operational processes, establishing adverse event and error reporting systems, investigating and analysing root causes of error, and fostering a safety culture where errors can be openly discussed and examined.⁸⁶

Healthcare financing and delivery has changed significantly in the past century, it can no longer be said that a solitary physician bears the sole responsibility for the welfare of a patient. It could be argued that the duties practitioners have toward their patients, shaped by the ethical imperative 'to help, or at least do no harm', should be extended to those who have substantial control, albeit indirect, over decision-making that can significantly affect patient wellbeing.⁸⁷ Whereas practitioners have been held accountable to a certain standard of ethical behaviour and practice, administrators and healthcare managers, who can arguably influence the quality of care and outcome just as much, have not traditionally been held to the same exacting standards. If one accepts that patient safety is an interdependent shared responsibility, it calls for prospective collective accountability or at least a more nuanced balance between individual and institutional accountability. Seeing as the complexities of institutionally delivered health care has altered the nature and scope of responsibility, prospective accountability allows us to reassess medical error, in light of what we now know of safety and error in complex, high-risk systems (bad systems, not bad people).

Prospective accountability aligns everyone who influences patient care (physicians, nurses, pharmacists, administrators, hospital managers and boards, technicians, information specialists etc.) toward safety improvement. Prospective accountability

⁸⁶ McCall and Pruchnicki (2017b) 94 *Safety science* 143.

⁸⁷ Allen (2000) 321 *Bmj* 608; Bell et al. (2011) 140 *Chest* 519; Aveling et al. "What is the role of individual accountability in patient safety? A multi-site ethnographic study." *Sociol Health Illn* (2016) 38 216; Stamm et al. "Medical Malpractice: Reform for Today's Patients and Clinicians." *Am J Med* (2016) 129 20.

ensures that healthcare professionals are seen as a solution to harness, not just as a problem to retrospectively control.⁸⁸ Accountability is the specified obligations that contribute to safer care. In terms of the systems approach, we now know that, in order to improve we will need to target latent conditions created at the organisational ‘blunt end’, system defects, and unsafe acts and psychological precursors at the ‘sharp end’.⁸⁹ Fulfilling this obligation and being truly accountable means that errors are reported, assessed, learned from, so as to implement system reforms and prevent future harm.

If the recurrence adverse events and patient harm cannot be prevented by blaming and punishing healthcare workers, in fact, it may even be counter-productive in the prospective accountability sense, where does it leave us? Prospective accountability creates an environment in which healthcare professionals can become more error-wise or ‘mindful’ of dangers.

4.2. ERROR WISDOM AND COLLECTIVE FORESIGHT

To enhance risk-awareness healthcare can learn from high-reliability organisations. One defining feature of these organisations is their preoccupation with failure, both technical and human.⁹⁰ In other words: ‘Individual mindfulness of danger needs to be sustained and supported by a collective mindfulness of the operational risks’.⁹¹

Reason submits that frontline staff equipped with ‘error wisdom’ or ‘foresight’ would be able to act as ‘harm-absorbers’ between the system’s weaknesses and the patient.⁹² He illustrates how this can be done with his Three Bucket mental model.⁹³ Where this approach focusses more on the individual, Macrae’s proposal to avoid harm aims to

⁸⁸ Reason (2008); Hollnagel (2014); Dekker (2014a).

⁸⁹ Reason (2016) 160.

⁹⁰ Sutcliffe (2011) 25 *Best Practice & Research Clinical Anaesthesiology* 133; Weick and Sutcliffe (2015) 224; Oster and Braaten (2016); Sutcliffe et al. (2017) 26 *BMJ Qual Saf* 248.

⁹¹ Reason (2016) 89.

⁹² Reason (2004) 13 *Suppl 2 Qual Saf Health Care* ii28.

⁹³ Reason (2016) 90.

identify early warnings and utilise collective foresight.⁹⁴ He adapted Turner's work, especially, the concept of 'incubation' to healthcare systems.⁹⁵

Organisational accidents are usually preceded by systematic and protracted periods of time wherein warning signs and signals of harm go unnoticed, or are either ignored or neglected. Macrae describes incubation in the healthcare context as follows:

'In healthcare organisations, some of the key sources of missed, miscommunicated or misinterpreted signals of risk are closed professional cultures, competing and conflicting demands, and the inherent ambiguity of many forms of adverse event.'⁹⁶

Macrae argues that, since the process of 'incubation' occurs incrementally and over a considerable period of time, it provides the opportunity for early detection and prevention. In other words, if emerging problems and indications of failure can be discovered and addressed before they accumulate, eventual organisational disasters and subsequent patient harm can be avoided. To make the most of this 'incubation' opportunity, Macrae proposes three practical steps that organisations and regulators can take: 1) Actively endeavour to uncover and amplify warning signals of risk, by continually challenging assumptions and organisational ignorance relating to safety; 2) Instil vigilance across the entire organisation by defining and constantly updating a set of specified, focussed fears of failure they must seek to avoid; and 3) Establish an independent body to routinely investigate and publicise the systematic causes of major failures.⁹⁷

Macrae's recommendations, which include uncovering early signs of ignorance, actively avoiding specified clinical and organisational risks, and routinely conducting independent system-wide investigations, could foster a 'collective foresight'. Thus,

⁹⁴ Macrae (2014) 23 *BMJ Qual Saf* 440; Macrae *Close Calls* (2014).

⁹⁵ Turner and Pidgeon (1997).

⁹⁶ Macrae (2014) 23 *BMJ Qual Saf* 2.

⁹⁷ These investigation bodies are common in aviation and the UK has recently established one for healthcare. Macrae and Vincent (2014) 107 *J R Soc Med* 439; Macrae (2016) 25 *BMJ Qual Saf* 71; Macrae and Vincent (2017) 110 *J R Soc Med* 90.

ensuring that managers and administrators of healthcare organisations, as part of a concerted effort involving the entire industry, actively anticipate accidents and put systems in place to support healthcare workers (exercising individual foresight as the last line of defence and inheritors of systemic defects) in their tasks and in uncovering latent conditions and error traps during the incubation phase. Detecting the early signs of failure is challenging and complex. It is ordinarily done by vigilant healthcare workers who notice and report potential problems. These, warning signs will, however, only ever come to light and be addressed if healthcare workers are assured of the institutional commitment to a culture of safety and feel comfortable in providing relevant safety information, without fear of adverse consequences. Clearly, the existence of a just culture would be a prerequisite for the effective realisation of 'collective foresight'.

5. HEALING

Harmful medical errors can have a devastating impact on all involved. This impact has often been exacerbated by inadequate responses in the aftermath of an adverse event. Until very recently, healthcare organisations have been peculiarly appalling and inept in dealing with injured patients.⁹⁸ In the wake of an injurious outcome these harmed patients and their relatives would often be met with evasion and a lack of openness.⁹⁹ They would not receive any support from the organisation or even a simple apology.¹⁰⁰ In many instances, their only contact with the hospital would be

⁹⁸ Vincent and Coulter (2002) 11 *Qual Saf Health Care* 76; Gallagher et al. (2003) 289 *JAMA* 1001; Gallagher et al. "Choosing your words carefully: how physicians would disclose harmful medical errors to patients." *Arch Intern Med* (2006) 166 1585; Iedema et al. "Patients' and family members' views on how clinicians enact and how they should enact incident disclosure: the "100 patient stories" qualitative study." *BMJ* (2011) 343 d4423.

⁹⁹ Loren et al. "Risk managers, physicians, and disclosure of harmful medical errors." *Jt Comm J Qual Patient Saf* (2010) 36 101.

¹⁰⁰ Liang (2002) 11 *Quality and Safety in Health Care* 64; Bismark et al. "Accountability sought by patients following adverse events from medical care: the New Zealand experience." *CMAJ* (2006) 175 889; Bismark "The power of apology." *N Z Med J* (2009) 122 96; Regis and Poitras "Healthcare mediation and the need for apologies." *Health Law J* (2010) 18 31; Kachalia and Bates "Disclosing medical errors: the view from the USA" *Surgeon* (2014) 12 64.

through their risk managers and legal representatives. Much of this iniquitous behaviour would be aimed at limiting hospitals' liability in the face of potential litigation.¹⁰¹ Ironically, such an opaque antagonistic response, coupled with the absence of an honest explanation or apology, owing to a fear of legal action, is exactly why patients resort to litigation.¹⁰² Patients expect to be informed when they are harmed by care, especially if the harm was caused by medical error.¹⁰³ Healthcare workers have struggled with this disclosure in the past.¹⁰⁴ Practitioners may have wanted to be open with their patients, but have been fearful of professional censure or litigation, felt ashamed and embarrassed, or might not have known how to effectively engage with injured patients and their families.¹⁰⁵ Many healthcare workers are also deeply affected by medical errors.¹⁰⁶ The negative emotional consequences

¹⁰¹ Lawthers et al. (1992) *Journal of Health ...* ; Vincent (1995) 4 *Quality in Health Care* 144; Vincent (1999); Vincent and Saunders (2005) 17 *International Journal of Risk & Safety in Medicine* 5.

¹⁰² Shapiro et al. "A survey of sued and nonsued physicians and suing patients" *Archives of Internal Medicine* (1989) 149 2190; Hickson et al. "Factors that prompted families to file medical malpractice claims following perinatal injuries" *Jama* (1992b) 267 1359; Beckman et al. "The doctor-patient relationship and malpractice: lessons from plaintiff depositions" *Archives of internal medicine* (1994) 154 1365; Levinson "Physician-patient communication: a key to malpractice prevention" *Jama* (1994) 272 1619; Vincent et al. (1994) 343 *Lancet* 1609; Levinson et al. "Physician-patient communication: the relationship with malpractice claims among primary care physicians and surgeons" *Jama* (1997) 277 553; Kraman and Hamm "Risk management: extreme honesty may be the best policy" *Annals of Internal Medicine* (1999) 131 963; Ambady et al. "Surgeons' tone of voice: a clue to malpractice history" *Surgery* (2002) 132 5; Gallagher et al. "Patients' and physicians' attitudes regarding the disclosure of medical errors" *Jama* (2003) 289 1001.

¹⁰³ Witman et al. "How do patients want physicians to handle mistakes?: A survey of internal medicine patients in an academic setting" *Archives of Internal Medicine* (1996) 156 2565; Gallagher et al. (2003) 289 *JAMA* 1001; Mazor et al. "Communicating with patients about medical errors: a review of the literature" *Archives of internal medicine* (2004a) 164 1690.

¹⁰⁴ Gallagher and Levinson (2005) 165 *Arch Intern Med* 1819; Gallagher et al. (2007) 356 *N Engl J Med* 2713; Carmichael "Barriers to medical error reporting and disclosure by doctors: A bioethical evaluation" (2017) Carmichael, is perhaps, the first to study error disclosure in the South African context.

¹⁰⁵ Stroud et al. "Teaching medical error disclosure to physicians-in-training: a scoping review" *Academic Medicine* (2013) 88 884; Perez et al. "Understanding the barriers to physician error reporting and disclosure: a systemic approach to a systemic problem" *Journal of patient safety* (2014) 10 45; Etchegaray et al. "Structuring patient and family involvement in medical error event disclosure and analysis." *Health Aff (Millwood)* (2014) 33 46; White et al. "Implementing an error disclosure coaching model: A multicenter case study." *J Healthc Risk Manag* (2017) 36 34.

¹⁰⁶ Wu (2000) 320 *BMJ* 726; Couper "What do we do about mistakes" *South African medical journal= Suid-Afrikaanse tydskrif vir geneeskunde* (2002) 92 433; Cooper "Obstetric errors-two patients and a doctor" *South*

are often profound and enduring.¹⁰⁷ Practitioners can be emotionally and psychologically wounded by their errors too, becoming 'second victims'.¹⁰⁸

The failure to deal with the repercussions of medical error and patient harm in a caring manner could perhaps be explained, by having regard to how our responses to the consequences of errors had been shaped by our traditional conception and understanding of the causes of errors.¹⁰⁹ Our retributive approach to medical error has done very little to ensure safer care, and even less to ensure healing after unsafe care. Leveson concisely describes the need for a system approach as follows: 'Blame is the enemy of safety. The focus should instead be on understanding how the entire system behaviour led to the loss and not on who or what to blame'.¹¹⁰ To improve safety we must acknowledge that errors are an indication of an organisational, operational, educational, or political problem – and therefore safety is everyone's responsibility. This does not diminish accountability, quite the opposite. Rather than only attributing responsibility and accountability to the healthcare worker at the 'sharp end', those responsible for creating operational pressures or providing inadequate oversight and those who create flawed systems that contribute to mistakes, are also held collectively accountable. In a just culture, accountability is implemented and understood

African Family Practice (2012) 17. Dr Cooper gives an intimate and honest account of his experience after his medical error in a South African labour ward: 'At this point I wanted to run away, to hide, to weep, to give up medicine - anything but go and tell that mother that her baby was dead. I went ahead and did it nonetheless. I do not remember what I said to her - I was in a daze - but basically went through the same process again as I went through with the first, without telling her of any mistake I had made or my feelings that I was a murderer. I never shared my agony with my patient, or asked for her forgiveness: "Somehow, I felt, it was my responsibility to deal with my guilt alone.'

¹⁰⁷ West et al. "Association of perceived medical errors with resident distress and empathy: a prospective longitudinal study" *Jama* (2006) 296 1071; Scott et al. "The natural history of recovery for the healthcare provider "second victim" after adverse patient events" *Quality and Safety in Health Care* (2009) 18 325; Sirriyeh et al. "Coping with medical error: a systematic review of papers to assess the effects of involvement in medical errors on healthcare professionals' psychological well-being." *Quality & safety in health care* (2010) 19 e43.

¹⁰⁸ Wu and Steckelberg "Medical error, incident investigation and the second victim: doing better but feeling worse" *BMJ Qual Saf* (2012) 21 267.

¹⁰⁹ Leape (1994) 272 *JAMA* 1851.

¹¹⁰ Leveson (2012) 431.

differently.¹¹¹ Intentional disregard for safety and gross negligence, in any sphere of the organisation, will of course be punished (though, such instances are very rare). However, accountability in the form of punishment is an unsound response to the vast majority of errors. Accountability is instead defined in terms of responsibility for finding solutions to the flaws in the system design, which allowed the mistakes to occur and cause harm.¹¹²

If our conception of accountability changes to align with the system approach, our responses to harmful errors can too. Instead of meeting harm with hurt, as is the case with our current retributive justice construct, we can attempt to heal.

5.1. FROM RETRIBUTIVE TO RESTORATIVE JUSTICE

One way in which healing could be promoted would be through initiatives grounded in restorative justice theory.¹¹³ The concept of restorative justice is especially relevant to the medical domain since it has the potential to address many of the needs that patients and healthcare workers have after the occurrence of an adverse event.¹¹⁴ Restorative processes and approaches could also be beneficial to safety efforts, as it allows direct stakeholder involvement, by creating a safe environment within which to openly discuss systemic failures, the harm experienced and needs of the patient, remedial actions, and perhaps most importantly, preventative strategies to ensure that others are spared a similar outcome.

The absence of adequate information is often cited as a reason why patients instigate legal proceedings.¹¹⁵ When information about the adverse event they suffered is not forthcoming, they resort to litigation as a way to uncover the details. Physicians that are advised to sever all ties with an injured patient, as a risk-management strategy, compound the problem. Open disclosure is not only linked to less legal animosity, it is

¹¹¹ Sidney (2014).

¹¹² Leveson "Applying systems thinking to analyze and learn from events" *Safety Science* (2011b) 49 55; Dekker (2012a).

¹¹³ Van Ness and Strong (2014).

¹¹⁴ McNeil (2007); Dekker and Braekey (2016) 85 *Safety science* 187; Braaten (2017).

¹¹⁵ Vincent et al. (1994) 343 *Lancet* 1609.

the ethical thing to do, and many doctors see it as a moral imperative.¹¹⁶ After all, the doctor-patient relationship does not simply cease to exist after an error has occurred, the fiduciary nature of the relationship, may still demand the compassionate exchange of information and continued direct dialogue, that existed immediately before the accident.¹¹⁷

This also shows that responsibility has been accepted for the harm and that there is accountability. It is not necessarily accountability in a legal sense. The accountability here arises from the needs of the patient and has to do with the obligations those needs create.¹¹⁸ Those needs are met by the practitioner and the organisation, as they attempt to rebuild the relationship and trust that once existed. Accountability is how the needs are met. Accountability is how the harm is repaired and the suffering is healed.¹¹⁹ Accountability is how the system learns from the error and ensures that it will not happen again.¹²⁰

Such accountability can only be achieved when all stakeholders participate in the process. When everyone is allowed to give their account of what happened and tell their story. These open and frank accounts will of course only be possible if

¹¹⁶ Fallowfield and Jenkins "Communicating sad, bad, and difficult news in medicine" *The Lancet* (2004) 363 312; Mazor et al. "Communicating with patients about medical errors: a review of the literature" *Archives of internal medicine* (2004b) 164 1690; Studdert et al. "Disclosure of medical injury to patients: an improbable risk management strategy" *Health Affairs* (2007) 26 215; ledema et al. "Final report: Evaluation of the national open disclosure pilot program" *Sydney: Australian Commission on Safety and Quality in Health Care* (2008).

¹¹⁷ Rodwin "Strains in the fiduciary metaphor: divided physician loyalties and obligations in a changing health care system" *Am. JL & Med.* (1995) 21 241; Finkelstein et al. "When a physician harms a patient by a medical error: ethical, legal, and risk-management considerations." *The Journal of clinical ethics* (1997) 8 330; Sharpe, "Why 'do no harm'" in (ed.), Springer, 1997, pp. 197-215; Kachalia et al. "Does full disclosure of medical errors affect malpractice liability? The jury is still out" *The Joint Commission Journal on Quality and Safety* (2003) 29 503; Scott (2008); Furrow "Patient safety and the Fiduciary Hospital: sharpening judicial remedies" *Drexel L. Rev.* (2009) 1 439.

¹¹⁸ Sharpe (2003) 33 *The Hastings Center report* S3.

¹¹⁹ Strang and Sherman "Repairing the harm: Victims and restorative justice" *Utah L. Rev.* (2003) 15.

¹²⁰ Leape et al. "Promoting patient safety by preventing medical error" *Jama* (1998b) 280 1444; Sharpe (2004); Woods "Conflicts between learning and accountability in patient safety" *DePaul L. Rev.* (2004) 54 485.

stakeholders are treated fairly and respectfully as part of a just process.¹²¹ Nothing constructive will come from a retributive process, where accountability is only thought of in terms of punishment.¹²² A retributive approach will see to it that things remain broken.¹²³ Conversely, a restorative approach seeks to repair and heal.¹²⁴ It could help repair the doctor-patient relationship. It may even allow us to strengthen the system, by revealing weaknesses that we can then confront.¹²⁵

Such an approach may provide an opportunity to reach a reparative agreement between all the stakeholders, giving practitioners and the organisation a chance to express regret, remedy the harm and ‘make things right’ by implementing changes aimed at achieving safer care.¹²⁶ Practitioners and healthcare organisations can also ‘make things right’ by providing ongoing support for patients and their families, and could even involve them in safety improvement processes. The organisation should also provide support for affected healthcare workers, who may be the forgotten ‘second victims’ of adverse events.¹²⁷

Finally, patients who suffer harm may face significant future medical expenses, loss

¹²¹ Waring (2005) 60 *Social science & medicine* 1927; Frankel et al. (2006) 41 *Health services research* 1690; Connor et al. (2007b) 33 *The Joint Commission Journal on Quality and Patient Safety* 617.

¹²² Mizrahi “Managing medical mistakes: ideology, insularity and accountability among internists-in-training” *Social science & medicine* (1984) 19 135; Runciman et al. “Error, blame, and the law in health care—an antipodean perspective” *Annals of internal medicine* (2003) 138 974; Leape “Errors in medicine” *Clinica chimica acta* (2009) 404 2.

¹²³ Liang “A system of medical error disclosure” *Quality and Safety in Health Care* (2002) 11 64.

¹²⁴ Todres (2006) *Conn L Rev* 39 667.

¹²⁵ McGivern and Fischer “Medical regulation, spectacular transparency and the blame business.” *J Health Organ Manag* (2010) 24 597; Dekker *Second Victim: Error, Guilt, Trauma, and Resilience* (2013); Macrae (2014) 23 *BMJ Qual Saf* 440; Hernan et al. “Patient and carer identified factors which contribute to safety incidents in primary care: a qualitative study.” *BMJ Qual Saf* (2015) 24 583; Braithwaite et al. (2016) 236; Etchegaray et al. “Patients as Partners in Learning from Unexpected Events.” *Health Serv Res* (2016) 51 Suppl 3 2600; Health “Patient Safety Learning Systems: A Systematic Review and Qualitative Synthesis.” *Ont Health Technol Assess Ser* (2017) 17 1.

¹²⁶ Johnstone and Van Ness (2013) 24.

¹²⁷ Dekker (2013); Santomauro et al. (2014) 3 *Journal of Hospital Administration* 95.

of income and other costs due to the injuries they have sustained.¹²⁸ Compensation remains an important part of the restorative resolution. Unfortunately, compensation has often in the past only been provided after protracted and adversarial medico-legal negotiations.¹²⁹ This can be immensely frustrating and damaging for patients and their families.¹³⁰ In some jurisdictions, such as Sweden and New Zealand, compensation is provided on a no-fault basis, abolishing the need to invoke onerous legal proceedings.¹³¹ However, even without no-fault compensation schemes, much more can be done to assist injured patients.

Communication and resolution programmes, that are founded on disclosure and transparency, encourage proactive efforts by healthcare providers, which could include early offers of compensation.¹³² CRPs have their roots partly in principles of Just Culture.¹³³ CRPs could prove to be an ideal vehicle with which to introduce restorative justice principles into the healthcare context.

6. MEDICAL ERROR AND THE LIABILITY SYSTEM

Before we consider alternative mechanisms to deal with medical errors, harm and compensation, it would be worth discussing the existing approach. Most countries, including South Africa, employ variations of a fault-based medical malpractice

¹²⁸ Harvard *Patients, Doctors, and Lawyers: Medical Injury, Malpractice Litigation, and Patient Compensation in New York, the Report* (1990).

¹²⁹ Weiler *A measure of malpractice: medical injury, malpractice litigation, and patient compensation* (1993b); Hyman and Silver "Medical Malpractice Litigation and Tort Reform: It's the Incentives, Stupid" *Vand. L. Rev.* (2006) 59 1085.

¹³⁰ May and Stengel "Who sues their doctors? How patients handle medical grievances" *Law and Society Review* (1990) 105; Taragin et al. (1992) 117 *Ann Intern Med* 780; Vincent and Coulter (2002) 11 *Qual Saf Health Care* 76.

¹³¹ Kachalia et al. (2008) 66 *Soc Sci Med* 387; Mello et al. "Administrative compensation for medical injuries: lessons from three foreign systems." *Issue Brief (Commonw Fund)* (2011b) 14 1.

¹³² Kachalia et al. (2010) 153 *Ann Intern Med* 213; Mello et al. (2014) 33 *Health Aff (Millwood)* 20; Mello et al. (2014) 33 *Health Aff (Millwood)* 30; Mello et al. (2016) 51 *Suppl 3 Health Serv Res* 2583; Mello et al. (2017) 36 *Health Aff (Millwood)* 1795.

¹³³ Gallagher et al. (2016) 51 *Suppl 3 Health Serv Res* 2569.

system.¹³⁴ Claims for medical malpractice are generally founded in tort/delict and based on the laws of negligence.¹³⁵ The malpractice system has essentially two core objectives.¹³⁶ It serves to deter substandard care and it aims to compensate those patients who were injured as a result of such negligent care.¹³⁷ The deterrence function thereof is particularly relevant to patient safety.¹³⁸ In theory, practitioners would avoid unsafe practices due to the threat of litigation and the consequent emotional and financial costs that would be incurred during a civil trial. Attorneys function as gatekeepers in the system, as they consider the merits of potential claims, along with other factors, when advising their clients to institute claims or not. If a claim succeeds, indemnity insurance ensures that practitioners are not bankrupted and that patients receive compensation. Theoretically the existing system is sound, in reality, however, there are numerous problems.¹³⁹ Empirical studies of the system have raised some serious concerns about the functioning and efficacy of the malpractice system (particularly, about how it fulfils its two core objectives).

6.1. COMPENSATION

A severe disconnect exists between patients who suffer harm due to negligent care and those who actually file claims.¹⁴⁰ Only a fraction of eligible claims ever reaches the malpractice system and even fewer still elicit compensation.¹⁴¹ Some have suggested that this implies that many frivolous claims are filed. However, the evidence suggests otherwise.¹⁴² The malpractice system actually does an adequate job of

¹³⁴ OECD (2006) 82.

¹³⁵ Giesen (1988); Oliphant and Wright (2013)

¹³⁶ Danzon *Medical malpractice: theory, evidence, and public policy* (1985)

¹³⁷ Corrective justice is often also mentioned as a third objective. Studdert et al. (2004) 350 *N Engl J Med* 283.

¹³⁸ Kessler and McClellan "The effects of malpractice pressure and liability reforms on physicians' perceptions of medical care" (1998); Mello and Brennan (2001) *Tex L Rev* 80 1595.

¹³⁹ Brennan and Mello (2003) 139 *Ann Intern Med* 267; Studdert et al. (2004) 350 *N Engl J Med* 283; Mello and Studdert (2007) *Geo LJ* 96 599.

¹⁴⁰ Weiler (1991); Localio et al. (1991) 325 *N Engl J Med* 245; Weiler (1993b); Thomas et al. (2000) 38 *Medical Care* 261.

¹⁴¹ Studdert et al. (2006) 354 *N Engl J Med* 2024.

¹⁴² Baker (2005) 33 *J Law Med Ethics* 501; Baker (2007); Furrow "The patient injury epidemic: medical malpractice litigation as a curative tool" *Drexel L. Rev.* (2011) 4 41.

distinguishing between legitimate and meritless claims.¹⁴³ Unfortunately, it does so in a highly inefficient and costly manner.¹⁴⁴ Claims generally take years to be resolved and the overhead costs of the system are exorbitant, with more than half of the expenditure going towards the administration thereof.¹⁴⁵

6.2. DETERRENCE

More concerning from a patient safety standpoint is that there is almost no evidence to suggest that the system is effective at deterring substandard care or that it improves the safety of care.¹⁴⁶ The poor correlation between negligent injuries and filed claims, likely explains why higher-risk malpractice environments do not result in improved care. The deterrence signal sent by relatively infrequent and haphazard claims may reduce the risk-reduction information derived from litigation.¹⁴⁷ Furthermore, since litigation is such an isolated event, individual practitioners may not see a reduction in claim rates even if incidences of negligent harm improve.¹⁴⁸ As indemnity insurance premiums are generally also not individually risk rated, the potential financial incentive is also diminished.¹⁴⁹

The lack of evidence for improvement may also be due to the structural nature of the existing liability system, which largely holds physicians to standards determined by professional customs.¹⁵⁰ Standards of care are essentially enforced in a largely self-regulatory manner and industry customs may not necessarily be aligned with evidenced-based best practice. The fear of liability in a system riddled with imperfect information may only bring modest improvements, if any, whereas liability contingent

¹⁴³ Peters “Empirical evidence and malpractice litigation.” *Spec Law Dig Health Care Law* (2004) 9; Peters Jr (2006) *Iowa L Rev* 92 1783; Peters (2009) 467 *Clin Orthop Relat Res* 352.

¹⁴⁴ Studdert et al. (2006) 354 *N Engl J Med* 2024.

¹⁴⁵ *Ibid.*; Seabury et al. (2013) 32 *Health Aff (Millwood)* 111.

¹⁴⁶ Schwartz and Komesar (1978) 298 *N Engl J Med* 1282; Mello and Brennan (2001) *Tex L Rev* 80 1595.

¹⁴⁷ Frakes and Jena (2016) 143 *J Public Econ* 142.

¹⁴⁸ Jena et al. (2011) 365 *N Engl J Med* 629.

¹⁴⁹ Sloan “Experience rating: Does it make sense for medical malpractice insurance” *The American economic review* (1990) 80 128; Sloan and Hsieh (1990) *Law and Society Review* 997; Sloan and Chepke (2008).

¹⁵⁰ Frakes (2015) *The University of Chicago Law Review* 317; Frakes et al. (2015) 171 *Journal of Institutional and Theoretical Economics (JITE)* 58; Frakes and Jena (2016) 143 *J Public Econ* 142.

upon the imposition of evidence-based standards and better-informed science may advance quality of care and patient safety.¹⁵¹

Ultimately, one would want to improve standards of care. Medical malpractice liability is one way. However, it is not the only way, and it might not even be the best way. Public reporting of quality information, susceptible regulation, financial incentives, and liability could all play complementary roles. Nonetheless, investigators caution that tort liability should not be relaxed without a substitute source of incentives.¹⁵²

The law could still play a valuable role in shaping clinical practices and health care quality, but we would have to better understand the liability structure that would be conducive thereto.¹⁵³ The excessive expenditure involved with the malpractice system might be reinvested in more effective quality and safety improvement strategies. There is evidence to suggest that, hospitals that invest in patient safety can significantly reduce malpractice claims, in addition to the direct benefits for patient outcomes.¹⁵⁴

6.3. ADDITIONAL PROBLEMS

There are additional problems with the malpractice system. Some of the problems, have to do with patient safety concerns, specifically the conflict in cultures and approaches to human error prevention and safety.¹⁵⁵ Other problems that are often cited, have more to do with the financial repercussions of the system.¹⁵⁶ This includes

¹⁵¹ Frakes (2015) *The University of Chicago Law Review* 317.

¹⁵² Zabinski and Black (2015); Black et al. (2017) 3 *American Journal of Health Economics* 109.

¹⁵³ Frakes (2015) *The University of Chicago Law Review* 317.

¹⁵⁴ Clark et al. "Improved outcomes, fewer cesarean deliveries, and reduced litigation: results of a new paradigm in patient safety" *American journal of obstetrics and gynecology* (2008) 199 105; Greenberg et al. "Is Better Patient Safety Associated with Less Malpractice Activity?: Evidence from California." *Rand Health Q* (2011) 1 1; Riley et al. "Decreasing Malpractice Claims by Reducing Preventable Perinatal Harm." *Health Serv Res* (2016) 51 Suppl 3 2453; Schiff et al. "Randomized Trial of Reducing Ambulatory Malpractice and Safety Risk: Results of the Massachusetts PROMISES Project" *Medical Care* (2017) 55 797; Black et al. (2017) 3 *American Journal of Health Economics* 109.

¹⁵⁵ These have already been mentioned. Reason (2000) 320 *BMJ* 768; Clinton and Obama "Making patient safety the centerpiece of medical liability reform" *New England Journal of Medicine* (2006) 354 2205; Mello and Studdert (2007) *Geo LJ*; Ridgely et al. (2016) 51 Suppl 3 *Health Serv Res* 2414.

¹⁵⁶ OECD (2006) 82.

indemnity payments, particularly the affordability and availability of insurance, administrative costs and defensive medicine.¹⁵⁷ These financial problems generally receive the bulk of the attention, which inevitably culminates in calls for reform.¹⁵⁸ As Sage states: 'For both emotional and financial reasons, few issues rival tort reform in terms of aggressive partisanship, overheated rhetoric, and suspicion of new ideas'.¹⁵⁹ Debates surrounding malpractice liability and reform are often discordant and permeated with misleading claims.¹⁶⁰ Stakeholders with vested interests in reducing the cost of malpractice claims are quick to propose liability-limiting reforms.¹⁶¹

7. SOUTH AFRICA - HEALTHCARE AND MALPRACTICE

South Africa is by all accounts currently facing many of the same challenges other countries have faced with their compensation and liability systems.¹⁶² Here too, concerns regarding the costs of the system have mainly been the catalyst for increased lobbying from stakeholders and attention from policymakers.¹⁶³

The public health system suffers from a range of systemic weaknesses that have likely impaired the provision of quality care.¹⁶⁴ These weaknesses, along with other factors,

¹⁵⁷ Mello et al. (2010b) 29 *Health Aff (Millwood)* 1569; Malherbe (2012) 103 *S Afr Med J* 83; Bateman (2016) 106 *SAMJ: South African Medical Journal* 1063.

¹⁵⁸ Baker (2007).

¹⁵⁹ Sage and Kersh "Medical Malpractice and the U.S. Health Care System" (2006) 339.

¹⁶⁰ Furrow (2011) *Drexel L. Rev.* 4 41.

¹⁶¹ Society "Challenging the cost of clinical negligence" (2015) 1; Howarth and Hallinan (2016) 106 *S Afr Med J* 141.

¹⁶² Pepper and Slabbert (2011) 6 *South African Journal of Bioethics and Law* 60.

¹⁶³ Bateman "Indemnity hike stirs up doctors." *S Afr Med J* (2005) 95 14; Bateman "Payouts against doctors spiralling upward." *S Afr Med J* (2005) 95 376, 378; Bateman "Possible MPS eviction 'an unmitigated disaster'-patient litigator" *South African Medical Journal* (2010) 100 700; Bateman (2011) 101 *SAMJ: South African Medical Journal* 216; Dhai (2015) 8 *S Afr J BL* 2; Motsoaledi (2015) 8 *S Afr J BL* 4; Bateman (2016) 106 *SAMJ: South African Medical Journal* 1063; Bateman (2016) 106 *South African Medical Journal* 9.

¹⁶⁴ Gordon (2004) 10 *Southern African Journal of Anaesthesia and Analgesia* 7; Gordon et al. (2006) 96 *South African Medical Journal* 630; Llewellyn et al. (2009) 37 *Anaesthesia and intensive care* 93; Coovadia et al. (2009) 374 *Lancet* 817; Bateman (2011b) 101 *SAMJ: South African Medical Journal* 294; Bateman (2011) 101 *SAMJ: South African Medical Journal* 364,366; Llewellyn et al. (2011) 101 *SAMJ: South African Medical Journal*

may have made the public sector especially vulnerable to malpractice litigation.¹⁶⁵ The substantial amounts spent on claims, cannot be spent on improving healthcare infrastructure and services.¹⁶⁶ Unfortunately, this could potentially compound the problem, and lead to more frequent and more severe harmful outcomes – with a greater number of subsequent claims.¹⁶⁷ Those in the private sector have also raised concerns about the current situation. Increasing claims have contributed to escalating indemnity insurance premiums, which could lead to passed-on costs, resource waste and reduced access to care.¹⁶⁸

319; Mayosi et al. “Health in South Africa: changes and challenges since 2009” *The Lancet* (2012) 380 2029; Cronje (2015) 21 *Southern African Journal of Anaesthesia and Analgesia* 147; Mayosi and Benatar “Health and health care in South Africa—20 years after Mandela” *New England Journal of Medicine* (2014) 371 1344; Mehta et al. (2014) 104 *S Afr Med J* 104; Bateman (2015) 105 *SAMJ: South African Medical Journal* 248; Bateman “Rendering a dangerous healthcare ocean safer” *SAMJ: South African Medical Journal* (2015) 105 799; Bateman (2015) 105 *SAMJ: South African Medical Journal* 11; Fawcus et al. (2016) 106 *SAMJ: South African Medical Journal* 472; Gebhardt et al. (2015) 105 *SAMJ: South African Medical Journal* 287; Bateman (2016) 106 *SAMJ: South African Medical Journal* 321; Bateman “Quality of care responsible for soaring maternal deaths-report” *SAMJ: South African Medical Journal* (2016) 106 540; Blignaut et al. (2017) 26 *Journal of Clinical Nursing/J Clin Nurs* 3610; Maswime and Buchmann (2016) 134 *International Journal of Gynecology & Obstetrics* 320; Kong and Clarke (2016) 106 *SAMJ: South African Medical Journal* 695; Biccard (2016) 22 *Southern African Journal of Anaesthesia and Analgesia* 5; Mathews et al. “The South African child death review pilot: A multiagency approach to strengthen healthcare and protection for children.” *S Afr Med J* (2016) 106 895; Mathews et al. (2016) 106 *SAMJ: South African Medical Journal* 851; Blignaut et al. (2017) 26 *Journal of Clinical Nursing/J Clin Nurs* 3610. Myer et al. noted this disturbing finding: “These data suggest that medical inpatient mortality rates at a large SA academic hospital have increased over the past decade. Furthermore, the overall hospital mortality rate of 12 - 17% is comparable to rates observed in North America during the mid-19th century and is substantially higher than the 2.1% mortality rate documented in contemporary Massachusetts.”

¹⁶⁵ Von Holdt and Murphy (2007) *State of the nation: South Africa* 312; Rowe and Moodley “Patients as consumers of health care in South Africa: the ethical and legal implications” *BMC medical ethics* (2013) 14 15; Karodia et al. “Investigating the Impact of Medical Malpractice Litigation on Healthcare Delivery in Gauteng” *Journal of Research and Development* (2016) 2 149.

¹⁶⁶ Malherbe (2013) 103 *S. Afr. Med. J. South African Medical Journal* 83; Dhai “Medico-legal litigation: Balancing spiralling costs with fair compensation” *South African Journal of Bioethics and Law* (2015) 8 2; Bateman (2016) 106 *SAMJ: South African Medical Journal* 1063; Bateman (2016) 106 *SAMJ: South African Medical Journal* 540.

¹⁶⁷ Howarth and Carstens (2014) 7 *S Afr J BL* 69; Pienaar “Calculating medical negligence costs” *repository.up.ac.za* (2015) 2015 37; Pienaar “Investigating the reasons behind the increase in medical negligence claims” *PER: Potchefstroomse Elektroniese Regsblad* (2016) 19 1.

¹⁶⁸ Howarth (2011) 4 *South African Journal of Bioethics and Law* 85; Howarth et al. “The importance of comprehensive protection in today’s healthcare environment” *SAMJ: South African Medical Journal* (2013) 103

7.1. REFORM ON THE HORIZON

Policymakers have noticed. Reform is on the agenda.¹⁶⁹ A Standards-monitoring regulatory body has been established and policies have been adopted to improve the quality and safety of care provided throughout the healthcare system.¹⁷⁰ Changes to the malpractice system are also being considered. According to the Minister of Health, malpractice claims threaten the establishment of the National Health Insurance scheme.¹⁷¹

It must, however, be noted that quality and patient safety have recently received renewed attention, as evidenced by the establishment of the Office of Health Standards Compliance and the adoption of the 'Ideal Clinic' initiative. It is unclear, if, or to what extent, the malpractice system incentivised this renewed focus on delivering sound care. If the system played a role in the adoption of these measures, it emphasises, as mentioned above, that liability should not be relaxed in the absence of other incentives. And certainly not, where we lack evidence regarding the influence of liability, as localised to our specific context (i.e. our bifurcated healthcare structure, public/private financing, regulatory framework, societal perceptions, etc.). The effect of malpractice litigation and the signal sent (general or specific deterrence) may well be different, seeing as provincial departments are held vicariously liable for the negligent conduct of their staff. This could mean that there is an incentive for wider system improvement.¹⁷²

453; Howarth (2013) 23 *Obstetrics and Gynaecology Forum* 33; Howarth (2013) 103 *S Afr Med J* 513; Howarth et al. (2013) 103 *S Afr Med J* 453; Howarth and Carstens (2014) 7 *S Afr J BL* 69; Howarth et al. (2014) 104 *S Afr Med J* 752; Howarth et al. "A good complaints system" *S Afr Med J* (2015) 105 425; Howarth and Hallinan (2016) 106 *S Afr Med J* 141.

¹⁶⁹ Commission (2017) 1; Society (2015) 1; Archer "Medical malpractice crisis deepens : new approach : correspondence" *SAMJ: South African Medical Journal* (2016) 106 536; Team, *Declaration Medico-Legal Summit*; National Department of Health (2017d).

¹⁷⁰ The Office of Health Standards Compliance.

¹⁷¹ Motsoaledi (2015) 8 *S Afr J BL* 4; Motsoaledi, *The real reason SA's doctors won't deliver your baby-Bhekisisa*, 2017.

¹⁷² This requires further investigation. Liability directed at the organisational level in order to induce safety interventions throughout the system, is the rationale behind 'Enterprise Liability' reform proposals. Whether,

For this reason alone, we should be circumspect of liability-limiting reforms, discussed below. As Furrow convincingly argues, liability, if fine-tuned, can reinforce good medical practice, articulate new duties of care, give a voice to mistreated patients, and expose obtuse organisations.¹⁷³ The weaknesses of the malpractice liability system should be addressed, but in the absence of radical change (i.e. moving to a voluntary administrative scheme), the system with all of its problems should probably be retained as a backstop. The system is also less likely to be captured by vested interests, seeing to it that the rights of patients are protected where healthcare providers, regulators or the state may have failed them. The underlying civil justice system could, however, still be refined to improve its efficiency and cost-effectiveness.

7.2. CONVENTIONAL LIABILITY-LIMITING REFORMS

In the past, reforms have been introduced with the sole objective of curtailing the financial costs of the malpractice system.¹⁷⁴ Conventional reforms have often specifically targeted the affordability and availability of insurance for healthcare providers by reducing the volume and cost of malpractice litigation. Financially impacted stakeholders are usually at the forefront of debates regarding reform. The Medical Protection Society in South Africa recently put forward their own proposal, which would, if implemented, make it harder for injured patients to institute claims and cap the damages they may be awarded.¹⁷⁵

liability sends the same signal in the public sector in the absence of accountability or financial/profit incentive remains unclear.

¹⁷³ Furrow (2011) *Drexel L. Rev.* 4 41.

¹⁷⁴ Hyman and Silver (2006) *Vand. L. Rev.* 59 1085; Sloan and Shadle (2009) 28 *J Health Econ* 481; Carrier et al. (2010) 29 *Health Aff (Millwood)* 1585; Thomas et al. "Low costs of defensive medicine, small savings from tort reform." *Health Aff (Millwood)* (2010) 29 1578; Mello et al. (2014b) 312 *JAMA* 2146; Deng and Zanjani "What Drives Tort Reform Legislation? Economics and Politics of the State Decisions to Restrict Liability Torts" (2015); Born and Karl "The Effect of Tort Reform on Medical Malpractice Insurance Market Trends: Medical Malpractice Tort Reform and Insurance Markets" *Journal of Empirical Legal Studies* (2016) 13 718; Reform "Premium deceit: The failure of "tort reform" to cut insurance prices" (2017) 1.

¹⁷⁵ Society (2015) 1; Howarth and Hallinan (2016) 106 *S Afr Med J* 141.

Conventional reforms can be divided into three categories:¹⁷⁶ 1) reforms that limit access to court; 2) reforms that change how damages are paid; and 3) reforms that directly address the size of damages awarded.

7.2.1. REFORMS THAT LIMIT ACCESS TO COURT

7.2.1.1. PRE-TRIAL SCREENING PANELS

Expert panels determine and make recommendations with regard to the merits of a claim at an early stage, before the matter proceeds to court.

7.2.1.2. CERTIFICATE OF MERIT REQUIREMENTS

The plaintiff patient must, at an early stage of the proceedings, present an affidavit which confirms that a qualified medical expert believes there is a reasonable and valid cause of action.

7.2.1.3. EXPERT WITNESS CERTIFICATION REQUIREMENTS

Expert witnesses in malpractice suits must satisfy certain requirements.

7.2.1.4. STATUTES OF LIMITATION AND REPOSE

Statutes that limit the amount of time a patient has to file a malpractice claim.

7.2.1.5. LIMITS ON ATTORNEYS' FEES

Limits the amount attorneys can take in terms of contingency-fee agreements. The limit can be set as a percentage of the award, or as a maximum value.

7.2.2. REFORMS THAT CHANGE HOW DAMAGES ARE PAID

7.2.2.1. JOINT-AND-SEVERAL LIABILITY REFORM

In cases involving multiple defendants, the financial liability of each defendant is limited to the percentage of fault respectively allocated. The patient is unable to collect the entire award from one defendant.

¹⁷⁶ Brennan (2004) 350 *The New England Journal of Medicine* 283; Mello and Kachalia (2010) *Medicare Payment Advisory Commission* ; Kachalia and Mello (2011) 364 *N Engl J Med* 1564; Mello et al. (2014b) 312 *JAMA* 2146; Mello and Kachalia "Medical Malpractice: Evidence on Reform Alternatives and Claims Involving Elderly Patients" *Medicare Payment Advisory Commission* (2016) 1.

7.2.2.2. PERIODIC PAYMENT

Malpractice awards are allowed to be paid over a period of time instead of a lump sum. Payment ceases when the patient passes away.

7.2.3. REFORMS THAT DIRECTLY ADDRESS THE SIZE OF DAMAGES AWARDED

7.2.3.1. MODIFICATIONS TO THE COLLATERAL SOURCE RULE

Collateral benefits or compensation is more readily allowed to be deducted from the amount the defendant must pay.

7.2.3.2. CAPPING OF DAMAGES

Limitations may be applied to the total amount or only the non-economic portion of the damages awarded. Malpractice lawsuits may then also be less lucrative for attorneys.

7.2.4. EFFECTIVENESS OF CONVENTIONAL REFORMS

Kachalia and Mello have conducted a comprehensive review of the available evidence on the effects of conventional reforms to the malpractice liability system.¹⁷⁷ They assessed the reforms according to a number of metrics, taking into account both liability-related measures (i.e. claims frequency and costs, patient compensation, overhead costs, insurance premiums) and care-related measures (i.e. defensive medicine, physician supply, quality of care). Their review showed that analyses of conventional reforms had focussed heavily on metrics related to liability costs, care-related metrics have generally been neglected. It also showed that, with few exceptions, these reforms have not resulted in many liability improvements.

Caps on damages, seem to be the exception. Caps are associated with a reduced frequency of claims, savings in average claim pay-outs, a modest reduction of insurance premiums, moderate improvements in physician supply, and a slight decline in at least some defensive practices. However, caps may also have a disproportionately large effect on claiming. Several states have also struck down caps, having ruled them unconstitutional. Other conventional reforms have not

¹⁷⁷ Mello and Kachalia (2016) *Medicare Payment Advisory Commission 1*.

demonstrated positive findings. Concerns have been raised that liability limiting reforms may diminish the incentive to invest in quality improvement and could lead to so-called ‘induced demand’ or ‘offensive medicine’. Practitioners may also opt for more remunerative procedures, which could be more invasive and higher-risk.¹⁷⁸

Mello *et al.* indicate that despite ‘the intuitive appeal of conventional tort reforms and advocates’ strong claims regarding their efficacy’, the available empirical evidence does not support the inference that traditional reforms are responsible for the relatively stable malpractice environment the United States experienced over the past decade. The authors state that ‘in general, malpractice crises may relate as much to cycles in insurance markets as to changes in claims costs’.¹⁷⁹

Conventional reforms have, at best, a modest effect on liability costs, without any significant trade-off for patients.¹⁸⁰ Tort reforms have not brought economically significant reductions in healthcare costs or utilisation. They also do not address the shortcomings related to the malpractice system’s two core objectives—deterrence and compensation. These reforms were never intended to deter substandard care and patients will continue to face the same, if not more, difficulties in obtaining compensation. As Avraham states, the system ‘is characterised by under-claiming and perverse incentives created by uncertain and potentially incorrect standards of care’.¹⁸¹

7.3. REFORMS THAT ADDRESS PATIENT SAFETY

Alternative approaches, which aim to enhance the incentives imposed by the malpractice system in order to improve care, have recently garnered attention.¹⁸² These approaches seek to address various weaknesses of the malpractice system.

¹⁷⁸ Currie and MacLeod (2008) 123 *Quarterly Journal of Economics* 795; Shurtz “Malpractice Law, Physicians’ Financial Incentives, and Medical Treatment: How Do They Interact?” *The Journal of Law and Economics* (2014) 57 1; Avraham and Schanzenbach (2015) *SSRN Journal*; Avraham and Schanzenbach “The impact of tort reform on intensity of treatment: evidence from heart patients.” *J Health Econ* (2015) 39 273.

¹⁷⁹ Mello et al. (2014b) 312 *JAMA* 2146.

¹⁸⁰ Baker (2007).

¹⁸¹ Avraham and Schanzenbach (2015) *SSRN Journal*.

¹⁸² Clinton and Obama (2006) 354 *New England Journal of Medicine* 2205.

At least, they are more ethical, since in contrast to the conventional liability-limiting reforms, these reforms not only seek to benefit practitioners and insurers, but patients as well.¹⁸³

Mello *et al.* provide an excellent overview of the non-traditional approaches to medical liability reform.¹⁸⁴ Interested readers are directed to their article, where these reforms are discussed in more detail. For the sake of convenience, the different approaches and a short description of each is reproduced here:

7.3.1. COMMUNICATION-AND-RESOLUTION PROGRAMS

Programs in which health care practitioners and institutions openly discuss adverse outcomes with patients and proactively seek resolution, including offering an apology, an explanation of what happened, and, if the standard of care was not met, compensation.

7.3.2. APOLOGY LAWS

Laws protecting statements of regret, apology, or fault, or all 3, made to patients by health care practitioners and preventing those statements from being used in malpractice suits.

7.3.3. STATE-FACILITATED DISPUTE RESOLUTION LAWS

Laws allowing voluntary filing by patients or health care practitioners or institutions with a state agency that will then assist the parties through a communication and resolution process. Conversations are generally protected from use in trial. If initial negotiations fail, the state will help find a mediator.

¹⁸³ Kachalia and Mello (2011) 364 *N Engl J Med* 1564; Battles et al. "Paving the Way for Progress: The Agency for Healthcare Research and Quality Patient Safety and Medical Liability Demonstration Initiative." *Health Serv Res* (2016) 51 Suppl 3 2401; Ridgely et al. (2016) 51 Suppl 3 *Health Serv Res* 2414; Mello and Kachalia (2016) *Medicare Payment Advisory Commission* 1; (AHRQ) "Advances in Patient Safety and Medical Liability" (2017) 1.

¹⁸⁴ Mello et al. "The medical liability climate and prospects for reform." *JAMA* (2014a) 312 2146.

7.3.4. SAFE HARBOURS

Laws giving health care practitioners and institutions a defence to a malpractice claim if they can show they followed an applicable guideline or protocol in caring for a patient.

7.3.5. JUDGE-DIRECTED NEGOTIATION

A court policy requiring malpractice litigants to meet early and often with the judge to discuss settlement. The court system employs an attorney with clinical training to help judges understand clinical issues. Judges assertively move parties toward settlement and retain responsibility for cases through trial.

7.3.6. ADMINISTRATIVE COMPENSATION SYSTEMS

Laws routing medical injury claims into an alternative adjudication process that uses specialized adjudicators, evidence-based guidelines for liability determinations and damages, neutral experts, and (under most proposals) a compensation standard that is broader than the negligence standard.

7.4. EFFECTIVENESS OF INNOVATIVE REFORMS

The evidence base for these innovative reforms is still very limited. Most have not been tested.¹⁸⁵ Those that have been tried, have not been operational for long enough to offer robust outcomes data. However, recently published findings suggest that some of these reforms may hold some promise.¹⁸⁶

7.4.1. PATIENT SAFETY AND MEDICAL LIABILITY INITIATIVE

The stabilisation of the insurance market in the United States shifted the focus of reform from controlling liability costs to improving patient safety (and reducing wasted healthcare resources). In 2006, then Senators Clinton and Obama called for a fair and

¹⁸⁵ Mello and Kachalia (2016) *Medicare Payment Advisory Commission* 1.

¹⁸⁶ Battles et al. (2016) 51 Suppl 3 *Health Serv Res* 2401; Gallagher et al. (2016) 51 Suppl 3 *Health Serv Res* 2569; Lambert et al. (2016) 51 Suppl 3 *Health Serv Res* 2491; Mello et al. (2016) 51 Suppl 3 *Health Serv Res* 2550; Ridgely et al. (2016) 51 Suppl 3 *Health Serv Res* 2414; (AHRQ) (2017) 1; Mello et al. (2017) 36 *Health Aff (Millwood)* 1795.

equitable solution to the complex problem of malpractice liability reform.¹⁸⁷ They proposed that all the parties involved (physicians, hospitals, insurers, and patients) should centre the discourse around the more fundamental issue—the need to improve patient safety.

‘To improve both patient safety and the medical liability climate, the tort system must achieve four goals: reduce the rates of preventable patient injuries, promote open communication between physicians and patients, ensure patients access to fair compensation for legitimate medical injuries, and reduce liability insurance premiums for health care providers. Addressing just one of these issues is not sufficient. Capping malpractice payments may ameliorate rising premium rates, but it would do nothing to prevent unsafe practices or ensure the provision of fair compensation to patients.’¹⁸⁸

In October 2009, in response to President Obama’s renewed call for action, the AHRQ launched the Patient Safety and Medical Liability (PSML) initiative. Seven demonstration projects were allocated \$25 million to test models that meet the four goals set out above.

A special issue of the journal, *Health Services Research*, reported on some of the findings of the projects and the tools generated by the interventions.¹⁸⁹

The PSML demonstration projects focused on three broad approaches: (1) improving provider–patient engagement through communication and resolution programs, (2) implementation of clinical ‘best practices’ to prevent harm and (3) alternative methods of settling claims.

Overall, the initiative found that these interventions can positively affect outcomes, however, they can be difficult to scale. There are, however, some indications that these interventions may have also contributed to an improved organisational safety

¹⁸⁷ Clinton and Obama (2006) 354 *New England Journal of Medicine* 2205.

¹⁸⁸ *Ibid.*

¹⁸⁹ Ridgely et al. (2016) 51 Suppl 3 *Health Serv Res* 2414.

culture.

This was the first investigation of its type. Hopefully, the positive results will encourage additional empirical research into the interface of patient safety and medical malpractice liability.

Ridgley *et al.*, after evaluating the PSML initiative, noted the following in their conclusion:

‘In our view, what was most innovative about the PSML portfolio was the simple idea that these two problems [patient safety and medical liability] can be understood as fundamentally related and (therefore) addressed simultaneously. This basic idea comports well with the last decade of the U.S. patient safety movement and the underlying belief that adverse events in health care are better understood as the result of complex “systems” failure, rather than of individual negligence. In part, the response of the health care system has been to try to analyze adverse events, prevent their recurrence, and to become more transparent and responsive while carrying out related self-improvement processes. None of this logic aligns well with traditional malpractice liability, which instead assumes fault on the part of individual providers, and which creates an adversarial incentive to defend and protect against potential claims, rather than to collaborate in investigating and reducing risk. Whatever viewpoint one has regarding the merits of statutory tort reform, one thing most people can agree on is that if other factors are held constant, it would be a good idea to reduce preventable injury rates in health care settings.’¹⁹⁰

¹⁹⁰ *Ibid.*

8. RECOMMENDATIONS - ALIGNING SYSTEMS TO PROMOTE SAFETY

Both the malpractice system and the healthcare system have one vitally important thing in common—the patient. Patients and their interests are central to both systems and there is perhaps, nothing patients value more highly than their safety. Therefore, patients and their safety should be our utmost concern when we attempt to address the weaknesses in both systems.

8.1. WHAT ARE THE WEAKNESSES?

8.1.1. HEALTHCARE SYSTEM - WEAKNESSES

The available evidence suggests that patients in developing countries may face an immense burden of harm.

Unfortunately, there is very little information or transparency on the incidence of adverse events in South Africa. Due to a number of factors, it could be severe.

The public health system in South Africa, which serves the vast majority of citizens, faces numerous systemic problems, which almost certainly adversely impacts the standard of care delivered. These problems are well documented and include, poor management, a lack of leadership, staff shortages, inadequate supplies, dilapidated infrastructure etc.

Many of these problems have their roots in our Apartheid past. However, through political, administrative, and regulatory failures, these problems have persisted at the expense of the most vulnerable members of our society.

A severe lack of accountability and the absence of an effective quality and safety regulatory system, has led to continuous deterioration to the point where the public sector can best be described as dysfunctional. Healthcare establishments and administrators in the public sector also have had no financial or other incentive to improve performance or quality. Nor, have there been repercussions for serious

abdications of responsibility. Budgets and salaries are not tied to care criteria or measures. In fact, such outcomes-measures rarely exist or are unreliable. This has made any meaningful oversight near impossible.

Disastrous management has also affected the regulation of health professionals. The Health Professions Council of South Africa has attracted criticism from professionals and patients alike. Raising serious doubts about the Council's ability to fulfil its crucial mandate.

The lack of adequate professional oversight and absence of independent external regulation has likely contributed significantly to the current tragic (probably harmful) state of public health care in South Africa.

8.1.2. MALPRACTICE SYSTEM - WEAKNESSES

The malpractice system aims to compensate and deter substandard care. However, studies suggest that it rarely does and that it instead creates a punitive environment which may compromise the establishment of a just culture, hampering safety efforts.

Unfortunately, there is no empirical data about the functioning of the South African malpractice system.

Most South Africans cannot afford to access the justice system. 'Contingency fee' agreements have allowed more litigants to access the system, but have been linked to undesirable practices. Attorneys only take on the most lucrative claims on a contingency basis. Less lucrative claims may never reach the justice system.

The costs of administering the system are disproportionately expensive, with legal fees making up as much as half of the total cost.

Claims resolution is slow. Cases can take years to be finalised and be prolonged by appeals. Medical negligence claims are also notoriously difficult to prove, except in the most clear-cut of cases. It is an adversarial process, which often leads to a breakdown in the doctor-patient relationship.

Claims likely contribute to higher insurance premiums (although, insurance cycles probably play a larger role).

8.2. WHAT STEPS ARE BEING TAKEN TO IMPROVE SAFETY?

8.2.1. HEALTHCARE SYSTEM – STEPS TAKEN TO IMPROVE SAFETY

Recent legislative and policy interventions demonstrate that the South African government recognises the need to improve the safety of care patients receive and there is newfound political will to address longstanding deficiencies.

The Ideal Clinic initiative was launched, following a baseline audit, to improve the standard of care provided by Primary Healthcare Facilities. Several policies and guidelines have been developed, some directly target patient safety.

The Office for Health Standards Compliance and a Health Ombud has been established. The OHSC will monitor and enforce norms and standards in all health facilities through certification and could at a later stage fulfil an accreditation function.

The Health Professions Council of South Africa, which is under new leadership, is currently taking steps to rectify the problems uncovered by the Ministerial Task Team's report.

Furthermore, quality improvement efforts have been prioritised and are viewed as a precondition to the successful implementation of the National Health Insurance.

8.2.2. MEDICAL MALPRACTICE SYSTEM – STEPS TAKEN TO IMPROVE SAFETY

Unfortunately, recent developments related to the South African malpractice system have been less positive in terms of patient safety. Discussions surrounding reform

have mostly been driven by financial concerns. There are indications that conventional liability-limiting reforms are receiving serious consideration.¹⁹¹

These reforms will make it more difficult for injured patients to obtain redress, with little-associated benefit.

Changes to the malpractice system, that would make it more accessible and efficient, have not received much attention. Court-annexed mediation is, however, currently being piloted in the lower courts and could be a promising alternative to litigation.

Changes to the system to enhance incentives for improved care and promote patient safety have received little to no attention.

8.3. WHAT FURTHER STEPS COULD BE TAKEN TO PROMOTE SAFETY?

8.3.1. HEALTHCARE SYSTEM – FURTHER STEPS TO PROMOTE SAFETY

Research and transparency surrounding medical errors and the incidence of adverse events are required. We cannot improve what we cannot measure.

Ensure that a regulatory framework that supports patient safety is implemented and enforced. The OHSC should remain independent and beyond reproach, the standards must be evidenced-based and set at appropriate levels. The OHSC is collaborating with regulators in other countries in this regard. The OHSC is said to be working with the Care Quality Commission in the UK and will hopefully gain insight from their experience and the changes made in the aftermath of Mid Staffordshire.

Once the OHSC is up and running, it could be useful to have it independently assessed and benchmarked from time to time (every 5-10 years), to ensure that it functions according to international best-practices. For instance, the International Society for

¹⁹¹ Commission (2017) 1; Motsoaledi (2015) 8 *S Afr J BL* 4; Motsoaledi “Declaration Medico-Legal Summit” (2016) 1; Motsoaledi, *The real reason SA’s doctors won’t deliver your baby-Bhekisisa*.

Quality in Health Care, or a similar organisation could assist in such an exercise. External accreditation of facilitates could also be beneficial. These proposals would provide an added layer of accountability.

The Health Professions Council of South Africa, as a quasi-external regulator (with several characteristics of self-regulation), could also play a more prominent role in the promotion of safe care. The Council has wide-ranging powers, which could be better harnessed to improve patient safety. With its authority and influence over education, training, registration and professional misconduct, it could have a significant impact.

The Council must ensure that its 'Continuing Professional Development' programme consists of targeted interventions, that are able to realistically improve the care provided. Additional training and competency tests could also be considered.

It is ideally situated to receive complaints from the public, which can then be translated into meaningful learning opportunities and improvement strategies. Transparency surrounding complaints should be emphasised to foster public trust in its processes.

Reporting and peer review should be encouraged so as to allow the Council to proactively monitor and assess competence. Problematic providers should be identified before they are able to cause harm. These practitioners could then be compelled to enrol in training programmes and undergo recertification processes to protect the safety of patients.

A concerted effort must be made by all stakeholders and leaders to foster a safety culture in healthcare establishments. A safety culture encourages openness, transparency and candour around errors.¹⁹² This requires the existence of a just culture, where honest errors can be freely reported and openly discussed, without fear of disciplinary action, in order to learn from them. Not only should errors be reported, but harmful errors should be disclosed to patients. As an ethical imperative. This may require that providers receive additional training in how to deal with and support injured patients. Patients may require an explanation, apology, or the reassurance that steps

¹⁹² Great and Department (2015); OECD "OECD Reviews of Health Care Quality Caring for Quality in Health Lessons Learnt from 15 Reviews of Health Care Quality" (2017) 84.

will be taken to prevent future reoccurrence. Where appropriate, an offer of compensation or redress should be made.

A just culture converges at the intersection of patient safety and liability and provides the opportunity to secure real accountability. Communication-and-resolution programmes could prove to be an ideal mechanism with which to merge safety and liability if implemented sincerely it also allows for a transition from retributive to restorative justice.¹⁹³

Kachalia *et al.* describe CRPs as follows:

‘These programs promise open discussion with injured patients about what occurred in which an appropriate apology and an explanation of what is known about the cause are communicated, regardless of whether the injury is determined to have been caused by error. When the hospital (in collaboration with its insurer) determines the standard of care was not met, the programs proactively offer fair compensation without waiting for the patient to file a malpractice claim. When the care was reasonable, the institution affirms to the patient and family its commitment to stand behind and to defend the involved providers should a malpractice claim be filed.’¹⁹⁴

CRPs are a drastic departure from traditional risk management practices, as such many feared that these programmes would significantly increase liability and litigation costs. Early results show that this has not been the case, CRPs have managed to provide compensation to more injured patients, whilst reducing litigation costs and claims.¹⁹⁵ CRPs have also created an environment conducive to patient safety. Similar programmes should be piloted to determine whether and how they can be translated

¹⁹³ Mentioned above in paragraph 7.3.1.

¹⁹⁴ Kachalia *et al.* (2016) 133 *Circulation* 661.

¹⁹⁵ Kachalia *et al.* (2010) 153 *Ann Intern Med* 213; Mello *et al.* (2014) 33 *Health Aff (Millwood)* 20; Mello *et al.* (2014) 33 *Health Aff (Millwood)* 30; Sage *et al.* (2014) 33 *Health Aff (Millwood)* 11; Gallagher *et al.* (2016) 51 *Suppl 3 Health Serv Res* 2569; Mello *et al.* (2016) 51 *Suppl 3 Health Serv Res* 2550; Mello *et al.* (2016) 51 *Suppl 3 Health Serv Res* 2583.

to our local context.¹⁹⁶ It could perhaps be attempted at an academic hospital, with the support of specially trained staff and a conditional grant from the national health department.

8.3.2. MALPRACTICE SYSTEM – FURTHER STEPS TO PROMOTE SAFETY

Reforms to the malpractice system should not come at the expense of injured patients' rights. The impact of malpractice on the injured patient and the significant difficulties faced in obtaining compensation necessitates that the complex debates regarding reforms be approached with the utmost regard for patients who have suffered harm. It is perhaps time to reconsider the role of the compensation and liability system as it relates to patient safety.

Innovative reforms, that seek to address the weaknesses of the malpractice system and simultaneously improve patient safety, have emerged in recent years. Enterprise liability, safe harbours for evidence-based practice guidelines, health courts and administrative compensation systems, have received particular attention from scholars and policymakers.¹⁹⁷ The evidence base for some of the innovative reforms is still very limited. However, promising results from the ARHQ demonstration projects have shown that these reforms merit further investigation.¹⁹⁸

More evidence is available for administrative compensation schemes.¹⁹⁹ Several

¹⁹⁶ Policymakers can support the adoption of CPRs by enacting laws, which protect apologies and disclosures from being admissible as evidence of an admission of fault during trial.

¹⁹⁷ Kachalia et al. (2008) 66 *Soc Sci Med* 387; Kachalia et al. "Greatest impact of safe harbor rule may be to improve patient safety, not reduce liability claims paid by physicians." *Health Aff (Millwood)* (2014) 33 59; Mello et al. (2014b) 312 *JAMA* 2146.

¹⁹⁸ (AHRQ) (2017) 1.

¹⁹⁹ Kachalia et al. "Beyond negligence: avoidability and medical injury compensation" *Social science & medicine* (2008) 66 387; Mello et al. "Administrative compensation for medical injuries: lessons from three foreign systems." *Issue Brief (Commonwealth Fund)* (2011) 14 1; Kassim et al. "Compensating Cerebral Palsy Cases: Problems in Court Litigation and the No-Fault Alternative" *Med. & L.* (2015) 34 335; Vandersteegen et al. "The impact of no-fault compensation on health care expenditures: An empirical study of OECD countries" *Health Policy* (2015) 119 367; Dickson et al. "No-fault compensation schemes: A rapid realist review" (2016); Cardoso et al. "Evaluative reports on medical malpractice policies in obstetrics: a rapid scoping review" *Systematic Reviews* (2017) 6 181.

countries have adopted administrative compensation schemes (voluntary and mandatory) as an alternative to malpractice litigation. These schemes are often grouped under the blanket term of ‘no-fault’, but there are large variations in their compensation criteria and operations.

The New Zealand and Scandinavian schemes have attracted the most attention and are often discussed as if they are synonymous. This is certainly not the case, for instance, in New Zealand, the tax-funded scheme (managed by the Accident Compensation Corporation) comes the closest to true ‘no fault’, having adopted an ‘unexpected treatment-related injury’ standard.²⁰⁰ Their scheme also replaces the patient’s right to file a civil suit. Whereas in Sweden the scheme is insurance-based, an ‘avoidability’ standard is applied and patients retain the right to file a claim in tort.²⁰¹

Administrative schemes, in diverse forms, have seen somewhat of a resurgence in recent years, France, Belgium, Germany, Poland, Japan, India, Mexico and Wales

²⁰⁰ Miller “An analysis and critique of the 1992 changes to New Zealand’s accident compensation scheme” *Md. L. Rev.* (1993) 52 1070; Weiler “The case for no-fault medical liability” *Md. L. Rev.* (1993b) 52 908; Davis et al. “Compensation for medical injury in New Zealand: does “no-fault” increase the level of claims making and reduce social and clinical selectivity” *Journal of Health Politics, Policy and Law* (2002) 27 833; Davis et al. “Preventable in-hospital medical injury under the “no fault” system in New Zealand” *Quality and Safety in Health Care* (2003) 12 251; Bismark et al. “Accountability sought by patients following adverse events from medical care: the New Zealand experience” *Canadian Medical Association Journal* (2006) 175 889; Bismark and Paterson “No-fault compensation in New Zealand: harmonizing injury compensation, provider accountability, and patient safety” *Health Affairs* (2006) 25 278; Wallis and Dovey “No-fault compensation for treatment injury in New Zealand: identifying threats to patient safety in primary care” *Quality and Safety in Health Care* (2011) bmjqs; Gibson “Is It Time to Adopt a No-Fault Scheme to Compensate Injured Patients” (2016); Moore and Mello “Improving reconciliation following medical injury: a qualitative study of responses to patient safety incidents in New Zealand” *BMJ Qual Saf* (2017) bmjqs.

²⁰¹ Danzon “The Swedish patient compensation system: lessons for the United States” *Journal of Legal Medicine* (1994) 15 199; Danzon “The Swedish patient compensation system: Myths and realities” *International Review of Law and Economics* (1994) 14 453; Pukk-Härenstam et al. “Analysis of 23 364 patient-generated, physician-reviewed malpractice claims from a non-tort, blame-free, national patient insurance system: lessons learned from Sweden” *Postgraduate medical journal* (2009) 85 69; Öhrn et al. “What can we learn from patient claims? A retrospective analysis of incidence and patterns of adverse events after orthopaedic procedures in Sweden” *Patient safety in surgery* (2012) 6 2.

have all implemented schemes that provide an alternative route to compensation.²⁰²

The schemes may hold benefits for patient safety.²⁰³ As discussed in the previous chapter, patient safety was at the forefront of the UK's NHS Redress Scheme, unfortunately, the scheme has been left to gather dust in the statute book.²⁰⁴ Wales have adopted their own version of the scheme, called 'Putting Things Right' and Scotland is currently considering a comprehensive no-fault scheme.²⁰⁵

Patient safety is on the agenda again in the UK and is the driving force behind many of their current initiatives.²⁰⁶ There is now a strong focus on improving patient outcomes and reducing incidents of harm, in order to manage the rising cost of litigation. This reasoning underlies the concerted approach adopted by the NHS. I believe South Africa can learn from and benefit from a similar approach.

The NHS Litigation Authority, which handles clinical negligence claims against the health service, has been relaunched as NHS Resolution, with a new mandate.²⁰⁷ It will now strive to resolve cases earlier and learn lessons, which will be disseminated throughout the healthcare system, in order to reduce future mistakes. NHS Resolution will no longer be confined to claims management, it will instead also intervene early and provide support to the patient, family and staff.²⁰⁸

²⁰² Cortez "A medical malpractice model for developing countries" *papers.ssrn.com* (2011); Dyer (2012) 345 *BMJ: British Medical Journal (Online)*; Dyer (2013) 347 *BMJ: British Medical Journal (Online)*; Oliphant and Wright (2013) 523; Barbot et al. "'No-fault' compensation for victims of medical injuries. Ten years of implementing the French model." *Health Policy* (2014) 114 236.

²⁰³ Studdert and Brennan "No-fault compensation for medical injuries: the prospect for error prevention" *Jama* (2001) 286 217; Mello et al. "'Health courts' and accountability for patient safety" *The Milbank Quarterly* (2006) 84 459; Öhrn et al. (2012) 6 *Patient safety in surgery* 2.

²⁰⁴ Donaldson (2003); Farrell and Devaney "Making amends or making things worse? Clinical negligence reform and patient redress in England" *Legal Studies* (2007) 27 630. NHS Redress Act (2006 c. 44).

²⁰⁵ Dyer (2012) 345 *BMJ: British Medical Journal (Online)*; Stephen et al. "A study of medical negligence claiming in Scotland" (2012); Rosser "The Welsh NHS Redress arrangements—Are they putting things right for Welsh patients" *Clinical Risk* (2014) 20 144.

²⁰⁶ Hunt "From a Blame Culture to a Learning Culture" (2016) 1.

²⁰⁷ "NHS Resolution" <https://resolution.nhs.uk>.

²⁰⁸ Great and NHS "NHS Resolution Annual report and accounts 2016/17 (NHS Resolution is the operating name of the NHS Litigation Authority)" (2017).

NHS Resolution will attempt to reduce legal costs by keeping cases out of formal court and deploying alternative models for dispute resolution. However, to save money, where no compensation is due claims will be robustly defended. Their positioning gives them increased insight into what drives the costs of harm and will allow them to develop interventions to respond to these in partnership with others in the health system.²⁰⁹

The current system for delivering compensation can be costly and could work better. Legal costs are disproportionate and cases are often pitched into litigation prematurely. High numbers of claims are brought where compensation is not recovered and claims for damages can be excessive, resulting in the parties taking polarised positions.

We know that claims are often pursued in search of an explanation or acknowledgement that something has gone wrong. Patients and healthcare staff do not want to find themselves in court proceedings, particularly when care is ongoing. Our experience of mediation and other forms of ADR is that a more effective solution can be found when the court process is set aside, and the ambiguity and range of views which often exists can be properly explored.²¹⁰

NHS Resolution will work together with healthcare providers to provide education and practical support on how to be more open when an incident occurs so that those who are harmed receive a prompt and transparent explanation and an assurance that lessons have been learned. It will work together with the healthcare system to create a just culture, where errors can be openly discussed.

A network of peer support for healthcare staff involved in an incident or claim will be established. Legal costs will be targeted and overcharging by claimant lawyers will be confronted. A cultural shift will take place within the organisation to ensure that a sympathetic, personalised approach and tone is taken in all cases.

²⁰⁹ NHS Resolution will regularly publish reports, such as this one, which examines cerebral palsy claims: Fellow “Five years of cerebral palsy claims: A thematic review of NHS Resolution data” *NHS Resolution* (2017).

²¹⁰ Resolution (2017).

NHS Resolution also plans to build an understanding of what constitutes an effective response to an incident (candour, investigation and learning) in conjunction with the Healthcare Safety Investigation Branch (which, is another essential component of the concerted effort to improve safety).²¹¹ Evidence on high-frequency claims and effective preventative strategies will also be distributed.

The South African government should consider establishing a similar entity, with similar objectives. The response to malpractice claims has often been disjointed. Claims management has been poor, costly delays are common. Attorneys for the state often do not have the necessary experience in this complex area of the law. They are also not given the opportunity to focus solely on malpractice in order to develop specialised expertise. Settlements, early interventions and alternative resolution mechanisms have not been utilised. Injured patients have received no support and have been neglected even when they had *prima facie* valid claims. Responses to claimants have been adversarial, possibly contributing to ‘frustration’ claims. Claims have not been used to foster learning. Coordination between stakeholders in the legal and healthcare systems has not been pursued. In addition, there is a lack of a clear overriding policy and mandate. The absence of a clear policy and strategy has very likely contributed significantly to the current litigation ‘crisis’.

Similar to South Africa, brain injuries at birth and maternity claims, have also been the single biggest driver of claims cost in the NHS. These claims are receiving special attention. NHS Resolution has established a specialist early intervention team to focus on these incidents to try to identify cases earlier, intervene quickly, and provide support to family and staff.²¹² It will do so, with the help of an early notification reporting scheme. They also plan to work closely with the Royal Colleges, NHS Improvement and the Care Quality Commission (similar to our OHSC), to share the insights they gather and promote learning to prevent future injuries and claims.

²¹¹ Authority (2014); Commission “Learning, Candour and Accountability: A Review of the Way NHS Trusts Review and Investigate the Deaths of Patients in England” (2016); Tingle “Learning, Candour and Accountability: reviews into patient deaths.” *Br J Nurs* (2017) 26 186.

²¹² Dyer (2017) 358 *Bmj* j4134; Dyer (2017) 356 *BMJ* j1181; Dyer (2017) 356 *BMJ* j1503.

As part of the concerted effort to tackle patient safety and liability, the UK government has also proposed a new voluntary administrative compensation scheme.²¹³ The ‘Rapid Resolution and Redress Scheme’ for avoidable birth injuries.²¹⁴

The scheme will have three main objectives:

- Reduce the number of severe avoidable birth injuries by encouraging a learning culture;
- Improve the experience of families and clinicians when harm has occurred; and
- Make more effective use of NHS resources

The scheme is based on a similar one adopted by Sweden in 2007. Sweden implemented an initiative called ‘The Safe Delivery Care Project’, which led to a reduction of claims for severe neurological birth injury.

The scheme consists of two stages:

Stage One focusses on improving investigations into severe avoidable birth injuries and ensuring learning is shared and implemented to reduce future harm.

Stage Two is concerned with ensuring families are provided with ongoing support and compensation, without the need to bring a claim through the courts.

The relationship between Stages One and Two is considered crucial for the success of the scheme. Evidence from Sweden suggests that the non-adversarial delivery of compensation in Stage Two is critical to the creation of an effective learning culture in Stage One.²¹⁵

An additional component in the UK’s concerted effort is the Healthcare Safety

²¹³ “Rapid resolution and redress scheme for severe birth injury” Department of Health (2017-03-02) <https://www.gov.uk/government/consultations/rapid-resolution-and-redress-scheme-for-severe-birth-injury>.

²¹⁴ Macleod “The National Maternity Review’s Rapid Resolution and Redress scheme model: A comparison with other worldwide compensation schemes” *Clinical Risk* (2016) 22 61; Tingle “Reforming the approach to clinical negligence in the NHS” *BJON British Journal of Nursing* (2017) 26 474.

²¹⁵ England “Better births: improving outcomes of maternity services in England. A five year forward view for maternity care” *NHS England, UK* (2016).

Investigation Branch (HSIB), which will operate independently from other regulators to investigate patient safety incidents throughout the entire system without apportioning blame or accountability. This is an approach that has been adopted in aviation with great success. As discussed in a previous chapter, the regulatory framework for aviation has developed to include support for safety improvement and the establishment of a just culture. Healthcare could very well benefit from the implementation of similar provisions, it seems that the HSIB is a step in that direction.

9. SUMMATION

The malpractice system has traditionally been the point at which the law and medical errors converge. This confluence and the recent regulatory and policy developments have been examined to assess whether it is possible to reconcile patient safety and liability. It is submitted that, by adopting a systems approach to error (as employed in other high-risk industries), inclusive of a safety/just culture, the healthcare and malpractice systems can be better aligned to foster prospective collective accountability. This approach, in turn, would not only create an environment conducive to safer care but could also allow for the application of processes rooted in restorative justice theory, that might assist in the healing of harm.

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