An analysis of medical risk inspections in the context of the Office of Health Standards Compliance (OHSC).

by

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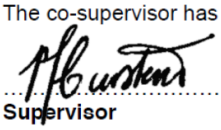

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Summary

Section 27 of the Constitution of the Republic of South Africa states, "everyone has a right to have access to healthcare services" and puts an obligation to the state to "take reasonable legislative measures within its available resources, to achieve the progressive realisation" of this right.

One of the steps taken by the state, for the progressive realisation of this right was the establishment of the Office of Health Standards Compliance (OHSC), as an independent entity and regulator in the healthcare sector, "to protect and promote the health and safety of users of health services." The OHSC implements its mandate by conducting annual health establishment inspections to monitor and enforce compliance with norms and standards prescribed by the National Core Standards (NCS).

This dissertation focuses on the Patient Safety, Clinical Governance and Care domain of the NCS. This domain is interrogated from a medical risk perspective and advances a proposal that the OHSC's mandate would be strengthened by adding operationally focused medical risk inspections when conducting their inspections. Using an integrated multi-layered approach, the proposal is built by using various legal sources, such as the Constitution, various legislations such as the National Health Act, the National Health Insurance Bill, case law, published reports and articles.

The dissertation highlights the aetiology of patient harm, the magnitude of harm and the ineffective role of medical malpractice litigation in improving patient safety. The ineffectiveness of tort law reforms has been discussed and likened to treating symptoms instead of root causes of patient harm. Blame culture of patient safety and reporting mechanisms are also discussed as areas that are also ineffective in promoting patient safety. Case law is used to provide practical examples of patient harm and motivation for an operationally focused medical risk standard.

It concludes by submitting a proposed medical risk inspection standard to complement domain two of the NCS for use by OHSC when conducting annual health establishment inspections.

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1 Chapter 1: Introduction

1.1 Statement of the problem

The Office of Health Standards Compliance (OHSC) was established in terms of the National Health Act 61 of 2003 (NHA),[1] as an independent entity and regulator in the healthcare sector.[2] The objective of the OHSC is to improve safety for people utilising health services in the country.[3] The safety is envisaged to be accomplished through monitoring and enforcing compliance by health establishments. There are set norms and standards that health establishments need to comply with, these norms and standards are prescribed by the department of health. The office is also responsible for receiving, investigating and resolving patient complaints in a fair and swift manner.

In February 2011, the National Department of Health published the National Core Standards (NCS), the purpose of which was to standardise quality health services for all healthcare facilities in the country. This standardisation assists the OHSC with ensuring that it is consistent when monitoring and enforcing compliance, and is using a standardised approach during the assessments.[4]

The NCS sets the benchmark of quality care for health facilities in the country and the OHSC uses these standards for service delivery monitoring.'[5] The NCS has seven domains, the first three being, "Patient Rights; Patient Safety, Clinical Governance and Care; and Clinical Support Services are those domains that are involved directly with the core business of the health system of delivering quality healthcare to our users or patients."[6]

These inspections are indispensable tools in promoting patient safety. They, however, need to be strengthened from a medical risk perspective. The purpose of this strengthening is to identify medical risks that endanger patients and to recommend measures that need to be implemented to reduce preventable harm to patients.

[1] National Health Act 61 of 2003.
[2] Office of Health Standards Compliance 'Annual inspection report' 2018/2019.
[3] "Section 78 of the National Health Amendment Act 12 of 2013 state the objects of the office as 'to protect and promote the health and safety of users of health services by:
- Monitoring and enforcing compliance by health establishments with norms and standards prescribed by the minister with relation to the national health system and
- Ensuring consideration, investigation and disposal of complaints relating to non-compliance with prescribed norms and standards in a procedurally fair, economical, and expeditious manner."

[4] Department of Health 'National Core Standards for Health Establishments in South Africa' (2011).
[5] As above.
[6] As above.

1.2 Rationale of the Study

In 2015 while addressing a medicolegal summit held in Pretoria, the previous South African National Minister of Health stated "litigation against healthcare providers has reached crisis levels. The nature of the crisis is that our country is experiencing a sharp increase, actually, an explosion in medical malpractice litigation."[7] On the same breath Africa Health Exhibition stated in 2018 that "within the public health sector, already stretched budgets cause provincial health departments to struggle with their obligation to provide healthcare services, while still having to pay out the billions in claims against them."[8]

This study advocates for comprehensive medical risk inspections to be included by the OHSC when conducting their annual health establishments inspections. It is envisaged that this inclusion will enhance patient safety and reduce medical negligence litigations.

1.3 Significance of the Study

It is envisaged that the study will develop and recommend a medical risk standard that can be incorporated in domain two of the NCS. It is anticipated that the incorporation of this standard in the OHSC inspections will bring the OHSC closer to achieving its objective of improving safety for people utilising healthcare facilities in the country.

1.4 Methodology

In conducting the study an integrated multilayered approach will be utilised. This approach takes the form of using various legal sources, such as, the provisions of the Constitution of the Republic of South Africa as the supreme law, relevant legislations, the applicable principles of common law and case law where relevant, published reports and articles.

The OHSC derives its mandate primarily from the NHA, however there are other laws that support the attainment of its mandate. The legislative framework that gives and supports the OHSC to meet its mandate will be analysed from a medical risk perspective.

[7] 'SA's Shocking Medical Malpractice Crisis' Health24, available at https://www.news24.com/health24/News/Public-Health/SAs-shocking-medical-malpractice-crisis-20150309 accessed on 12 February 2021.

[8] 'Medical malpractice litigation: Undermining South Africa's health system' available at https://www.africahealthexhibition.com/en/media/news/Medical-malpractice-litigation-Undermining-South-Africas-health-system.html, accessed on 12 February 2021.

Literature on medical malpractice and patient safety will also be analysed. An analysis of relevant medical negligence case law will be conducted, specifically focusing on matters relevant to patient safety.

1.5 Limitations of the Study

Medical risks permeate all the NCS domains, it is not limited to the "Patient safety, Clinical governance and Care domain". The limitation of this study is that it is confined to domain two of the NCS. This limitation is brought about by the fact that this study is a mini dissertation.

1.6 Ethical Implications of the Study

The study has no ethical implications. The analysis that will be conducted will use publicly available information. The study will not make use of any confidential or private data.

1.7 Structure of this Study

1.7.1 Chapter 1: Introduction to the Study

This chapter introduces the entire study. It outlines the mandate of OHSC and the application of the NCS in fulfilling this mandate through conducting annual health establishments inspections. The chapter highlights the areas where the current OHSC inspections can be strengthened by addition of medical risk inspections. The chapter advocates for the development of a medical risk standard that should be utilised by the OHSC in their annual health establishment inspections. It highlights the rationale for conducting such a study and the envisaged contribution to the body of knowledge regarding protecting and promoting safety of users of health establishments. A summary of the various chapters that make up the study are included in this chapter.

1.7.2 Chapter 2: The OHSC Legislative Framework

This chapter elucidates the important role OHSC plays in strengthening the South African health system. It demonstrates that the OHSC's mandate is not only derived from the National Health Amendment Act and the National Core Standards but there are several other statutes that strengthen the mandate. The discussion of these statutes is not exhaustive, but it adequately demonstrates that the role OHSC plays starts from the Constitution right down to various policy documents. The focus of the chapter is on patient safety aspects of the mandate.

1.7.3 Chapter 3: Medical malpractice and patient safety

This chapter describes the relationship between patient safety and medical malpractice litigation. It begins with definitions of patient safety concepts to ensure a common patient safety language. The aetiology and magnitude of patient safety is described. In the aetiology, the various areas where patients are harmed in health establishments are described. The chapter then presents quantification of patient safety, describing the number of patients who are unnecessarily harmed while receiving health services. The effectiveness of medical malpractice in compensating patients that are harmed and in improving patient safety is also presented.

1.7.4 Chapter 4: Patient Safety: The elephants in the room

Despite the focus on patient safety over decades, there is no demonstrable evidence that medical errors have reduced, and patients are safer. This chapter discusses prevalent approaches that are used to curb medical negligence and weaknesses in patient safety reporting measures. The chapter discusses three approaches as elephants in the room.

1. The effectiveness of tort law reform measures in decreasing healthcare costs and improving health outcomes.
2. The practice of apportioning patient harm errors to individuals rather than on the system.
3. Utilising unidimensional reporting mechanisms, such as incident reports for reporting and managing patient harm and adverse events, rather than a multidimensional approach.

1.7.5 Chapter 5: Patient safety: Lessons from medical negligence case law

This chapter provides an analysis of various medical negligence cases. The intention of the analysis is, through case law, to demonstrate areas within health establishments where medical risks arise, with the aim of highlighting areas of focus for medical risk inspections and audits. Most cases that are analysed are South African public sector cases.

1.7.6 Chapter 6: Proposed medical risk inspections standard

Informed by the discussions and findings from the previous chapters, this chapter provides a recommended medical risk standard that can be incorporated in domain two of the NCS. It is anticipated that the standard could be utilised by the OHSC when conducting their annual health establishments inspections.

2 Chapter 2: The OHSC legislative framework

2.1 Chapter Introduction

This chapter elucidates the important role OHSC plays in strengthening the South African health system. It demonstrates that the OHSC mandate is not only derived from the National Health Amendment Act and the National Core Standards but, there are several other statutes that strengthen the mandate. The discussion of these statutes is not exhaustive, but it adequately demonstrates that the role OHSC plays starts from the Constitution right down to various policy documents. The focus of the chapter is on patient safety aspects of the mandate.

2.2 The OHSC Mandate

The OHSC was established "to protect and promote the health and safety of healthcare users."[9] One of the methods the OHSC uses to achieve its mandate is through "monitoring and enforcing compliance by health establishments to the NCS and in investigating complaints."[10]

The OHSC plays a crucial role in the improvement of quality of healthcare delivery in South Africa. The health system is a complex system with areas that are interdependent. A systems approach is therefore required to ensure safety of healthcare users. It is for this reason that the OHSC is guided by the NCS in implementing its mandate. The role of the OHSC is influenced by other legislations not just the NHA and the NCS.

2.3 The Legislative Framework

2.3.1 The Constitution

The Constitution, as the supreme law of the Republic of South Africa, affirms the values of human dignity and safety for the citizens.[11] The Constitution includes the Bill of Rights that has provisions related to health. Section 27 states, "everyone has a right to have access to healthcare services."[12] The Constitution also puts an obligation to the state to "take reasonable legislative and measures within its available resources, to achieve the progressive realisation" of this right.[13]

The OHSC is one of the measures used by the state for the progressive realisation of access to health. The mandate of the OHSC therefore ensures that the accessed health services are safe and of good quality.

[9] Office of Health Standards Compliance (n 2 above).
[10] As above.
[11] The Constitution of the Republic of South Africa, 1996.
[12] S 27(1)(a).
[13] S 27(2).

There are other relevant sections of the Constitution that supports the OHSC mandate, such as the right to dignity[14], this right is imperative in the context of the role OHSC plays because one of the commonest complaints in the public sector is around the way patients are treated when visiting healthcare facilities. The right to life[15] is also an important right that needs to be protected and if a healthcare user dies due to unnatural circumstances the OHSC can be called to play a role in investigating the cause of death.

When patients visit healthcare facilities they expect to be treated with dignity and to have the right to decide on all matters concerning their health and the offered or suggested treatment. This is the right to bodily and psychological integrity[16] that ensures that patients are not subjected to treatments without their informed consents. Harm in healthcare environment does not only come from the clinical setup, but it can also come from the infrastructure, equipment, medical waste, etc. It is the responsibility of the OHSC that patients are not exposed to harm when they are in a healthcare facility. This responsibility is embedded in section 24(a) of the Constitution.[17]

The various sections of the Constitution as outlined above, reinforce the important role OHSC plays in promoting and protecting health and safety of patients. Compliance by healthcare facilities to the provisions of the various sections of the Constitution will assist in the progressive realisation of good quality and safe healthcare provision in South Africa.

2.3.2 The National Health Act

The objective of the National Health Act is "to regulate the national health and to provide uniformity in respect of health services across the nation."[18] Amongst others, the objectives include "protecting, respecting, promoting and fulfilling the rights of the people of South Africa to the progressive realisation of their constitutional right to access to health care services"[19] and to protect them from "an environment that is not harmful to their health or wellbeing."[20] The two highlighted objectives of the NHA are derived directly from Sections 27(2) and 24(a) of the Constitution.

[14] Section 10 "Everyone has inherent dignity and the right to have their dignity respected and protected."
[15] Section 11 "Everyone has the right to life."
[16] Section 12(2) "Everyone has a right to bodily and psychological integrity, which includes the right – (a) to make decisions concerning reproduction; (b) to security in and control over their body; and (c) not to be subjected to medical or scientific experiments without their informed consent."
[17] Section 24(a) "Everyone has the right to an environment that is not harmful to their health or wellbeing."
[18] Act 61of 2003.
[19] S 2(c)(i).
[20] S 2(c)(ii).

Section 18(1) states that "any person may lay a complaint about the manner in which he or she was treated at a health establishment and have the complaint investigated."[21] This section of the NHA strengthens one of the objectives of the OHSC which is "ensuring consideration, investigation and disposal of complaints relating to non-compliance with prescribed norms and standards. …"[22]

Section 47(1) states that "all health establishments must comply with the quality requirements and standards prescribed by the Minister after consultation with the National Health Council."[23] "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 way users are accommodated and treated."[24]

Section 47 clearly expresses that health establishments must provide quality and safe services to health users. The enforcement of this requirement is stated in Section 47(c) as "the Office of Standards Compliance and the inspectorate for health establishments must monitor and enforce compliance with the quality requirements and standards contemplated in subsection (1)."[25]

One of the cornerstones and foundational principle of provision of health services, is the doctrine of primum non nocere. This doctrine is generally applied in the clinical setup, rather than the overall service provided by a health establishment. It is however applicable to all services, including provision of safe environment, pharmacy services, nutritional services, medical waste management, etc. Patient autonomy is an ethical principle and a human right that is prescribed by section 12(2) of the Constitution. Disregarding patient autonomy can be regarded as doing harm to the patient. The OHSC has an obligation to monitor and enforce compliance to 'doing no harm' to patients.

With regards to patient autonomy, the NHA states clearly that patients must be fully informed of the kind of illness they suffer from[26], including the treatment options available to them. For each treatment option the benefits, risks and possible consequences must be explained in an understandable language.

[21] S 18(1).
[22] Office of Health Standards Compliance (n 2 above).
[23] S 47(1).
[24] S 47(2).
[25] S 47(3).
[26] Section 6(1) "Patients must be informed of their health status, range of available diagnostic procedures and treatment options, benefits, risks, costs and consequences associated with each option and the right to refuse health services."

Patient autonomy is generally accepted in the clinical setup as the informed consent process. Providing treatment to patients without the informed consent can be interpreted as doing harm to the patient. In a medical risk standard, the OHSC will be required to inspect the informed consent processes used by the health facility.

2.3.3 The National Health Insurance Bill (NHI Bill)

The South African government embarked on a process of transforming the national health system by proposing an implementation of National Health Insurance (NHI). The objective of the NHI is to achieve universal health coverage for all citizens irrespective of their socio-economic status, with no risk of financial hardship. The NHI is essentially a health financing system that pools funds to provide assess to quality health services.[27]

Section 6 of the NHI Bill states – a user of healthcare services purchased by the fund is entitled to receive quality healthcare services, to be treated with professionalism, to make reasonable decisions about his or her healthcare.[28] The OHSC plays an important role in the implementation of the NHI. To be a service provider to the NHI Fund, a health establishment needs to be accredited[29] and the accreditation and registration status of the providers must be monitored.[30] Section 39(2) states "in order to be accredited by the Fund, a healthcare service provider or health establishment, as the case may be, must: *(a)* be in possession of and produce proof of certification by the OHSC and proof of registration by a recognised statutory health professional council, as the case may be."[31]

2.3.4 Policy on quality in healthcare for South Africa

This policy document sets out the government's objective of assuring quality in the provided healthcare. To achieve quality healthcare, health facilities are expected to measure services rendered to patients and commit to improve the standard of care provided.[32]

The significance of this document is in its acknowledgment of exposure of patients to significant levels of medical error when it states that "significant levels of error occur with healthcare, which often result in injury to patients.

[27] Office of Health Standards Compliance 'Annual Performance Plan' 2020/2021.
[28] Bill 11 of 2019 sec 6.
[29] S 7(e).
[30] S 10(1)(l).
[31] S 39(2)(a).
[32] Department of Health 'Policy on quality in healthcare for South Africa' 2007.

Healthcare and health status can be improved by way of improving patient safety and reducing the level of error in healthcare delivery."[33] Based on this policy document, the OHSC is expected to select standards that are relevant to the level of care provided by that health facility and to monitor and inspect the quality of services rendered against those standards.

2.3.5 The patient's rights charter

The national department of health launched the patients' rights charter. This charter is an attempt by government to improve access to health services by patients as guaranteed in the Constitution. The charter sets a "common standard for achieving the realisation of the right to access health services."[34]

The patient's charter amongst others, lists rights such as, "a right to a healthy and safe environment, a right to participate in decision-making on matters affecting one's health, right of access to health services, a right to be given full and accurate information about the nature of one's illness, a right to complain about healthcare services and to have such complaints investigated and to receive full response on such investigation."[35]

Core to the patient's rights charter is patient safety. The mandate of the OHSC through its monitoring, compliance inspections and complaints functions must ensure that the patient's rights charter is effectively realised and the patients are safe.

2.4 Conclusion

Utilising a multi-layered approach, this chapter has illustrated that the OHSC's role is supported by various statutes. Various sections of The Constitution of the Republic of South Africa have been mentioned that demonstrate the alignment of the OHSC mandate with the Constitution. Sections within the National Health Act were also been mentioned, such as ensuring access to health services, complaints processes and ensuring respect for patient autonomy. These sections support the OHSC in protecting and promoting the safety of patients who are accessing health services. The accreditation, certification and compliance monitoring roles are emphasized in the NHI Bill. Reduction of exposure of users to medical errors, reduction of hazards and reduction of consequences of error are emphasised by the department of health's policy on quality in healthcare. This reduction is the function of the OHSC.

[33] As above.
[34] Department of Health 'National patients' rights charter' 1999.
[35] As above.

3 Chapter 3: Medical malpractice and patient safety

3.1 Chapter Introduction

This chapter describes the relationship between patient safety and medical malpractice litigation. It begins with definitions of patient safety concepts to ensure a common patient safety language. The aetiology and magnitude of patient safety is described. In the aetiology, the various areas where patients are harmed in health establishments are described. The chapter then presents quantification of patient safety, describing the number of patients who are harmed unnecessarily when receiving health services. The effectiveness of medical malpractice in compensating patients that are harmed and in improving patient safety is also presented.

3.2 Patient Safety

The International Classification for Patient Safety (ICPS) was proposed by the World Alliance for Patient Safety "to define, harmonize and group patient safety concepts into an internationally agreed classification in a way that is conducive to learning and improving patient safety across (health) systems."[36]

3.2.1 Definitions

In its attempt for standardisation of concepts and norms pertaining to patient safety, the ICPS developed the following definitions.[37]

> "Patient safety – is the reduction of risk of unnecessary harm associated with healthcare to an acceptable minimum."
>
> "Healthcare-associated harm – is harm arising from or associated with plans or actions taken during the provision of healthcare, rather than an underlying disease or injury."
>
> "A risk – is the probability that an incident will occur."
>
> "A patient safety incident – is an event or circumstance that could have resulted, or did result, in unnecessary harm to a patient."
>
> "An error – is a failure to carry out a planned action as intended or application of an incorrect plan."

[36] World Alliance for Patient Safety 'International classification for patient safety statement of purpose' (2008) – available at http://www.who.int/patientsafety/taxonomy/ICPS_Statement_of_Purpose.pdf accessed on 08 April 2021.
[37] World Health Organisation 'Conceptual framework for the international classification for patient safety Version 1.1: Final technical report' (2009).

The purpose of the NCS is to ensure that there is no contradiction or different definitions for what is meant by quality care within different health facilities in the country. The standardised definitions act as a guide for the public who uses health facilities and for the health facility employees at all levels.[38] The NCS does not have a definition of clinical risk nor a definition of patient safety incident, this implies that the standard against which the OHSC inspects is inadequate, because without clear standardised definitions, each establishment or inspector is left to use his or her own understanding of what clinical risk or incident is, and that may compromise the quality of inspections and by inference patient safety.

The ICPS definitions can therefore be foundational definitions that can be utilised by the NCS and OHSC in domain two to improve patient safety reporting, inspection and implementation of mitigation measures to improve patient safety.

3.3 Aetiology of unsafe patient care

Healthcare is rooted in the principle of primum non nocere. However, despite the best intentions to do no harm, regrettably sometimes healthcare interventions that are intended to help people do present harm to the patient.[39] In a healthcare facility harm can present in various forms, such as, hospital acquired infections, wrong diagnosis leading to wrong treatment, equipment or instrument failures and many other types of incidents. It is for this reason that patient safety needs to be prioritised by different health systems.

Patient safety incidents can be understood or viewed from two perspectives, system errors and/or individual errors. System errors are those "from flaws in the system of medical practice…through unavailability of medical records, confusing labelling of medications, long working hours, faulty equipment, etc."[40]

Individual errors "result from omissions or commissions due to (health professional's) lack of knowledge, skill or attentiveness, and is primarily responsible for them."[41] K Moodley describes individual errors to include, "failures to correctly identify a patient, failure to take adequate history, failure to make a correct diagnosis, failure to treat a patient and failure to keep good medical records, illegible or poor medical

[38] Department of Health (n 4 above).
[39] World Health Organization 'Patient safety in developing and transitional countries' (2011)
[40] K Moodley Medical Ethics Law and Human Rights a South African Perspective (2017).
[41] As above.

records, incorrect diagnosis and treatment, wrong site operation, using equipment without the necessary training, skill and experience."[42]

The individual errors described above should be interpreted from a perspective of understanding the complexity of health systems operations. The prima facie evidence could be that the error has been committed by an individual, however the root cause could be embedded within the system. In a healthcare setting the individual and the system cannot be easily separated, therefore blaming individuals for errors because the assumption might be that the individual was forgetful, weak or inattentive, overlooking that the underlying cause could be embedded on the work conditions which this individual works.[43] Therefore any healthcare incident should be assessed from a systems approach that focuses on the work conditions and endeavour to "build defences to avert errors or mitigate their effects."[44]

"Patient safety incidents arise from active failures and latent conditions."[45] In a healthcare environment, there are various people who are in direct contact with the patient, this includes healthcare professionals, porters transporting patients from one area to another, cleaners, caterers, etc. Unsafe acts committed by these people are known as active failures which could be in the form of mistakes made while doing their jobs. On the other hand, latent conditions are system driven, it is the environment where the individual operates. This environment could be inadequate equipment or instruments to fulfil the requirements of the job, time pressures to deliver the required services, shortage of skilled and experienced people or staff shortages in general, inadequate infrastructure and poor support from management or leadership of the health establishment.

Domain two of the NCS focuses on high level measures and the standard is generic. The assessment criteria for the standard includes inspecting the presence of protocols, guidelines and procedures. The deficiency of the inspection criteria is that it does not make a provision for assessing the operational aspects of the protocol, the guideline or the procedure. Patients are harmed at an operational level and therefore the standard would be enhanced by addition of operational aspects. It is in the operational space where the individual and the system interdepend. Errors committed by an individual could be because of system matters such as, long working hours, staff shortages, defective equipment, poor record keeping, etc. An operationally focused medical risk standard would enhance the inspections by OHSC.

[42] As above.
[43] J Reason 'Human Error Models and Management' (2000) British Medical Journal 320: 768-70.
[44] As above.
[45] As above.

3.3.1 The magnitude of unsafe patient care

The World Health Organisation (WHO) released an article highlighting the magnitude of unsafe patient care.[46] The report highlighted the magnitude of unsafe care due mostly to preventable medical accidents. Most unsafe patient care happen in the hospital set up than in outpatient environments. The risk of patient death in a hospital is estimated to be 1 in 300 in high income countries and the ratio in low-income countries can even be one in ten. Patients endure these accidents while receiving treatment. Unsafe patient care is estimated to be of the ten leading causes of death and disability in the world.

The type of harm experienced by the patients range from diagnostic errors[47] leading to patients being given incorrect medication, such as incorrect dosages, unclear instructions, or wrong prescriptions, these errors occur in about 5% of patients and 10% of patient deaths. Diagnostic errors account for up to 17% of harmful events in hospitals. All of these is avoidable harm to patients, that can be corrected through a systems approach to protecting and promoting safe patient care within health establishments. Eighty percent of harm taking place in hospitals is considered to have been preventable. The harm put extra strain on health systems because about 15% of total expenditure in a hospital could be attributed directly results of adverse events.

Surgical errors are considered to result in high rates of preventable deaths with up to 25% of patient harm resulting from unsafe surgical care procedures. Radiation errors incidents that involve overexposure, wrong patient, wrong site also count as high as 15 per 10000.

There are several other studies that demonstrate the magnitude of unsafe patient care.

- "Unsafe care is one of the top ten leading causes of death in the world."[48]
- "Unsafe healthcare accounts for more lives lost than either lung cancer (1.7 million), diabetes (1.6 million) or road injuries (1.4 million)."[49]
- "In 2013, over 420 million hospitalisations each year around the world resulted in nearly 43 million adverse events."[50]

[46] World Health Organisation '10 facts on Patient Safety' (2019). Available at http://www.who.int/features/fact files/patient_safety/en/index.html Accessed 20 April 2021.
[47] 'Diagnostic error is the failure to identify the nature of an illness in an accurate and timely manner.'
[48] National Academies of Science 'Crossing the Global Quality Chasm: Improving Health Care Worldwide' (2018). Available from: https://www.nap.edu/catalog/25152/crossing the-global-quality-chasm-improving-health-care worldwide Accessed on 24 April 2021.
[49] As above.
[50] AK Jha, et al 'The global burden of unsafe medical care: analytic modelling of observational studies. British Medical Journal (2013) 22(10):809–15.

This report by the WHO highlights the magnitude of unsafe patient care and patient harm happens at the coalface of treatment. In general, health establishments have clinical protocols, operational guidelines and procedures but patients continue to be harmed. Each patient safety incident needs to be investigated and mitigation measures need to be implemented to prevent recurrence. One of the approaches that can contribute to mitigation is proactive operational medical risk inspections and audits.

3.4 Medical malpractice litigation

Over the past few years there has been a significant rise in medical negligence claims in private and public sectors. According to the Medical Protection Society (MPS) "the cost of reported claims more than doubled over a recent 2-year period prior to 2013. Claims exceeding R1 million have increased by nearly 550% compared with those of 10 years ago, while claims valued at over R5 million have increased by 900% in the past 5 years."[51] When one considers the magnitude of unsafe care, as mentioned above, the significant rise in medical negligence claims is not surprising.

What does the rise in medical negligence claims imply? Does it imply that lawyers are hounding doctors and litigate at the drop of a hat? Does it mean patients have easy access to the litigation system? Does it mean there is increased patient activism to improve patient safety by using the legal system? Does it mean there is progressively poor doctor-patient relationships that patients resort to litigations to attain justice?

Answers to these questions are beyond the scope of this dissertation, however, is the rise in medical negligence claims a true reflection of the number of patients that are iatrogenically injured?

Taking into consideration the magnitude of unsafe patient care compared to the number of patient complaints, there are very few patients "that complain, file claims, or otherwise express dissatisfaction with care than the number who could."[52] The findings from a study by L Andrews confirmed that the majority of patients harmed do not take action against the healthcare professional of the hospital. In this study only 3.7% of patients made an enquiry regarding care they received. The total number of patients in this study was 1047.[53] They requested that their medical records be forwarded to themselves, lawyer of to another health practitioner, an inference was therefore made of a possible indicator of

[51] J Malherbe 'Counting the cost: The consequences of increased medical malpractice litigation in South Africa' (2013) South African Medical Journal. Vol. 103, No. 2.
[52] L Andrews 'Studying Medical Error in SITU: Implications for Malpractice Law and Policy' (2005) 54 De Paul Law Review 357.
[53] As above.

dissatisfaction. In the same study "five patients (less than half of 1%) sent letters of complaint to the president of the hospital, thirteen patients brought a claim."[54] Andrews further analysed 185 patients who experienced errors with serious effects and reported that "eight made a request for records, one wrote a letter of complaint and four instituted a claim."[55]

Baker refers to medical malpractice myth as, "the real problem is not too much litigation; it is too much medical malpractice. The real costs of medical malpractice are measured in lost lives, additional medical expenses, lost productivity, and pain and suffering."[56] "The vast majority of those injured by malpractice never file a claim seeking to hold the wrongdoers accountable. Even though medical malpractice kills some 195 000 hospital patients every year and injures many more, only about one in eight of those injured files a claim."[57] "Many negligently injured patients do not bring suit and are not compensated for their injuries. Several studies have found that as little as one in thirty patients who are negligently injured by medical mistakes files suit against the doctor responsible."[58]

Considering the findings by Andrews, and the report by Noah, referencing Baker, that far fewer patients litigate compared to those that are injured, considered together with the MPS concerns of increasing litigations, the potential for increased litigation exists as long as patients continue to be injured and medical risk mitigation measures are not strengthened.

Litigation is a structured and tedious process, Chandler provides various reasons for low litigation figures related to patient safety errors as 'attorneys' unwillingness to take malpractice claims; difficulty in winning medical malpractice lawsuits because jurors are typically pro-doctors and because, "unless the patient has suffered big damages, the cost and the difficulty of bringing a medical malpractice suit makes it unfeasible for a plaintiffs' attorney to proceed with the suit."[59]

[54] As above.
[55] As above.
[56] BA Noah 'Book Review 16 L. & Pol. book review (2006) 253 (reviewing Tom Baker, The medical malpractice myth (2005)).
[57] TA Brennan, LL Leape, et al, 'Incidence of adverse events and negligence in hospitalized patients. Results of the Harvard Medical Practice Study I'(1991) 324 New England Journal of Medicine 370.
[58] G Chandler 'Medical malpractice crisis: A problem with no answer' Law Review (2005) Available at: https://scholarship.law.missouri.edu/mlr/vol70/iss1/14.
[59] As above.

3.5 Medical malpractice and patient safety

The theoretical function of medical malpractice litigation is to compensate injured patients, identify and deter sub-standard care and dispense corrective justice.[60] The previous sections have outlined the burden and magnitude of unsafe care caused by medical error. There is "awareness and acknowledgement of medical error, and active efforts to address this problem, the effectiveness of the tort system itself in deterring negligence, compensating patients, and exacting corrective justice is being called into question."[61]

The previous section alluded to the fact that far fewer patients institute claims against the hospital or doctor for injuries incurred during their treatment. Clearly, only a fraction of eligible claims ever reaches the legal system. This implies that the medical malpractice litigation system is not reflective of the extent of patient injuries and therefore its compensation function for injured patients is limited to those that institute claims. This begs the question, how is patient compensation for those claims that reach the legal system?

D Golann reviewed "a sample of 3,695 claims brought against physicians, hospitals, and other medical providers closed during the period 2006 – 2010."[62] This review revealed that most claims were abandoned or dropped before finalisation. Some of the reasons for abandonment include frustrations with the long and tedious litigation process, where no quick resolutions are found and the mental health impact the process has on the litigant. Some cases were dropped by lawyers because during the discovery process new information is acquired that have an influence on prospects of succeeding with the claim. There may be unforeseeable events that occur while the case is pending, such as the medical condition of the plaintiff may change or the legal firm changes their focus area.

The length of time claims may take to be finalised is also experienced in South Africa. The South African Law Reform Commission (SALRC) provided examples of durations of nineteen cases. According to SALRC "the shortest period that had elapsed between the cause of a claim and its finalisation was 1 year and 6 months, while the longest period was 16 years and 1 month."[63]

[60] TA Brennan & MM Mello 'Patient safety and medical malpractice: a case study' (2003). Annals Internal Medicine. 139(4):267-73.
[61] Joint commission on accreditation of health organisations 'Health care at the crossroads: strategies for improving the medical liability system and preventing patient injury' (2005).
[62] D Golann 'Dropped medical malpractice claims: their surprising frequency, apparent causes, and potential remedies (2011) Health Affairs 30:7 1343.
[63] South African Law Reform Commission Issue Paper 33 (Project 141) *Medico legal claims* (2017).

The SALRC stated that "15 out of 20 (75%) of the cases referenced, took longer than five years to be finalised. One of the main problems with pursuing claims through the courts in terms of the common law is the inevitable delays that occur: due to the often-sluggish legal processes, full court rolls, delays caused by witnesses being unavailable, trouble in obtaining evidence, and so forth. As expressed by the maxim ―justice delayed is justice denied."[64]

The medical malpractice litigation system is complex and does not sufficiently lead to compensation of the injured patients. The lack of sufficient compensation of the injured patients is not an indication to abandon the litigation system. The insufficient compensation is not a reflection of a bad system but highlights the complexity of litigation where the trial process itself is embedded with technicalities, there are witness limitations especially because of the technical nature of medical malpractice, where clinical information needs to be presented in a simple easily understandable manner. There are instances where the plaintiffs are compensated and "people who receive medical malpractice payments do deserve the money."[65]

Critics of malpractice law present an argument that the civil justice system is "an irrational lottery in which a plaintiff's chance of receiving a substantial settlement has nothing to do with the defendant's fault."[66] They also argue that some "undeserving claims are compensated, and compensation is simply not correlated well to the nature and intensity of provider error."[67] Peters argues that this assertion is incorrect and is based on the 1996 findings of the Harvard Medical Practice Study (Harvard Study)[68] only, and is perpetuated by tort critics and media. The Harvard Study concluded that "the merits of a malpractice claim have no bearing on the likelihood of a settlement."[69] The authors of the study even suggested that the entire adjudicative process is "an expensive sideshow."[70]

[64] As above.
[65] PG Peters 'What we know about malpractice settlements' (2007) 92 Iowa Law Review 1783.
[66] As above.
[67] BR Furrow 'The patient injury epidemic: medical malpractice litigation as a curative tool' (2011) Drexel Law Review.
[68] Harvard study in Peters (n 68 above).
[69] As above.
[70] As above.

Several studies have examined the relationship between the strength of a plaintiff's malpractice claim and the eventual settlement of his or her case.

Taragin et al found a significant association between negligence and the probability of settlement. "The plaintiff received a settlement payment in 91% of the cases where medical care was judged to be negligent, in 59% of the cases where liability was unclear, and in 21% of the cases in which the medical care was defensible."[71]

There is a strong relationship between the provided care and the healthcare provider's disposition. There is a direct correlation between the quality of care provided and the settlements in cases where patients have litigated. If the care is judged to be good, settlements are least likely. Faber and White observed that with perceived good care settlements were at 24.2%, compared to situations where the patient was uncertain with quality of care where settlements were at 68.9%. "Most likely to settle were the cases of "bad" care over 89% of these cases ended with a settlement."[72]

The findings by Faber and White were also supported by Ogburn et al, when they reported that the settlements were significantly associated with the quality of care received by the plaintiff. In their study, "plaintiffs received a settlement payment in 90% of the cases involving negligent medical care and in 55% of the cases involving proper medical care."[73]

Sloan and Hsieh also found a positive correlation between liability and settlements. Plaintiffs that acted against service providers, where liability was considered probable, were more likely to receive payment. Where liability was unclear, or cases with unconvincing evidence, payments were less likely.[74]

The findings from the above studies are that there is a strong correlation between negligence and compensation. These studies rebut the conclusion of the Harvard study as related to compensation for medical errors.

[71] MI Taragin, et al 'The influence of standard of care and severity of injury on the resolution of medical malpractice claims'(1992) 117 Annals of internal medicine 780.
[72] HS Faber & MJ White 'Medical Malpractice: An empirical examination of the litigation process'(1991) 22 Rand Journal of Economics 199 203.
[73] PL Ogburn et al 'Perinatal medical negligence closed claims from the St. Paul company 1980-1982' (1988) Journal of reproductive medicine 33(7) 608 – 611.
[74] FA Sloan & CR Hsieh 'Variability in medical malpractice payments: Is the compensation fair?' (1990) 24 Law & Society review 997 1003-04.

The medical malpractice litigation system therefore fulfils one of its theoretical functions, to compensate patients that have been negligently injured when they litigate and complete the litigation process. The next question is 'does it deter substandard care and improve patient safety?'

One of the assumptions by advocates of medical malpractice litigation is that litigation could lead to a cautious practice by doctors, to reduce injurious errors that lead to patient harm. The theory is that medical malpractice litigation improves patient safety and reduce the cost of practice for medical practitioners. This could be achieved through a "notion that providers alter their clinical behavior in response to perceived malpractice risk and an assumption that providers internalize a large portion of the costs of errors through the malpractice system."[75]

Mello and Brennan analysed the information available on the deterrent effect of medical malpractice litigation, including evidence from studies that, they had previously completed of medical injury and malpractice litigation in New York, Utah, and Colorado. After this analysis, their conclusion was "there is some limited evidence of deterrence, but overall, the evidence is thin."[76]

Mello and Brennan provided context to their conclusion by stating that, the three large studies of adverse events and medical malpractice they analysed, were originally designed for a different purpose, which was not the deterrence effect. Therefore, analysing these studies for deterrence would inevitably encounter data shortfalls. Methodological complexities of this type of analysis should also not be understated. "The fact that deterrence has not been proven in existing studies does not lead us to conclude that it cannot be proven."[77]

Entman, et al conducted a study to "examine the relationship between prior physician malpractice experience and patient satisfaction with care"[78] and their findings were that patients were more likely to be dissatisfied with physicians that had a high number of complaints against them. Patients felt that these physicians did not sufficiently pay attention to their condition, they felt rushed, were never given any explanations, and felt ignored. The commonest complaint was poor doctor-patient communication. These physicians received twice as many complaints from patients compared to those who had never been sued.

[75] MM Mello & TA Brennan 'Deterrence of medical errors: Theory and evidence for malpractice reform (2002) 80 Texas Law Review 1595-1637.
[76] As above.
[77] As above.
[78] SS Entman, et al 'The relationship between malpractice claims history and subsequent obstetric care' (1994) 272 Journal of American Medical Association 1588 1591

They concluded that "physicians who have been sued frequently are more often the objects of complaints about the interpersonal care they provide even by their patients who do not sue."[79] The findings and conclusion of this study shows that litigation did not improve the behavior of those physicians with high frequency of medical malpractice litigation. Therefore, medical malpractice litigation fails in its theoretical medical errors deterrence purpose.

Frakes and Jenna used "clinically validated measures of healthcare treatment quality, constructed using data from the 1979 to 2005's National Hospital Discharge Surveys, and the 1987 to 2008's Behavioral Risk Factor Surveillance System records, to examine the relationship between medical liability forces on the one hand and medical errors and healthcare quality on the other."[80] Their findings suggest at most, "a modest degree of deterrence stemming from the present liability system. The mean point estimates suggest that this system generates little to no benefits in health care quality."[81]

Mello et al conducted a "systematic search of multiple databases for studies published between 1 January1990 and 25 November 2019, examining the relationship between malpractice liability risk measures and health outcomes or structural and process indicators of healthcare quality."[82]

Their findings were as follows – "Most studies suggest that higher risk of malpractice liability is not significantly associated with improved health care quality. Studies that examined obstetrical care were most likely to have identified some significant associations, but even in that domain there was inconsistency across analyses, including analyses within the same study, and most analyses did not identify evidence of deterrence. Notwithstanding some methodological shortcomings, collectively this body of evidence is enough to support a conclusion that higher tort liability risk is not systematically associated with safer or higher-quality care in the hospital setting. Although gaps in the evidence remain, the available findings suggested that greater tort liability, at least in its current form, was not associated with improved quality of care."[83]

[79] As above.
[80] M Frakes & AB Jena 'Does medical malpractice law improve health care quality?' (2016) Journal of Public Economics 143:142-158.
[81] As above.
[82] MM Mello, et al 'Malpractice liability and healthcare quality: A review' (2020) Journal of American Medical Association 323(4):352-366.
[83] As above.

Van Rooij and Brownlee[84] reviewed empirical work on the deterrent effect of tort across seven domains. The largest of these domains was the medical malpractice liability which was the most systematic and up to date. Another larger body of work that was reviewed was about corporate director and officer liability in relation to liability insurance, and the third larger reviewed body of work was the effect of liability in preventing car accident damages.

They reported that in six of the seven domains reviewed, there is no conclusive evidence that changes in tort systems have a clear effect on risk taking and damaging behaviour. In theory, liability for medical malpractice should have a deterrent effect and improve the quality of care for patients. If doctors become liable for damages their work causes to patients, they may use a higher standard of care, and work to reduce medical errors. The body of empirical work does not show clear evidence that higher tort liability creates more deterrence and lowers risk, or that lower tort liability creates less deterrence and heightens risk.[85]

They concluded their review by stating – "as the evidence is mixed and inconclusive, neither can we say that the literature proves that tort deters or that it does not deter. The best we can conclude right now, based on this body of work, is that we do not know."[86]

3.6 Conclusion

In developing a robust medical risk audit standard, clear definitions of the patient safety concepts are required. This chapter has provided patient safety definitions as recommended by the ICPS. These definitions will play an important role for the OHSC when conducting their health establishments inspections for patient safety. To implement measures to improve patient safety, various areas and activities that pose a risk to patient safety have been described. These areas and activities will assist health establishment to focus on them in patient safety risk mitigation measures. The chapter has shown that medical malpractice litigation is effective in compensating injured patients and is not effective in improving patient safety. However, the compensation function is limited by the numbers of patients who lodge claims against health services and the high number of dropped cases. The overall conclusion is that medical malpractice litigation is not an effective means to improve patient safety.

[84] B van Rooij & M Brownlee 'Does tort deter? Inconclusive empirical evidence about the effect of liability in preventing harmful behaviour' (2020) Amsterdam Law School Research Paper No. 2020-22.
[85] As above.
[86] As above.

The chapter strengthened the argument that the NCS need to be strengthened by inclusion of medical risk standards that are more operationally focused in order to detect medical risks that are prevalent in patient safety. The chapter has also demonstrated that patient safety improvements cannot rely on the theoretical functions of medical malpractice litigation, rather on proactive management through in-depth patient safety inspections.

4 Chapter 4: Patient Safety: The elephants in the room

4.1 Chapter Introduction

Despite the focus on patient safety over decades, there is no demonstrable evidence that medical errors have reduced, and patients are safer. This chapter discusses prevalent approaches that are used to curb medical negligence and weaknesses in patient safety reporting measures. The chapter discusses three approaches as elephants in the room.

- The effectiveness of tort law reform measures in decreasing healthcare costs and improving health outcomes.
- The practice of apportioning patient harm errors to individuals rather than on the system.
- Utilising unidimensional reporting mechanisms, such as incident reports for reporting and managing patient harm and adverse events, rather than a multidimensional approach.

4.2 Tort Law Reforms

The South African Law Reform Commission (SALRC) called for inputs for regulating medicolegal claims, because in South Africa there is no legislation that addresses these claims, and "the escalation in medical negligence litigation has become a cause for concern."[87] The call was prompted by the escalation in medical negligence litigation damages sought and awarded, and the commission stated that if no action is taken in the form of law reforms the national healthcare system will be paralysed.

It is concerning that the SALRC is considering legislative changes to regulate medical negligence litigation rather than considering legislative reforms, if any, to improve patient safety. The escalation in medical negligence litigation is because of poor patient safety measures in health establishments. Law reforms to regulate medical negligence litigations are not new.

A MacLennan, et al, made several [law reform] recommendations related to cerebral palsy medical negligence litigation. The recommendations include "creation of a no-fault system for resolving disputes over birth outcomes, establishment of special health courts, policing by the medical profession of those offering expert opinion and alternative dispute resolution mechanisms."[88]

[87] n 66 above.
[88] A MacLennan, et al 'Who will deliver our grandchildren? Implications of cerebral palsy litigation' Journal of the American Medical Association. (2005 294) 1688-1690.

G Howard and P Carstens, highlight the complexity of striking a balance between compensation for patient injuries and limiting the cost of litigation. Their approach on the recommendations for legal reform is carefully introduced as follows:

> "Any legal assessment …should be approached with reference to the guiding medicolegal framework consisting of the supreme Constitution of the Republic of South Africa, the common law, the applicable healthcare legislation, and consideration of applicable medical ethics."[89]

They highlight that the South African system for damages and compensation is based on fault, and they suggest a 'no fault' systems and capping of noneconomic damages for medical negligence awards. The suggestions are influenced by the economic realities of unprecedented escalation of obstetric negligence in South Africa. They argue that their suggestion is sustainable and substantive and "seems to be the more appropriate and legally less invasive option."[90]

G Howarth and E Hallinan argued for legal reforms in South Africa "not only to reduce the burden of mounting costs but also to create a system that both ensures reasonable compensation for patients and allows for a fair and robust defence where necessary. An efficient and cost-effective legal system that works for patients and their families, as well as for healthcare professionals, is crucial."[91]

Their reform proposal included several suggestions that include limits to general damages, future care costs, claims for loss on future earnings. They propose a system where a patient-centred complaints process is established that will be consistent, efficient and promote or allow local resolution of disputes. Legislative reforms should consider encouraging alternative dispute resolution mechanisms for medical negligence allegations including an introduction of pre-litigation resolution framework and tariffs for general damages.[92]

Law reforms as recommended by the various proponents, highlighted above, serve a purpose that does not necessarily promote patient safety. In medical terms, law reforms are equal to treating symptoms rather than the cause. The reforms are mostly to reduce costs of litigation. One of the elephants in the room is that patients will continue to be harmed even if the costs of litigation are curbed as suggested by

[89] G Howarth & P Carstens 'Can private obstetric care be saved in South Africa?' (2014) South African Journal of Bioethics and Law Vol 7 No 2 69 at 70.
[90] As above.
[91] G Howarth & E Hallinan 'Challenging the cost of clinical negligence'(2016) South African Medical Journal 16;106(2):141-142.
[92] As above.

law reformists. The required reforms are those that will focus on improving patient safety. It was discussed in the previous chapter that medical malpractice fails in its theoretical reason of deterring harm to patients. What does empirical evidence say regarding the impact of law reforms on patient safety?

Z Zabinski and BS Black studied "the effect of medical malpractice liability on patient safety in hospitals…by analysing the adoption of medical malpractice reforms, including caps on non-economic damages in five states between 2003 and 2005."[93] They found that there was a broad increase in adverse patient events following damage cap adoption, across both most individual patient safety indicators and across composite measures that combine related patient safety indicators, for each reform state, and pooled across states.[94] After reforms, there was "a meaningful increase of about 15% on average in adverse events. This is consistent with hospitals reducing investments in patient safety."[95]

DP Kessler and MB McClellan reported that, direct [tort] reforms reduced treatment intensity, this implies that physicians reduced the practice of defensive medicine, where unnecessary investigations would be conducted, in case the patient litigates. Their conclusion however was that these reform induced reductions in treatment intensity did not have any significant impact on health outcomes.[96] They also concluded that "reducing other costs of the liability system to physicians can reduce defensive practices substantially …in contrast they found no consistent evidence of any substantial effects on health outcomes of reducing measures of malpractice pressure."[97]

J Currie and WB Macleod conducted a study "on millions of individual births from 1989 to 2001."[98] Their study was to review and assess the impact of tort reforms on the types of obstetric procedures performed associated health outcomes for mothers and their infants. Their focus was on "four of the most important reforms – caps on punitive damages, caps on noneconomic damages (pain and suffering), reform of the rule of joint and several liability (JSL, the so-called deep pockets rule), and reforms of the collateral source rule."[99]

[93] Z Zabinski & B S Black 'The deterrent effect of tort law: Evidence from medical malpractice reform'(2015) Social Science Research Network.
[94] As above.
[95] As above.
[96] DP Kessler and MB McClellan 'How liability law affects medical productivity?' (2000) National Bureau of Economic Research Working Paper No 7533
[97] As above.
[98] J Currie & WB Macleod 'First do no harm? Tort reform and birth outcomes' (2008) The Quarterly Journal of Economics 795 – 830.
[99] As above.

Their findings were that tort reforms that sought to join all parties that were involved in a case and seek damages from all of them were more effective in reducing Cesarean sections and reduced labour and delivery complications. They attributed this reduction to the fact that aligning malpractice risk closely to the doctor's actions, increased the doctor's awareness of his or her actions and keeps the doctor aware and avoid unnecessary and potentially harmful procedures.[100]

Joint and Several liability reforms were also found to have a positive impact on the hospital side, where hospital were more willing to undertake patient safety systematic reforms, in order to avoid being held responsible for a large share of the damages in medical malpractice cases.[101]

In contrast, "caps on damages were found to increase procedure use, and hence costs. They also increase complications of labor and delivery in some specifications. Hence, in one important example, tort reform that reduces the malpractice risk facing doctors, appears to increase rather than decrease procedure use, with potentially harmful effects on patients."[102]

The above empirical studies found that legislative changes have no impact on patient safety, unless the reforms are on the rule of JSL. It is however important to view legislative reforms based on their purpose. Their purpose might be on litigation cost containment not necessarily for patient safety. The study by Curie and Mcleod however also reported that restrictions on caps on damages increased procedure use and hence costs. If the purpose is on litigation cost containment, it may be necessary to conduct in depth studies or analysis of tort reforms on healthcare costs. Such analysis is beyond the scope of this dissertation.

One of the law reforms that was forwarded for consideration by the SALRC relates to amendment of the State Liability Act 20 of 1957. This consideration was presented as follows:

> "Due to the detrimental impact of the substantial amounts awarded as compensation for medical negligence claims, it is recommended that consideration be given to amending the State Liability Act 20 of 1957 as an interim measure. The purpose of the amendment would be to make specific provision for structured settlement orders, which would include periodic payments, in cases of medical negligence claims against the state."[103]

[100] As above.
[101] As above.
[102] As above.
[103] n 63 above.

The South African parliament published the State Liability Amendment Bill in Government Gazette No. 41658 of 25 May 2018, in its preamble, the Bill aims to amend Act 20 of 1957, seeking to "provide for structured settlements for the satisfaction of claims against the State as a result of wrongful medical treatment of persons by servants of the State."[104]

In its submission, Section 27, a public law centre, stated that they are of the view that

> "the proposed amendment to the State Liability Act is not the appropriate solution to reducing the burden of medical negligence claims and we accordingly do not support the promulgation of the State Liability Amendment Bill."[105] They supported their reasons by stating that "medical negligence claims are symptoms of the general decline in the health system, [such as] severe human resource constraints which have led to increased workload, failure to maintain equipment, medicine stock outs and poor planning, budgeting and record keeping all contribute to the grim state of healthcare and directly to the increase in medical negligence claims in South Africa."[106] They concluded by saying "as such it is our view that unless these issues are addressed first, the proposed amendments will not achieve their intended goals."[107]

The argument by Section 27 opposing the amendment to Act 20 of 1957 is based on the understanding that medical negligence is the primary cause of medical negligence litigation. If government wants to reduce the costs of medical negligence litigation, it must implement measures to reduce medical negligence. They are proposing a system approach rather than a law reform approach.

4.3 Patient safety: Who is to blame?

"The human error problem can be viewed in two ways: the person approach and the system approach. Each has its model of error causation, and each model gives rise to quite different philosophies of error management. Understanding these differences has important practical implications for coping with the ever-present risk of mishaps in clinical practice."[108] "The person approach focuses on the errors of individuals, blaming them for forgetfulness, inattention, or moral weakness. The system approach concentrates on the conditions under which individuals work and tries to build defences to avert errors or mitigate their effects."[109]

[104] State Liability Amendment Bill in Government Gazette No. 41658 of 25 May 2018.
[105] https://section27.org.za/2018/10/section27-submission-on-state-liability-amendment-bill-16-of-2018/ accessed on 21 June 2021.
[106] As above.
[107] As above.
[108] Reason (n 43 above).
[109] As above.

LT Kohn, JM Corrigan et al report that the default position or approach when a medical error occurs is to find an individual to blame. However, the reality is that errors occur mostly due to the convergence of multiple contributing factors. These factors are systemic in nature, even in single error events can be multifactorial. "Blaming an individual does not change these factors and the same error is likely to recur. Preventing errors and improving safety for patients require a systems approach in order to modify the conditions that contribute to errors. The problem is not bad people; the problem is that the system needs to be made safer."[110]

The current medical negligence litigation system in South Africa is a fault-based person approach system, often to find fault caused by a health professional, be it a nurse or a doctor. However, the work reality of health professionals is that they work in an environment that is interdependent therefore patient errors may not entirely be due to an individual mishap. In apportioning blame, the realities health professionals must cope with, need to be considered.

The healthcare environment, specifically the clinical environment is a complex environment where health practitioners must balance decisions made by administrators, clinical protocols, availability of the necessary resources and the best interest of the patient. All these factors have a direct impact on the quality of services practitioners can provide for patients.[111] It is expected that practitioners must perform their duties in accordance with a reasonable practitioner standard, however the standard can be elusive because of hinderances that are often beyond the control of the practitioner.

N Leveson, A Samost, et al, conducted a "study aimed to demonstrate the use of a systems theory-based accident analysis technique in healthcare applications as a more powerful alternative to the chain-of-event accident models currently underpinning root cause analysis methods."[112] The technique is called "Causal Analysis based on Systems Theory (CAST) and is described and illustrated on a set of adverse cardiovascular surgery events at a large medical centre."[113]

In their report Leveson et al provide a case study of a patient that did not receive immunosuppression treatment preoperatively even though it was ordered. Consequently, the patient developed complications post operatively. In their report they stated the following:

[110] LT Kohn, et al *To Err Is Human: Building a Safer Health System* (2000) 49.
[111] As above.
[112] N Leveson, et al 'A systems approach to analysing and preventing hospital adverse events' (2016) Journal of Patient Safety 2 162 – 167.
[113] As above.

> "Individual behaviour is impacted by both process model flaws and the context in which the behaviour occurs. In these adverse events, the actors directly involved in the events all had incorrect process models. The surgeons and circulating nurse thought that immunosuppression medication had been administered, while the cardiac care unit nurse was not aware she needed to give an immunosuppressant. How could all these process models be dangerously wrong? One reason a process model may be incorrect is that the person gives an order to do something and assumes it was accomplished and no feedback is provided in the system design to correct that misimpression. Alternatively, there may be feedback designed into the system, but that feedback is inadequate, for example, it may be incorrect, ambiguous, or missing."[114]

The report highlights the importance of a systems approach to safety. This approach can be implemented in the healthcare environment as has been done and effective in reducing accidents in commercial aviation and other industries. In the example provided by Leveson et al the actions of individuals are influenced or impacted by process flaws, this implies that if procedures and protocols are inadequate, errors will always occur. "The goal of a systems approach, however, is not to reduce human behaviour to rule following, but to design a system in which individual responsibility and competence can effectively help create desired outcomes. Achieving this goal includes the design of the system to reduce human errors."[115]

MM Mello, MD Frakes, et al,[116] posits that patient safety can be improved by adopting enterprise liability. This type of liability is aligned with the operational aspects of clinical care, where practitioner's actions are embedded and dependent on system factors. This liability shifts the primary locus from the individual to the larger organisation where the individual works. By translocating the primary liability, patient safety improvement changes that transcend the individual can be implemented by health organisations.

DP Kessler supports this hypothesis by stating that "medical errors are caused by systemic errors rather than the carelessness of individual physicians, assigning liability to institutions could lead to systemwide quality improvement."[117] The arguments by Mello, Frakes and Kessler are aligned with the Currie and Mcleod's JSL argument, in that "if a physician makes a mistake during a delivery and the attending nurse has some culpability, then the patient may sue (the physician and) the nurse's employer, usually the

[114] As above.
[115] As above.
[116] n 82 above.
[117] DP Kessler 'Evaluating the Medical Malpractice System and Options for Reform' (2011) Journal of Economic Perspective.25(2): 93–110.

hospital, for full damages."[118] The awareness by the health establishment that they are jointly liable with the physician in medical negligence matters, will most likely lead them to implement systems and processes towards patient safety improvements. The positive impact of JSL is summarised by Currie and McLeod by reporting that reforms that focus on "caps on noneconomic damages increase preventable complications by 6% whereas JSL reformed reduce them by 13%."[119]

The foregoing demonstrated the second elephant in the room, that of individual blame when it comes to medical negligence. Patient safety matters are system matters more than individual matters. A focused approach on operational systems is more likely to yield better patient safety results than the currently dominant individualistic approach. A proactive approach through identifying medical systemic risks by using regular inspections is proposed. The systems approach is also proposed for use after incidents or adverse events rather than looking for a fault by an individual, the focus should be on the system.

4.4 Adverse events: To report or not to report.

L Andrews conducted "a prospective observational study (in a large teaching hospital) of the internal hospital system of work rounds and clinical meetings in which healthcare providers themselves identified and responded to errors in the care of surgical patients."[120]

The hospital had a reporting system for errors using what is called an 'occurrence report forms and potential claim files.' When the reports were reviewed, serious errors identified in the work rounds and meetings were not reported or captured. These reports did not "capture errors that occurred at the key junctures of diagnosis and surgery."[121] It was also observed that errors that were reported were not necessarily those with serious consequences for the patients or with high litigation potential. "For example, 91% of the errors reported on those forms involved no injury to the patient. The institution also had various risk management activities. However, information about problems in care identified at clinical meetings was rarely transmitted to the entities charged with patient safety or risk management."[122]

[118] n 113 above.
[119] As above.
[120] n 52 above.
[121] As above.
[122] As above.

The findings by Andrews are what KG Shojania described as the "frustrating case of incident reporting systems."[123] Shojania states that incident reporting systems are useless tools for capturing patient error incidents. They frustrate those who are committed to improving patient safety, their uselessness is because the captured incidents are usually mundane events or a very small percentage of target incidents.[124] Therefore relying on the incident reporting systems for patient safety improvement programmes is a futile activity.

The incident reporting systems were recommended by the 1999 Institute of Medicine report "To err is human" as referenced by I Mitchell, A Schuster, et al, based on the learnings and experiences from aviation and other high risk industries."[125] They stated that this report, made several recommendations for the healthcare system to contribute towards patient safety improvements. By implementing the reporting systems "healthcare organisations could learn from adverse events, mitigate contributing factors, prevent future errors and ultimately make patients safer.'[126] "The vast majority of hospitals rely on incident reporting to identify internal threats to patient safety. Yet, incident reporting suffers from major limitations. It detects only a small percentage of serious incidents, reported incidents are often minor or represent inappropriate targets for detailed investigation, and the frequency of data generated cannot track changes in safety over time because variations more likely reflect changes in reporting patterns than alterations in underlying hazards."[127]

Shojania further expands on the limitations of incident reporting by saying what you see depends on how you look. He explains the limitations as follows:

> "In a famous Indian fable, five blind men walk away with a drastically different picture of an elephant, likening it to a wall, spear, snake, tree, or fan, depending on the body part with which each came in contact. Similarly, it appears that a hospital's picture of patient safety will depend on the method used to generate it. The hospital that relies on incident reporting will perceive patient safety as identifying the right patient and making sure that he or she does not fall."[128]

[123] KG Shojania 'The frustrating case of incident reporting systems'(2008) Quality and safety in healthcare Vol 17. No 6.
[124] As above.
[125] Reason (n 43 above).
[126] I Mitchell, et al 'Patient safety incident reporting: A qualitative study of thoughts and perceptions of experts 15 years after 'To Err is Human' (2016) British Medical Journal Quality and Safety;25:92–99.
[127] Kessler (n 136 above).
[128] KG Shojania 'The elephant of patient safety: What you see depends on how you look'(2010) The Joint Commission Journal on Quality and Patient Safety Volume 36 Number 9.

> "By contrast, a hospital focusing on malpractice claims will see patient safety as the pursuit of appropriate diagnosis and treatment, a subject of no apparent relevance to executives who participate in walk rounds and regard patient safety as a series of broken sinks, dysfunctional information systems, and problematic work environments."[129]

With an understanding of the limitations of incident reports, O Levtzion-Korach, A Frankel, et al,[130] conducted a study "to examine and compare information gleaned from five different reporting systems within one institution: incident reporting, patient complaints, risk management, medical malpractice claims, and executive walk rounds."[131] These reporting systems were examined concurrently and included the following[132]

- *Incident reporting*: Confidential reporting by hospital personnel on any event that they perceive might be an issue. Examples could be patient identification mishaps, patient falls, medication errors, etc.
- *Risk Management*: Reporting of adverse events, patient safety errors and poor treatment outcomes. These are reported by doctors and nurses to the risk management department. A feedback loop is then utilised to provide feedback to hospital management and to the healthcare providers for risk mitigation measures.
- *Patient complaints*: Complaints by the patients or family submitted directly to the hospital.
- *Executive walk rounds*: These are walk rounds by hospital leadership together with safety officers, analysts and pharmacy representatives. They would look at equipment problems, other infrastructure related challenges like security and electronic records, etc.
- *Malpractice claims*: Review of reports with a medicolegal potential is done together with review of submitted malpractice claims. "Potential claim reports include reports related to poor clinical judgment related to diagnosis and treatment, communication, technical skills, and problems with medical records (incomplete, illegible, or missing)."

The main findings of Levtzion-Korach study were that "each system produces a substantially different picture, and as individual systems, they all are incomplete. This implies that to gain a full picture of the safety issues in an organization, it is essential to consider a composite perspective."[133]

[129] As above.
[130] O Levtzion-Korach, et al, 'Integrating incident data from five reporting systems to assess patient safety: Making sense of the elephant' (2010) The Joint Commission Journal on Quality and Patient Safety Volume 36 Number 9.
[131] As above.
[132] As above.
[133] As above.

They concluded that the disaggregated approach used by incident reporting systems is inadequate to provide complete picture of the patient error incidents. The current system identified different yet complementary patient safety issues. "To obtain a comprehensive picture of their patient safety problems and to develop priorities for improving safety, hospitals should use a broad portfolio of approaches and then synthesize the messages from all individual approaches into a collated and cohesive whole. Data collection should include more sources than those used in most organizations today."[134]

Measures to improve patient safety are enhanced by multidimensional risk reporting mechanisms. Poor reporting or inadequate reporting focusing on only one aspect, such as, incident reports are inadequate for a comprehensive patient safety approach. The third elephant in the room is the focus by health establishments on utilising one reporting mechanism for patient safety.

4.5 Conclusion

The chapter explored various approaches that are used to reduce the costs of medical negligence litigations and measures to improve patient safety. Suggested and implemented tort law reforms were discussed with regards to their effectiveness in reducing the costs of litigation, this approach was criticized as an approach that is focusing on symptoms rather than on the cause. The focus should be on measures to improve patient safety because one of the consequences of improving patient safety is the reduction in medical negligence litigation. Prevalent reporting approaches were also explored where their focus is unidimensional, only focusing on incident reporting and seeking to apportion blame to individuals rather than measures that use a systems approach. These were described as the three elephants in patient safety that continue to be implemented though they are not effective in proving patient safety.

[134] As above.

5 Chapter 5: Patient safety: Lessons from medical negligence case law

5.1 Chapter introduction

This chapter provides an analysis of various medical negligence cases. The intention of the analysis is, through case law, to demonstrate areas within health establishments where medical risks arise, with the aim of highlighting areas of focus for medical risk inspections and audits. Most cases that are analysed are South African public sector cases.

5.2 Never events[135]

Despite efforts to improve patient safety, never events continue to occur although solutions to these problems are available within healthcare systems. They include "wrong site surgery, retained foreign objects and wrong route medication administration. They also include cases in which there is no patient harm."[136] These events "pose serious risks to healthcare organizations' morale and reputation, in addition to the trauma and harm caused to patients and staff."[137]

5.2.1 Medicine storage

In *Smith v MEC Health KwaZulu Natal*,[138] (Smith case) Mrs Smith, while in the theatre recovery room requested the attending anaesthetist for a glass of water. The anaesthetist went into the nearby sluice room and decanted what she thought was a cup of water from a container and gave the cup to Mrs Smith to drink. She immediately reacted, and the anaesthetist quickly realised that she had given her a medicine cup of formalin[139] to drink. Due to the corrosive nature of formalin, she endured, amongst others, pain and suffering, remained in hospital for six weeks longer than she should have, severe vomiting, abdominal pain and diarrhoea, inability to enjoy a normal diet, a significant weight loss weight loss. On assessing all the evidence, the court ruled that there had been negligence on the side of the hospital employees and accordingly held that the hospital authority was liable for damages.

[135] "Never events are patient safety incidents that result in serious patient harm or death and are preventable using organizational checks and balances."
[136] JE Anderson & AJ Watt 'Using Safety-II and resilient healthcare principles to learn from Never Events' (2020) International Journal for Quality in Health Care, 32(3), 196–203.
[137] As above.
[138] Smith v MEC for Health, Province of KwaZulu-Natal 2016 ZAKZPHC 68.
[139] "Formalin is 37% aqueous (water) solution of formaldehyde that is used as an antiseptic, disinfectant, and especially today as a fixative for histology (the study of tissues under the microscope). It is irritating, corrosive and toxic and absorbed from all surfaces of the body. Ingestion can lead to immediate deleterious effects on almost all systems of the body including gastrointestinal tract, central nervous system, cardiovascular system and hepato-renal system, causing gastrointestinal haemorrhage. No specific antidote is available. Treatment of toxicity is supportive care of the various organ systems."

Discussion

Formalin is commonly used in surgical theatres for preservation of tissue specimens, that are sent for pathology investigations. It therefore requires to be stored in designated areas within the theatre in containers that are clearly marked and have a chemical hazard label. Hospitals should have policies and procedures for storage, handling and dispensing of formalin and other chemicals used in theatre. In this case formalin should not have been in a container that can be confused with a water container.

Of serious concern in this case is the fact that this event was never formally reported within the hospital system for root cause analysis and recurrence prevention. The court stated that during the trial the sister in charge accepted that one her duties was to record negative incidents. Mrs Smith's incident ought to have been reported and recorded. The sister in charge did not give any explanation for the fact that she did not record the incident. She had made several other records under the heading "Complications in Recovery Room, but none of them mentioned the administration of the formalin."[140]

A similar incident occurred as reported in *Gibson v Berkowitz & Another*,[141] (Gibson case) Ms Gibson, when she was about to undergo a Lletz[142] procedure, "she was negligently swabbed with 100% instead of 3% glacial acetic acid causing burns to her vulva, perineum, peroneal region and vagina. The acid was washed down from her vagina with water and ran down her natal cleft, soaking into the towelling under the small of her back causing extensive full thickness third degree burns to her sacrum and buttocks, covering in all about 15% of the body."[143]

The above cases point to failures in patient safety risk management systems. It is possible that blame was apportioned to the anaesthetist in the Smith case and to the surgeon in the Gibson case. It is also possible that the affected hospitals have policies or procedures for handling such chemical products and incident reporting policies. In the Smith case, the incident was not reported and by inference no investigation took place to prevent recurrence. Effective medical risk inspections and audits are essential to curb such errors.

[140] Smith case (n 138 above).
[141] Gibson v Berkowitz & Another1996 (4G2) QOD 16.
[142] "LLETZ stands for large loop excision of the transformation zone. It is a treatment to remove abnormal cells in the cervix. Acetic acid solution is applied to the cervix to allow any abnormal cells to become visible."
[143] Gibson case (n 141 above).

5.2.2 Wrong prescription.

Another never event is the case of *Kgosiemang v MEC for the Department of Health, North West*,[144] (Kgosiemang case), where Mrs Kgosiemang's daughter was wrongfully and recklessly given Phenobarb.[145] The facts of the case as they appear from the judgment of Landman J are that, the child did not suffer from epilepsy and therefore Phenobarb was wrongfully prescribed. The child developed Steven Johnson Syndrome (SJS)[146] as a complication of the wrongfully prescribed Phenobarb and had to undergo several treatment sessions in hospital. The events surrounding the prescription were not well documented and the court had to rely mostly on probabilities to come to a decision. The court held that the employees of the department of health were negligent.

Discussion

"Medication errors (MEs) are probably the most common type of patient safety incidents worldwide and cause harm to patients, distress to medical staff and costs to the healthcare system. Systematic reporting of errors is fundamental for detecting patient safety problems."[147] There are several types of MEs, such as, wrong drug, wrong dose, wrong patient, wrong route, omission to administer a drug, unauthorised drug, etc. As discussed previously, patient safety errors are traditionally reported using a fault-based approach, however errors result from a complex interplay between individual and system factors.

In the Kgosiemang case, the error could have originated anywhere in the medication supply chain, starting from clinical assessment of the patient, where a history of allergies is discussed and possible medication complications, then correct diagnosis, prescription of medication, dispensing of medication and administration of medication. In this, context medical risks inspections and audits need to be conducted at an operational level rather than policy or protocol existence level.

[144] Kgosiemang v MEC for the Department of Health, North West 2013 ZANWHC 14.
[145] "Phenobarb is a prescription medicine used to treat and prevent the symptoms of seizures, sedation, hypnotics, insomnia and status epilepticus. Phenobarb may be used alone or with other medications."
[146] "Stevens-Johnson syndrome (SJS) is a rare, serious disorder of the skin and mucous membranes. It is usually a reaction to medication that starts with flu-like symptoms, followed by a painful rash that spreads and blisters. Then the top layer of affected skin dies, sheds and begins to heal after several days. Stevens-Johnson syndrome is a medical emergency that usually requires hospitalization. Treatment focuses on removing the cause, caring for wounds, controlling pain and minimizing complications as skin regrows. It can take weeks to months to recover. A more severe form of the condition is called toxic epidermal necrolysis (TEN). It involves more than 30% of the skin surface and extensive damage to the mucous membranes."
[147] KS Björkstén, et al 'Medication errors as malpractice – a qualitative content analysis of 585 medication errors by nurses in Sweden' (2016) Bio Medical Center Health Services Research, 16:431.

In *S v Mkwetshana,*[148](Mkwetshana case), a newly qualified doctor (intern) diagnosed the patient with asthma and administered 20ml of aminophylline intravenously. With no improvement after 5 minutes, he decided that it was epilepsy and administered 20ml paraldehyde. The patient improved but died 15 minutes later due to the lethal doses of paraldehyde.

Paraldehyde can be administered via several routes, namely intramuscularly, intravenously, orally or rectally. The dosage varies with the route of administration and 20mls intravenously is an excessive dose. The court noted that when paraldehyde is administered intravenously, it acts rapidly and the dose must not be more than 5mls. Even the 5mls must be diluted with a sodium chloride solution.[149]

In addressing this case, it is common cause that the doctor committed the error, what might be challenging to elucidate is 'why did he commit it?' What were the surrounding factor that contributed to the error? The doctor initially thought the patient had an asthma attack and later he thought it was epilepsy. Medical risk audits therefore need to focus on the training aspects, clinical competence and support structures offered to interns and other health professionals. Interns work under supervision, the requirement therefore is that a senior doctor should be at hand to support and guide the intern. In conducting medical risk inspections these aspects need to be inspected, on the surface of this error it seems like an individual can be blamed, the possibility exists that this could be a systems error.

5.2.3 Retained foreign objects after surgery[150]

"The problem of retained surgical bodies (RSB) after surgery is an issue for surgeons, hospitals and the entire medical team. They have potentially harmful consequences for the patient as they can be life threatening and usually, a further operation is necessary. The incidence of RSB is between 0.3 to 1.0 per 1,000 abdominal operations, and they occur due to a lack of organisation and communication between surgical staff during the process. Typically, the RSB are surgical sponges and instruments located in the abdomen, retroperitoneum and pelvis."[151]

[148] S v Mkwetshana 1965 (2) SA 493 (N).
[149] Carstens PA & D Pearmain. Foundational principles of South African medical law. Durban: Lexis Nexis, 2007.
[150] "A retained foreign body, retained foreign object, or retained surgical body is any item left inside a patient after a surgery that should not be there. Any surgical tool, instrument, or material unintentionally left inside the body cavity after an operation is a retained foreign body. Follow-up surgeries are typically necessary to remedy retained foreign bodies, as the patient cannot safely continue living with the object in the body cavity."
[151] VA Zejnullahu, et al 'Retained surgical foreign bodies after surgery' (2017) Macedonia Journal of Medical Science. 5(1):97-100.

In *Potgieter v MEC Health Limpopo*[152] (Potgieter case), Mr Potgieter took action for damages after a surgical needle was retained during a laparotomy. He presented with a non-penetrative abdominal stab wound. The wound was treated conservatively and turned septic. After several visits to the hospital, a decision was taken to perform an exploratory laparotomy that did not discover any pathology or injury. It is during this laparotomy that a surgical needle was retained. The needle was discovered a few months later when his laparotomy wound developed an abscess and burst open. The surgeon who performed the laparotomy did not make any clinical notes. "The reason was that he had simply been too busy. The court ordered that the first and second defendants are jointly and severally declared liable for payment of the plaintiff's proven or agreed damages."[153]

Discussion

Performance of surgery involves participation of several role players. There is the central sterile services department (CSSD) that provides the sterile instruments or equipment used during surgery, there is a complement of theatre nurses, there is a surgeon or surgeons and the anaesthetist. All of them have a role to play for the surgery to be successful. A system is therefore required to be in place to avoid retaining surgical objects after surgery. The responsibility for prevention should be distributed across the team not just to the scrub nurse or the surgeon.

In the case of *Goliath v MEC Health Eastern Cape*[154] an abdominal swab was retained after Ms Goliath underwent an abdominal hysterectomy, she suffered pain and discomfort lasting several months. The surgeon's response was that he was not accountable for the correct number of swabs but the scrub nurse. The same applied to *Els v MEC of Health, Northern Cape*[155] where a tip of surgical needle was left in her breast after an operation. Ms Els endured several months of pain, suffering and discomfort due to this error and the hospital blamed the surgeon for the error. Liability for retained surgical objects should apply the rule of joint and several liability. Medical risk inspections and audits should look beyond the individuals and audit the full process and assist in implementing processes that take into consideration the interdependencies and feedback loops.

[152] Potgieter v Member of the Executive Committee for Health and Social Development: Limpopo and Another 2012 ZAGPPHC.
[153] As above.
[154] Cecilia Goliath v Member of the Executive Council for Health, Eastern Cape 2014 ZASCA 182.
[155] Els v MEC: Department of Health, Northern Cape 2017 ZANCHC 7.

5.3 Equipment or instrument failure

When patients go or are admitted in a health establishment, the expectation is that they will receive appropriate and safe medical care to resolve their healthcare needs. In the process of resolving the patient's healthcare needs, health professionals make use of several instruments and equipments. It is not uncommon that these machines and instruments cause undue harm to the patient or exacerbate their medical problems.

5.3.1 Patient burns

In *Makgetla v MEC Health Free State,*[156] (Makgetla case), Mrs Makgetla took action in delict, claiming that doctors in the employ of the Free State department of health breached their duty of care, when she sustained burns on her back, caused by a diathermy plate, during a thyroidectomy operation. The facts are as follows – Mrs Makgetla underwent a thyroidectomy operation for a duration of more than two hours. On completion of the operation, it was discovered that she sustained burns on her back, where the diathermy plates were placed. The burn wounds were treated and managed adequately. "Mrs Makgetla could not dispute that the doctors who performed the operation on her, took all the necessary precautions expected of them to avoid burn wounds. Although she did not think that they were negligent, she added that she also was not at fault."[157] The court dismissed her claim.

Discussion

"Diathermy involves the deliberate use of electrical energy to produce tissue damage and despite the incorporation of various safety measures, injury to patients still occurs."[158] There is a widespread use of diathermy during surgery, it is however startling that several surgeons and anaesthetists remain ignorant of hazards associated with diathermy use.

The Makgetla case demonstrates the difficulties of medical negligence litigation, in that, for negligence to be proven there are five elements that need to present (conduct, wrongfulness, fault, causation and damage), her claim was dismissed in spite of her *prima facie* evidence. Diathermy plate burns are preventable injuries. An audit process assessing the competence of health professionals in diathermy operations would go a long way towards preventing these unnecessary and preventable patient injuries.

[156] Makgetla v MEC for Health: Free State Province 2016 ZAFSHC 164.
[157] As above.
[158] DE Boyd & JH MacG Palmer 'Surgical diathermy'(2013) Anaesthesia & Intensive Care Medicine. Volume 14, Issue 10, 431-433.

5.3.2 Equipment failure

In *Michael v Linksfield Park Clinic*,[159] (Michael case), Mr Michael sustained a nose injury and was operated on, to correct a deviated septum. During the operation he went into cardiac arrest. Resuscitation efforts were commenced and "by the time resuscitation had restored heart function he had sustained, major brain damage as a result of cerebral anoxia. He has been left in a permanent vegetative state."[160]

This is a case where a defibrillator (Lohmeier) was thought to be defective because it could not produce the necessary cardiac response during resuscitation. The plaintiffs in this case suspected that the Lohmeier was defective because it could not deliver the required charge to restore Mr Michael's heartbeat during the resuscitation process. However evidence was led that the defective Lohmeier inference could possibly been incorrect because reducing digital display was a known feature of the Lohmeier and this does not impede the functionality and efficacy of the equipment.

It was also evident that the sister in charge was always ignorant of the functionality of the Lohmeier as she did not claim that she had forgotten what she was once told or trained on. The same applied to the aneasthetist, who was in charge of the resuscitation, he was also ignorant of the functionality of the Lohmeier. The court stated that "a defibrillator is specifically intended for use in an emergency life-saving situation it is plainly a reasonable requirement that the anaesthetist must know how it works."[161] The court found both the sister in charge and the anaesthetist negligent with regards to the resuscitation aspect of the case.

Discussion

This case straddles two areas in patient safety risk management. The first being the ability of health professionals operating an equipment to know and understand its functionality and how it is operated. If a health professional is found to be ignorant of the functionality of the equipment and patient harm result, then the professional can be found to be negligent. "In *Dale v Hamilton* a physician used an X-Ray appliance to diagnose a condition and the plaintiff sustained serious burns. It transpired that the Coolidge tube[162] had been placed too near to the patient, causing the burns. The court found that the radiologist was obliged to ascertain the appliance's operational safety and that he was not entitled to rely on the expert's installation thereof."[163] In a hospital environment, equipment is the property of the hospital and its responsibility to ensure that the equipment functions as expected.

[159] Michael and Another v Linksfield Park Clinic (Pty) Ltd and Another 2001 ZASCA 12.
[160] As above.
[161] As above.
[162] This is a device used for creating a beam of X-rays. The glass flask contains a vacuum. A cathode (inside right of flask) is heated and releases electrons that eventually lead to X-Ray emission.
[163] SF Otto 'Medical Negligence'(2004) South African Journal of Radiology 8(4).

It is the hospital that bears the responsibility to ensure that all health professionals that will use the equipment are trained on the operational aspects of the equipment. In the Michael case, the two health professionals were found to have been negligent. From a medical risk management perspective, inspections and audits would need to be done to determine and ensure that firstly the equipment is indeed not defective, this can be achieved through auditing service records and secondly to audit whether health professionals are adequately trained to operate the equipment.

The second area relates to a defective or malfunctioning medical equipment leading to patient harm. In the context of Consumer Protection Act 68 of 2008[164] "previously the patient had to prove (defect) was the result of negligence on the part of the (equipment) manufacturer, (currently) he or she may claim damages from anyone in the supply chain"[165] this includes the health professional who was operating the equipment or who inserted the equipment and the health establishment. This therefore requires that from a medical risk audit perspective, health professionals are required to understand the liability and to receive the necessary training for them to operate equipments that they use in the management and treatment of patients. The liability aspect may need to be included in the informed consent obtaining process.

5.4 Delays in medical interventions

Timing of medical interventions are sometimes a matter of life and death or permanent disability. Patients can take action against a medical professional and health establishment on the grounds of delayed medical intervention. Delays often happen due to the health professional deviating from acceptable clinical guidelines.

In *Oppelt v Western Cape Head of Health*,[166] (Oppelt case), Mr Oppelt brought a claim arising from delayed treatment after he sustained a spinal cord injury, from a rugby match, that left him paralysed. The claim is based on the assertion that "where low velocity spinal injuries are treated (by closed reduction) within four hours, the patients had a substantially better prospect of not suffering permanent damage, or of suffering damage to a lesser degree than those that are not treated within the four-hour period."[167] In Mr Oppelt's case the spinal reduction was performed approximately thirteen hours after the injury.

[164] Consumer Protection Act 68 of 2008.
[165] M Slabbert % BH Pienaar 'Using locum tenens in a private practice' (2013). Potchefstroom Electronic Law Journal (16)4.
[166] Oppelt v Head: Health, Department of Health Provincial Administration: Western Cape 2015 ZACC 33.
[167] As above.

The Constitutional Court "upheld the claim on the basis that the employees of the department of health had wrongfully and negligently failed to treat the applicant's spinal cord injury by way of a closed reduction procedure, within four hours of its occurrence. It concluded that the respondent was liable for the applicant's proven damages."[168]

Discussion

There is a saying amongst spinal surgeons that 'time is spine.' This is because of the devastating nature of spinal cord injuries. "Early surgical decompression of the injured spinal cord is one of few available interventions that can potentially alter the long-term recovery trajectory for this devastating condition."[169] D Rafter, R Vasdev, et al, reviewed medical literature and legal cases "from 1972 to 2018 resulting in awards or settlements to identify whether surgeons are vulnerable to litigation despite the existence of guidelines not mandating specific timing of care."[170] They reported that "timing of intervention was related to claims in 59 (36%) of 163 cases involving spinal cord injuries. All 22 trauma cases identified cited timing of intervention, sometimes related to delayed diagnosis, as a reason for the lawsuit. The mean award of 10 cases in which the plaintiffs' awards were disclosed was $4,294,384. In most cases, award amounts were not disclosed."[171]

The Oppelt case is an example of the importance of health professionals and health establishments to understand the timing requirements for spinal cord injuries. Timing for intervention is linked directly to the health establishment resources both for treatment and/or transfer of patients. The review by Rafter et al, also highlights that even in the absence of clear timing guidelines, health establishments and health professionals can be held liable for delays in interventions related to spinal cord injuries.

Timing for medical intervention is not only linked to spinal cord injuries, but vascular diseases interventions are also time sensitive. The case of *Harmse NO v MEC Health Gauteng*[172] was an action for damages, where doctors and staff were alleged to have delayed diagnosing "an occluded femoral artery on a patient's leg, and to take timeous effective action to deal with the occlusion appropriately when the diagnosis was made."[173]

[168] As above.
[169] CS Ahuja, et al, 'Time is spine: the importance of early intervention for traumatic spinal cord injury'(2020). Spinal Cord 58, 1037–1039.
[170] D Rafter, et al, 'Litigation risks despite guideline adherence for acute spinal cord injury: time is spine' (2020). Neurosurgical Focus, 49(5) E17.
[171] As above.
[172] Harmse NO obo Jacobus v Mec for Health: Gauteng Province 2010 ZAGPJHC 110.
[173] As above.

Due to this delay the patient had to undergo an above knee amputation of his left leg. Based on the expert evidence "once the artery is occluded, action must be taken within six (6) to eight (8) hours to ensure that the damage to the tissue does not occur."[174] In this case action was taken 24 hours later and it was not possible to salvage his leg.

5.5 Informed consent

Informed consent in health practice is embedded both in ethics and in law. From an ethical point of view, informed consent falls under the autonomy principle. Autonomy literally means self-rule, it refers to the right of every person to make decisions for him or herself on matters that directly affect him or her. This means that a patient should be allowed to make the final decisions regarding his or her treatment after being provided with all the relevant information. Form a legal point of view informed consent is grounded in section 12(2) of The Constitution, where it states "everyone has the right to bodily and psychological integrity, which includes the right: (b) to security in and control over their body; and (c) not to be subjected to medical or scientific experiments without their informed consent."[175] It is therefore unlawful and unethical for health professionals to conduct or perform procedures on patients without their informed consents.

The case of *Isaacs v Pandie*[176] (Isaacs case), is an example where a health professional (obstetrician) performed a sterilisation procedure on a patient without the patient's informed consent. In this case the doctor believed that he had obtained the consent, on the other hand the patient was adamant that she did not consent for the sterilisation procedure. The facts of the case are that on the day of the operation the patient informed the nurses that she does not want a sterilisation done and she deleted the sterilisation section on the consent form.

At the trial, the doctor stated that 'he does not take written consent from a patient in hospital and he does not check whether the consent form is signed by the patient or not before commencing with the operation. He informed the court that "ultimately it is the scrub sister, who would have to check when the patient comes to theatre whether the patient has signed the consent form. He did not consider necessary to ask Ms Isaacs if she (still) wanted sterilisation."[177]

[174] As above.
[175] The Constitution of the Republic of South Africa, 1996 sec12(2).
[176] Isaacs v Pandie 2012 ZAWCHC 47.
[177] As above.

The court held that the Dr acted wrongfully, negligently, and in breach of his legal and professional duty in performing the sterilisation procedure on Ms Isaacs.

Discussion

Ultimately the responsibility for taking informed consent lies with the health professional who will undertake the procedure. Health Professions Council of South Africa (HPCSA) states this responsibility clearly as follows:

> "A healthcare practitioner providing treatment or undertaking an investigation, has the responsibility to discuss it with the patient and obtain consent, as the practitioner will have a comprehensive understanding of the procedure or treatment, how it is to be carried out, and the risks attached to it. A healthcare practitioner will remain responsible for ensuring that, before he or she starts any treatment, the patient has been given sufficient time and information to make an informed decision and has given consent to the investigation or procedure."[178]

Strengthening the informed consent process in health establishments is imperative to reduce medical negligence liability. The Isaacs case demonstrates the weakness in the individual blame culture of medical negligence, whereas the patient informed the nurses about her change of mind, the information was not relayed to the surgeon. The surgeon on the other hand relied on the nurses to inform him of any changes. From a medical risk management perspective inspecting and auditing the full informed consent process could play an essential role in reducing liability. The joint and several liability approach can also ensure that checks and balances are embedded in the informed consent obtaining process.

5.6 Obstetrics

"In South Africa (SA) contingent liabilities for alleged medical negligence by state facilities have increased exponentially over recent years, from ~ZAR56.96 billion in 2017 to ZAR98 billion in 2019."[179]
"Claims in relation to obstetrics have been identified as the predominant determinant of financial risk for indemnifiers. In 2017, 4 063/7 889 claims (52%) against the state in SA were related to obstetrics and gynaecology (O&G). Of these, 3 089 (76%) were for cases of cerebral palsy, accounting at ZAR36.633 billion for 94% of the demands made in terms of O&G, or 64% of total demands."[180]

[178] Health Professions Council of South Africa 'Seeking patients' informed consent: The ethical considerations'(2016) Booklet 4.
[179] C Bateman 'NHI Bill set to worsen SA's medico-legal nightmare – experts' Medical Brief, 18 September 2019. https://www.medicalbrief.co.za/archives/nhi-bill-set-to-worsen-sas-medico-legal-nightmare-experts/ (accessed 8 July 2021).
[180] B Taylor & S Cleary 'A retrospective, observational study of medicolegal cases against obstetricians and gynaecologists in South Africa's private sector' (2021) South African Medical Journal, 111(7):661-667.

The nature of obstetric practice lands itself to high-risk category because of inherent unpredictable risks to the child and the mother.

5.6.1 Retinopathy of Prematurity[181]

In *M v MEC Health KwaZulu Natal*,[182] (Ms M case), Ms M claimed for damages on behalf of her baby who developed stage five retinopathy of prematurity (ROP). The baby was born prematurely at 28 weeks and she weighed 1.13kg and was placed in neonatal intensive care unit, where oxygen was administered to her.

In this case the court was asked to determine whether the hospital, in administering oxygen to the premature baby adhered to the National Guideline on Prevention of Blindness in South Africa that state that the acceptable levels are 86% - 92%.[183] During the trial it was discovered that "the oxygen saturation levels maintained on the baby were consistently higher than 95%, which is regarded as the safe upper limit for such saturations, the levels were fluctuating between 97 and 100 % with the majority being at 100%."[184]

In her judgment Poyo Dlwati J stated, "it is my view in fact, that the doctors that treated the baby at the hospital were not concerned with the high oxygen saturation levels. One wonders whether they knew that the oxygen saturation levels were not supposed to be above 92%."[185] The court found the defendant liable for all of the plaintiff's proven or agreed damages arising out of the blindness.

Discussion

"Retinopathy of prematurity (ROP), is one of the most common causes of preventable blindness in preterm neonates, is emerging as a 'third epidemic' in middle-income countries including South Africa. This is due to the increasing survival of preterm neonates, insufficient monitoring of oxygen saturation (SaO2) in most centres, and lack of a ROP screening guideline in most neonatal units."[186]

[181] "Retinopathy of prematurity (ROP) is a disease of the eye affecting prematurely born babies generally having received neonatal intensive care, in which oxygen therapy is used due to the premature development of their lungs. It is thought to be caused by disorganized growth of retinal blood vessels which may result in scarring and retinal detachment. In serious cases it leads to blindness."
[182] M v Member of the Executive Council for Health KwaZulu Natal 2016 ZAKZDHC 5.
[183] As above.
[184] As above.
[185] As above.
[186] L Visser, et al 'Guideline for the prevention, screening and treatment of retinopathy of prematurity.' (2013) South African Medical Journal;103(2):116-125.

Core to prevention of ROP is for health professionals to know the risk factors and prevention guidelines. Health professionals therefore need to be made aware of the risks and be trained on prevention. In Ms M case, the judge commented that she wondered whether the doctors knew the acceptable oxygen saturation level.

This comment can also be inferred in the cases of *Bunge NO v MEC for Health KZN*[187] and also *Lochner v MEC Health and Social Development, Mpumalanga.*[188] From a medical risk management perspective, hospital equipment to monitor the saturation levels are important, in cases where the equipment is not available, clear protocols are needed to ensure that babies are transferred timeously. Training of health professionals on the screening and management of ROP is also as important.

5.7 Cerebral palsy

"Cerebral palsy (CP) is a static, nonprogressive disorder caused by brain insult or injury in the prenatal, perinatal, and postnatal period, is the major developmental disability affecting function in children. It is characterized by the inability to normally control motor functions, and it has the potential to have an effect on the overall development of a child by affecting the child's ability to explore, speak, learn, and become independent."[189] "High-value claims against obstetricians in litigation in both the public and private sectors are mostly related to cerebral palsy (CP) cases on the basis of intrapartum hypoxia resulting in hypoxic-ischaemic foetal brain damage and, by extension, invoking negligent intrapartum care."[190]

[187] Bunge NO v MEC for Health, KZN & others 2009 JOL 24369: In this case the plaintiff's son was born at a hospital under the control of the first defendant. The child was born prematurely, at an estimated gestational age of 28 weeks. After his discharge from the hospital, the child was taken to a private ophthalmologist who diagnosed severe retinopathy of prematurity, as a result of which he was totally and irreversibly blind. The court discovered that on most occasions oxygen saturation readings were taken twice a day. There were no readings showing oxygen saturation levels within the recommended range; they all exceeded this range.

[188] Lochner v MEC for Health and Social Development, Mpumalanga 2014 JDR 0034 (GNP): The plaintiff instituted action against the defendant in her personal and representative capacity as mother and guardian of her minor daughter who was born premature and due to negligence at Witbank Hospital, her daughter developed ROP resulting in her daughter's blindness.

[189] MW Jones, et al, 'Cerebral Palsy: Introduction and Diagnosis (Part I)' (2007) Journal of Pediatric Health Care; Volume 21, Issue 3 46-152.

[190] I Bhorat, et al. 'Cerebral palsy and criteria implicating intrapartum hypoxia in neonatal encephalopathy – an obstetric perspective for the South African setting.' (2021). South African Medical Journal; 111(3b):280-288.

In *Buys v MEC for Health and Social Development, Gauteng,*[191] (Buys case), Ms Buys instituted a claim for payment of damages in her personal and representative capacity as the mother of her minor child, who suffered a hypoxic ischaemic encephalopathy during labour resulting in severe and permanent brain damage. This was a high-risk pregnancy "caused by two risk factors, high gestation (42/43 weeks) and the position of the baby which was, according to the clinical notes, an occipital posterior."[192] This pregnancy therefore required close monitoring which is every 20 – 30 minutes while in labour.

The birthing process monitoring is a clinical protocol driven activity, in low-risk labour monitoring takes place every thirty minutes and in high risk labour it is in every 20 minutes. In Buys case protocols were not followed or were not adhered to. This was a high-risk labour, however "according to the clinical notes it appears that four cardio-tocographs were taken during the period 23:00 until 08:55 which, according to the witness, was insufficient for a patient that was 42 weeks pregnant. It also indicates that these examinations were done sporadically and not continuously."[193]

One of the witnesses stated that:

> "The clinical notes "are so poor, as they were, I have to construct a picture in my mind of how things actually developed. He then pointed out that not to record completely on the foetal heart, the whole pattern, all those parameters, I think that is to me, gross negligence. Later, he also pointed out the absence of notes indicating what the contraction pattern was as well as what was found during a vaginal examination. According to him this is very poor recordkeeping. There was poor monitoring of the plaintiff with very poor documentation; the standard protocol for the management of a patient in labour was not followed which increased the risk for foetal distress passing unnoticed. Of importance is the allowance of a prolonged second stage of labour. The diagnosis of poor progress during labour (first and second stage) and the diagnosis of foetal distress fall entirely within the practice of midwives and general practitioners. A timely caesarean section should have been performed."[194]

[191] Buys v MEC for Health and Social Development of the Gauteng Provincial Government 2015 ZAGPPHC 530.
[192] As above.
[193] As above.
[194] As above.

Discussion

As mentioned in 5.7 above, 76% of obstetric medical negligence cases are related to cerebral palsy and specifically, allegations of poor labour monitoring leading to hypoxic ischaemic encephalopathy (HIE). It is also important to understand that not every cerebral palsy case is due to HIE.

> The (cerebral palsy) "pathophysiological processes are often juxtaposed on antenatal factors, genetics, toxins, foetal priming, failure of neuroscientific autoregulatory mechanisms, abnormal biochemistry and abnormal metabolic pathways. Placing this primed compromised compensated brain through the stresses of an intrapartum process could be the final straw in the pathway to brain injury and later CP. It is therefore simplistic to base causation of CP on only an intrapartum perspective with radiological 'confirmation', as is often the practice in medico-legal cases in South African courts."[195]

The Buys case highlights several aspects that need to be strengthened by health establishments and health professionals to mitigate patient harm and reduction in medical negligence cases. The following areas need strengthening -

- Patient record keeping – this includes antenatal care records, intra-partum records and post-partum records. The records need to be legible and detailed enough.
- Monitoring protocols – pregnancy and delivery are protocol and guideline driven, it is imperative that the antenatal, natal and post-natal care is supported by guidelines and protocols.
- The second stage of labour[196] – in many cases HIE happen due to a prolonged second stage of labour, this is where timing of medical intervention plays a crucial role. In general, the second stage of labour lasts between two and three hours, however, when a second stage lasts more than 30 to 60 minutes with a second baby and the head remaining high, a caesarean section is indicated.

5.8 Conclusion

This chapter provided few examples of medical negligence case law, highlighting some of the patient safety risk areas. The presented case laws demonstrated preventable patient errors that continue to happen within health establishments. Examples of never events, medication and chemical mishaps, retained products after surgery, equipment and instrument failures, inadequate informed consents and obstetric errors were discussed. Suggestions were offered on how medical risk inspections and audits could be utilised as risk mitigation measures for the presented patient risk areas relevant to the discussed case.

[195] Jones (n 189 above).
[196] The second stage of labour commences with complete cervical dilation (10cm) and ends with the delivery of the neonate.

6 Chapter 6: Proposed medical risk inspections standard

6.1 Chapter introduction

Informed by the discussions and findings from the previous chapters, this chapter provides a proposed medical risk standard that can be incorporated in domain two of the NCS. It is anticipated that the standard could be utilised by the OHSC when conducting their annual health establishments inspections.

6.2 Medical risk standard

The core business of health systems is delivering quality healthcare to patients. In the delivery process, there are several elements that need to interact to produce patient safety. This implies that patient safety is an emergent property delivered from the interaction of various health system elements or agents. The relationship between the emergent outcome and the health system elements is nonlinear, this implies that any standard that seeks to improve patient safety must be aware of the nonlinear interactions prevalent in health systems.

6.3 Motivation for a medical risk standard

The previous chapters of this mini dissertation have illustrated that patient safety in health establishments is still elusive. The elusiveness is not a reflection of poor or no effort, it is likely because of the complex nature of health systems. What has emerged from this study is that preventable patient harm, happens at an operational level, this is demonstrated in chapter five by way of case law examples. Case law discussed in chapter five, supported the discussions of medical malpractice and patient safety as discussed in chapter three in that, the aetiology of unsafe care is at an operational level, errors result from active failures and latent conditions. The nature of case law however does not present the full picture, it provides facts regarding patients that were harmed, without providing root cause. It is understandable that root cause analysis is not the function of case law.

Chapter three also discussed the shortfalls of medical negligence litigation in curbing preventable patient injuries. These shortfalls are partly due to the nature of the litigation process, where in most cases, blame is apportioned to an individual rather than in joint and several liability. In chapter four the tort law reforms were discussed and had insignificant contribution to reduction of patient injuries and are likened to symptomatic treatment. Incident reporting systems were also discussed and described as not fulfilling prevention of patient injuries.

Considering all the above and the realisation that OHSC inspections are focused on a higher level, and are mostly generic in nature, this medical risk standard is proposed to complement the OHSC patient safety inspections, by including more operationally focused inspections.

6.4 Introducing the medical risk standard

This medical risk standard is designed to assist in improving the quality of care and improve patient safety. It is anticipated that the standard will be disseminated throughout the health system for use as a guide by the clinical managers, hospital risk management, supervisors or team leaders and the operational health personnel. With the standard at hand, the health establishment itself can conduct self-assessment inspections against the standard and determine gaps within their systems. When the OHSC conduct the inspections, the health establishment would have already assessed themselves. The purpose of inspections should always be correctional rather than punitive.

6.4.1 Structure of the medical risk standard

For the purposes of this mini dissertation, the medical risk standard does not include policy, protocol and guidelines standards, because they are higher level standards rather than operational standards. The proposed medical risk standard has four elements as follows:

- Management and governance: The success of the standard is dependent on the commitment and support by health establishment management. This element assesses the commitment and support provided by management in a form of making all the necessary resources available to implement, monitor and correct any medical risk deficiencies.
- Legal and regulatory: For the purposes of this mini dissertation this standard is presented as an example focused on informed consent and patient medical records because they are the two most common areas of weakness especially for medical negligence litigation claims. There are other legal and regulatory aspects that can be included in the standard.
- Unit specific standards: The purpose is to have an inspection standard relevant for each health establishment department, for example, operating theatre, outpatient department, pharmacy, surgical wards, mental health wards, medical wards, Intensive Care Unit, etc. The reason for unit specificity is because of the differences in operations of the various health establishment units. A generic example is presented below.
- Obstetric care: An example is presented below because of its high-risk nature in the final standard it will form part of the unit specific standard.

Management and Governance

Medical Risk Standard			
			Assessment Scoring*
Risk Area	**Standard**	**Question/Measure**	**Inspection**
Management and Governance	Each health establishment must appoint a person to fulfil the role of medical risk manager.	Is there an appointed medical risk manager?	Review the appointment letter and job description and associated reports generated by the manager.
	All health professionals must receive medical risk training.	Has medical risk training been provided for all health professionals?	Inspect the attendance register with signatures of the attendees. Review the content of provided training.
	Multidisciplinary medical risk meetings are scheduled and held.	Are there scheduled multidisciplinary medical risk management meetings?	Inspect the availability of the schedule, attendees and minutes of the meetings.
	The necessary equipment and human resources are adequate to deliver quality safe patient care.	Are there adequate resources to deliver quality safe care? (Human resources and physical resources)	Interview healthcare professionals from different disciplines and departments to assess the adequacy of staff and equipment.
	A non-punitive environment exists in the health establishment. The environment promotes patient safety and just culture.	Is a non-punitive environment created to ensure to ensure free reporting of errors and mistakes?	Interview employees with regards to the culture of the establishments when it comes to reporting medical risks. What is the attitude of management when risks are reported?
	Each ward/department must have an appointed medical risk officer.	Does each ward/theatre/lab have an appointed medical risk officer?	Review and verify the names, employee numbers and their role descriptions of medical risk officers.
	All medical risk officers must be trained.	Have medical risk officers received appropriate training relevant to their area of responsibility?	Assess the training register with names and signatures of attendees and verify the contents of training received.
	Internal medical risk audits must take place on a scheduled basis.	Are there scheduled internal medical risk audits?	Review internal medical risk audit schedule and review internal audit reports. Specifically assess root causes and implemented mitigation measures.
	To promote nonpunitive patient safety culture, transparency on the medical risk initiatives must be published to all employees.	Are medical risk programmes, inspection results, incidents and successes publicised within the health establishment?	Review the different methods of communicating the medical risk initiatives.
	All new employees must receive induction on the medical risk programme.	Is there a medical risk induction programme for new employees?	Inspect attendance register with names and signatures of the trained new employees. An interview with human resources is compulsory to inspect the number of new employees.

* Achieved = 1; Partially achieved = 2; Not achieved = 3:
A scoring of two or three must be accompanied by possible root causes of why the standard is not achieved and corrective measures must be included.

Legal and Regulatory

Medical Risk Standard			
			Assessment Scoring*
Risk Area	**Standard**	**Question/Measure**	**Inspection**
Informed Consent	The health establishment must have a comprehensive legally valid informed consent form.	Does the health establishment have standardised informed consent forms?	Request to see the informed consent form
	Contents of informed consent forms must comply with the NHA requirements.	Do the contents of the informed consent forms comply with the legal standard?	Review the informed consent form for compliance with NHA sections 6(1) and 6(2).
	All patients for surgery must sign informed consent.	Do all patients going for surgery and investigations sign informed consents?	Ask to see previous consent forms and specifically look for patient signatures (de-identification of patients is important)
	Informed consent must be obtained by the health professional who will undertake the procedure or who knowledgeable of the procedure.	Whose responsibility it is to obtain informed consent from patients?	Interview health personnel to gain an understanding of who discusses the informed consent with the patient. Verify from the informed consent form that a health professional signs the form.
	The operating team or team that performs an investigation must have a checklist to ensure that consent has been obtained and is still valid before the operation or the investigation.	Does the health establishment have an informed consent checklist procedure?	Interview the surgical team on the process they follow to verify the patient and that the patient has consented to the procedure or the investigation. Ask for documentation if any.
Patient medical records	Patient medical records must be stored according to the legislative requirements.	Are the storage of patient medical records in accordance with legal guidelines?	Review the management of patient health records according to the NHA sections 13 – 17 requirements read together with the HPCSA guidelines.
	Contents of medical records must comply with the appropriate legislative guideline.	Are the contents of patient medical records meet the required guidelines?	Review de-identified medical records assessing legibility, level of detail, date and signature, etc. Look for the presence of pathology and radiology reports.
	A health establishment must have a template for capturing medical records including health professional notes.	Does the health establishment have a template of how the contents of medical records should be like?	Assess whether the health establishment has a template that is used for capturing medical records. Ask for the template and review its adequacy against the legislative requirement.

* Achieved = 1; Partially achieved = 2; Not achieved = 3:
A scoring of two or three must be accompanied by possible root causes of why the standard is not achieved and corrective measures must be included.

Unit specific risks[197]

Medical Risk Standard			
			Assessment Scoring*
Risk Area	**Standard**	**Question/Measure**	**Inspection**
Patient safety	All patient beds must be fitted with rails for high-risk patients and with bed frames that prevent mattresses from sliding off the bed.	Are patient beds suitable for use and have features to prevent patient falls?	Conduct observations in the wards assessing the structure of the bed and its suitability for purpose.
	Wards should be free of hazards that can injure patients.	Is ward housekeeping according to an acceptable standard?	Observe the ward for cleanliness and other hazards like electrical cables, connection pipes, railings etc.
	No medication or chemical should be left unattended in the ward and all medication containers must be labelled.	Is the ward free of unlabelled medication bottles or chemical products?	Inspect the medication storage trolley or cabinet for medication. Enquire from the staff the process that is followed to reduce the risk of dispensing wrong medication to a right patient or to wrong a wrong patient.
	All equipment used in patient treatment management must be fully operational and serviced accordingly.	Is medical equipment safe for use and maintained or serviced?	Inspect the list of equipment used in the unit/ward and look for service record where relevant. Interview health professionals assessing if they have been trained on the functionality of the equipment.
	All patients must wear identification bands.	Do all patients wear identification badges?	Conduct a random sample of patient and inspect the presence, correctness and legibility of identification bands.
	Medical waste must be kept away safe in designated containers, with correct labelling.	Are medical waste containers kept in a safe location, are labelled correctly and are not over-filled?	Conduct a walkabout in the ward observing if there is a designated area in the ward where medical waste is kept and secifcally look for sharps and medical waste that have a potential to transmit infections, such as blood, body tissues, swabs, bandages, etc.
	All surgical team members are required to be aware of possible surgical risks and be empowered to initiate measures to fix the risks.	Are all surgical team members empowered and comfortable speaking up if they recognise a risk?	Conduct interviews with surgical team members ascertaining whether each one of them is confident and empowered to raise any risk irrespective of the role the member plays in the team and rank of the staff member.
	Each ward must have a process or protocol that ensures that patients receive correct medication.	Is there a procedure that ensures that correct patients receive correct medication?	Interview the employees ascertain if there are checklists used or feedback mechanism that are employed to ensure correctness of dispensed medication.
	All operating theatres must make use of checklist to assess all aspects of the surgery.	Do surgical staff have checklist rituals pre and post-surgery?	Inspect the checklist document or procedure and interview theatre staff for implementation thereof.
	Each health establishment must conduct safety evacuation drills.	Are staff familiar with safety evacuation protocols?	Interview employees and inspect evacuation safety drill reports.

* Achieved = 1; Partially achieved = 2; Not achieved = 3:
A scoring of two or three must be accompanied by possible root causes of why the standard is not achieved and corrective measures must be included.

[197] This is an example of a standard that can be used for a ward/ICU/outpatient unit, etc. Due to the limitations of the mini dissertation the above standard does not present an in-depth proposal but an example that can be expanded. It is anticipated that each unit to have its own relevant medical risk standard that covers the unique features of the work conducted in that unit.

Obstetric care[198]

Medical Risk Standard			
			Assessment Scoring*
Risk Area	**Standard**	**Question/Measure**	**Inspection**
Obstetric care	Obstetric patient records must have a designated storage area that is separate from general other medical records.	Are obstetric records kept safe and separate from all other hospital records?	Inspect the storage of records, specifically looking for accessibility, security and ease of retrieval.
	Obstetric unit must always have the full complement of required staff.	Do the obstetric wards have the required full complement of staff?	Inspect obstetric shift schedules and staff required staff complement compatible with how busy the unit is.
	All obstetric staff members must be trained and be competent in managing birth. Monitoring guidelines must be displayed in every labour room.	Are all staff members trained on managing birthing process?	Interview staff for their understanding of the birthing process and review training reports and inspect if protocols are displayed
	Each labour room must have full complement of required equipment and instruments.	Does the ward have all the necessary equipment to monitor the birthing process?	Conduct an equipment audit of the obstetric unit. Interview the unit staff for their understanding of the functionalities and interpretations of the birthing monitoring equipment.
	All obstetric unit health professionals must be trained on the recognition of HIE and ROP risks.	Are all obstetric employees aware and have been trained on prevention of HIE and ROP?	Review training records. Interview health professionals assessing their understanding of the HIE and ROP risks.
	All obstetric units must have a dedicated obstetric theatre.	Is there available emergency theatre?	Inspect the presence of an obstetric theatre
	Obstetric emergencies must be dealt with in less than an hour.	Is emergency theatre available and ready in less than one hour during an emergency?	Interview the obstetric staff regarding the time it takes for the theatre to be ready.
	Each obstetric unit must have an associated neonatal facility with all the necessary required resources for neonatal care.	Does the hospital have neonatal unit that is fully functional with all the necessary equipment and staff?	Inspect the neonatal unit and its equipment and also interview neonatal staff for their understanding and neonatal care training.

* Achieved = 1; Partially achieved = 2; Not achieved = 3:
A scoring of two or three must be accompanied by possible root causes of why the standard is not achieved and corrective measures must be included.

7 Conclusion

This chapter presented a proposed medical risk standard. The standard focuses on the operational aspects of health establishments and is also focused on patient safety. Because of the limitations of the requirements of a mini dissertation the proposed medical risk standard does not cover all aspects of a health establishment and is not detailed enough. An opportunity exists to conduct further comprehensive study and develop the medical risk standard and test its suitability through empirical inspections.

[198] Obstetric care is highlighted due to its high-risk nature and because as discussed in chapter five the bulk of medical ligation and long-term injuries originate from obstetrics. The proposed standard is not exhaustive.

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