AN EVALUATION OF THE EFFECTIVENESS OF A HOSPITAL CLINICAL ADVERSE EVENT PREVENTION PROGRAMME

BY

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Thesis submitted in fulfilment of the requirements for the degree

PHILOSOPHIAE DOCTOR IN HEALTH SYSTEMS

PhD

SCHOOL OF HEALTH SYSTEMS AND PUBLIC HEALTH

UNIVERSITY OF PRETORIA

2013

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DECLARATION

I declare that *"An evaluation of the effectiveness of a hospital clinical adverse event prevention programme"* is my original work, except where acknowledgements indicate otherwise, and that no part of this thesis is being or has been submitted for another degree at this or any other university.

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ACKNOWLEDGEMENTS

This thesis is dedicated to my mother Grace Kabane and my late father Lockington Gqira Kabane for the important developmental and parental role they have played in my life.

Without the love, dedication, tolerance and support of my wife Spa and my children; Mpumelelo, Busisiwe and Zanele; who have been with me through thick and thin, this work would not have been started and completed. I sincerely hope that my children will be truly inspired by what can be achieved by hard work, dedication and the good genetic predisposition that they already have.

The academic focus, guidance, attention to detail and the quality of this work is all owed to the chief promoter Professor Eric Buch who succeeded in motivating and energising me through our "sessions", whilst diplomatically indicating the long way that we still had to go before the work was complete.

The experience, support and mentorship that was provided by the co-promoter Professor Stuart Whittaker in this endeavour is highly appreciated. The staff at COHSASA especially Ms Petro De Beer who created and maintained the databases that were used in this research is also highly appreciated.

The valuable contributions by the statisticians, Prof Carl Lombard and Dr Perpetual Chikobvu in the planning, execution and writing up of the final reports is also acknowledged.

Ms Barbara English is responsible for the academic English version of this thesis report through her tough but thorough appraisal of this work and related articles.

The final product is due to the immense contributions made by the following administrative support staff at the different stages of the study: Ms Mildred Maleka; Mr Fezile Nkomo; Ms Zodwa Rikhotso and Ms Sibongile Yingwane.

The Free State government, especially the Department of Health is acknowledged for identifying my potential as well as sponsoring and resourcing this study in the many different ways that it has. I sincerely hope that the recommendations that have been articulated and shared with the department will be enthusiastically implemented- "the whole world is watching".

To the University of Pretoria authorities, your patience is appreciated and I hope this product was worth the wait.

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ABBREVIATIONS

ABBREVIATIONS	DEFINITION
AHRQ	Agency for Healthcare Research and Quality
AIMS	Advanced Incident Management System
AMCu	AIMS, Management and Cultural Interventions
AORN	Association of Operative Registered Nurses
APC	Association of Police Chiefs
BCMAS	Bar Coded Medicine Administration System
CEO	Chief Executive Officer
COHSASA	Council for Health Services Accreditation of Southern Africa
CQI	Continuous Quality Improvement
DDG	Deputy Director General
DOCI	Duty of Care Incidents
DOH	Department of Health
EMS	Emergency Medical Services
FMEA	Failure Mode Effectiveness Analysis
FMECA	Failure Mode Effectiveness Critical Analysis
HCAI	Health Care Associated Infections
HITS	Healthcare Incident Types
HOCS	Head of Clinical Services
HOD	Head of Department

HON	Head of Nursing
HPCSA	Health Professions Council of South Africa
HSE	Health Safety Executive
ICPS	International Classification for Patient Safety
ICU	Intensive Care Unit
IDT	Incident Decision Tree
IHI	Institute for Healthcare Improvement
IOM	Institute of Medicine
ISQUA	International Society for Quality Assurance in Health Care
JCAHO	Joint Commission on the Accreditation of Health Organisations
MEC	Member of the Executive Council
NHI	National Health Insurance
NHS	National Health System
NPSF	National Patient Safety Foundation
OECD	Organisation for Economic Co-operation and Development
PFMA	Public Finance Management Act
PDE	Patient Day Equivalent
PDSA	Plan Do Study Act
PHC	Primary Health Care
PRA	Probabilistic Risk Assessment
PSI	Patient Safety International
RCA	Root Cause Analysis
SAC	Severity Assessment Coding
SANC	South African Nursing Council
UK	United Kingdom
USA	United States of America
WAPS	World Alliance for Patient Safety
WHA	World Health Assembly
WHO	World Health Organisation

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Executive Summary:

Introduction:

This is a report of a hospital based study that was conducted between January 2008 and December 2010 in the Free State Province in South Africa. The study examined the health system from a patient safety and health care services quality improvement intervention's perspective. A key element of the research was to study the effects of the implementation of a computerised incident reporting system known as AIMS (Advanced Incident Management System) in a group of Free State hospitals. This primary intervention was implemented in the intervention sites for the first 9 months and was extended to the control sites for the last 27 months.

The secondary interventions of the study were a set health care quality and patient safety culture initiatives, which together with AIMS are collectively known as AMCu (AIMS, Management and Culture interventions). These secondary interventions include the revision of incident management structures and the introduction of measures to entrench a reporting and just culture within the Free State Department of Health. These interventions were implemented in all the 31 hospitals in the Free State.

Aims:

This study had two key aims:

1. To determine whether a set of patient safety culture and health care quality interventions (AMCu) built around a computerised incident reporting system (AIMS) could be successfully implemented in a developing country setting.

2. To develop a hospital patient safety risk reduction model based on the existing quality frameworks and the study results for the Free State Province.

Objectives

The objectives of the study are best articulated through the following key questions:

1. Can AIMS can be successfully implemented and maintained at an operational level in a developing country setting?

2. Does AIMS provide insight into the risks associated with reported incidents and adverse events that inform health system managers about sustainable policy and clinical interventions?

3. Does AMCu improve health care quality outcomes?

4. Stemming from question 3 as set out above, the sub-questions that follow represent a breakdown of the health care quality outcome issues raised:
   a. Does the implementation of AMCu improve the safety climate?
   b. Does the implementation of AMCu improve patient safety culture?
   c. Does the implementation of AMCu improve patient satisfaction?

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d. Does the implementation of AMCu improve quality as measured by the Council for the Health Services Accreditation of Southern Africa (COHSASA) evaluation system

Design and methodology:

This is an interventional study in which twenty four hospitals were randomly selected and divided into control and intervention groups. The implementation of the computerised incident reporting system is the primary intervention that was exclusively implemented for the first nine months of the study at the intervention hospitals in order to determine its effectiveness. This implementation as happens in health systems research, occurred against a back-drop of a host of study and non-study safety culture programmes as well as the COHSASA accreditation programme which are seen as secondary interventions. All twenty four hospitals were for study as well as ethical reasons exposed to all the interventions after nine months. The collection, analysis and reporting of data therefore reflects the first nine months and the last twenty-seven months as the two main phases of the project. In order to determine the impact of the secondary interventions, three surveys were carried out (safety climate; hospital safety culture and patient satisfaction) and the COHSASA scores that were collected as part of the accreditation programme were examined at the different time points.

Interventions:

The first key intervention of the study was the exclusive implementation of a computerized incident reporting system also known as AIMS at the 12 intervention sites for the first 9 months of the study between January and September 2008. This is also known as the primary intervention. During this first nine months of the study, the effectiveness of the computerized incident reporting system was tested.

The second intervention of the study was the group of activities that began in September 2007, and were aimed at preparing the organization to move from the old paper based system to the new computerized incident reporting system, and continued until December 2010. These activities, also known as the secondary interventions were intended to improve the safety climate and culture.

Measurements:

The measurements of the study were directly linked to the interventions. In the first 9 months, the main intervention was the implementation of the computerized incident reporting system (AIMS) at the intervention sites. In order to determine the effectiveness of the implementation of AIMS during this period, reported incidents per hospital were measured and their rates were compared from month to month. Reported incidents per 100 000 patient day equivalents were also measured, in order to link the reported incidents with the level of clinical activities at each hospital.

During the first 9 months, the baseline measurements for the patient safety climate, patient safety culture were completed. The COHSASA baseline evaluation

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measurements on the other hand were completed in December 2007, which was shortly before the implementation of AIMS in January 2008.

In the last 27 months of the study, the reported incidents were measured at both the intervention and control sites. In addition to that, 2 more patient safety climate and patient safety culture surveys were completed in November 2008 and November 2009, respectively. The measurements of the baseline and final patient satisfaction surveys were done in February 2009 and February 2010 respectively. The final COHSASA evaluation was completed in December 2010. The survey to determine the perceptions of personnel on AIMS was also completed during this period in June 2010.

Results:

Primary Intervention:

First nine months:

- A total of 706 incidents were reported in the intervention sites compared to 3 in the control sites over the period
- The reported incidents per 100 000 PDE ranged between 95 and 172 in the intervention sites compared to the 0 to 2 in the control sites during the period under study
- These differences were found to be statistically significant

Beyond the first nine months:

- AIMS was demonstrated to be still effectively in place in Free State hospitals beyond the first 9 months
- The reporting of incidents were demonstrated to be still increasing at both the control and intervention sites during this period

Personnel Survey on effectiveness of AIMS

- Approximately 71% of the respondents indicated that AIMS was more user friendly than the paper-based system and nearly 86% believed that AIMS was more effective at reporting incidents and adverse events than the paper-based system.
- Approximately 70% of 394 respondents indicated that they would recommend AIMS to other hospitals or other provinces

Secondary Intervention:

Patient Safety Climate:

- Nearly three-quarters of the participants at each survey point agreed that they had followed the proper channels to direct questions about patient safety
- About two thirds of respondents agreed that they are encouraged by colleagues to report any safety concerns they might have

- Nearly 70% of the participants at each survey point agreed that briefing personnel before the start of a shift is an important part of safety
- Up to 40% of respondents agreed that senior leadership in their hospital listen to them and care about their concerns

Patient Safety Culture:

- More than 80% of the participants agreed that they were actively doing things to improve patient safety during all the surveys
- More than 70% agreed at all three survey points that "we work together as a team to get work done".
- Only 35% of the participants agreed that they felt free to question decisions or actions taken by those with more authority.
- Only 40% of the participants agreed that they received feedback about changes put into place based on event reports for all the three time points
- The intervention and control groups showed that 4/12 domains demonstrated statistically significant differences between the three survey points

Patient Satisfaction Survey:

- More than 88% of the participants evaluated the facilities and waiting times as good in both years. However, the ratings for 2010 were higher than those for 2009.
- More than 90% of the patients had a positive perception of the admission process for both years under study
- The proportion of patients with positive perceptions regarding doctors was at least 99% for both years for all the items assessed
- At least 95% of the patients had a positive perception about hospital staff in general for both years

COHSASA quality scores:

- There is a statistically significant ($p<0.05$) improvement in the average performance scores of all the study hospitals across all the key performance areas between 2007 and 2010.
- The overall facility scores for all study hospitals show a significant (all p-values <0.05) improvement in terms of COHSASA standards between the baseline in 2007 and the evaluation values measured in 2010, except for one hospital where there was a significant decrease from 89.1% to 83.3%

Discussion:

Primary Intervention:

First nine months:

There is a clear indication that the incident reporting system was successfully implemented in a developing country setting. This is demonstrated by the increased reporting of incidents that is significantly higher in the intervention compared to the control sites. This was found to be true even when these were reported as incidents per 100 000 Patient Day Equivalents (PDE) and the randomisation bias is removed.

Beyond the first nine months:

A very strong case is presented that the effectiveness of the incident reporting system was successfully maintained for an additional twenty-seven months and beyond, in a developing country setting. This is demonstrated by the increased reporting of incidents in both the control and intervention sites beyond the first nine months. The utility of AIMS was also demonstrated by its ability to provide insights based on the characteristics of reported incidents, which enabled health system managers to develop sustainable interventions.

Personnel Survey on effectiveness of AIMS

There was overwhelming evidence that the majority of the personnel believed that not only was AIMS effective in its own right, but that it was also superior to the pre-study paper based reporting system.

Secondary Interventions:

Patient Safety Climate:

The findings with respect to whether the implementation of the collective interventions including the incident reporting system (AIMS) improved the patient safety climate were inconclusive.

Patient Safety Culture:

The findings reported for the improvement of the safety culture were largely positive, but these were only on selected areas.

Patient Satisfaction Survey:

The patient perception scores that were measured through the surveys indicated that there was an increase in patient satisfaction during the time when the collective interventions including the incident reporting system (AIMS) were in place.

COHSASA quality scores:

There was an improvement of the quality of services as measured by the COHSASA evaluation scores between 2007 and 2010. This is improvement was even more

marked in those hospitals that were designated as intervention hospitals, and this therefore supported the argument that the collective group of interventions that include the incident reporting system (AIMS), have contributed towards the quality improvement.

The Model

The hospital based patient safety risk reduction model is a product of the methodology, implementation plans and the study results. It is an indication of how patient safety was improved through the implementation of a set of health care quality, patient safety culture interventions that are centred on an incident reporting system in the Free State. This model is accorded a chapter on its own.

Recommendations:

A number of recommendations that are proposed arising from the study which are general, methodological or specific to the study as well as those that are specific to areas of services. At the heart of these are patient safety and health care quality improvement and they make use of the patient safety risk reduction model as a point of reference.

CHAPTER 1: INTRODUCTION

1.1 Motivation for the study

According to the World Health Organization (WHO) in its landmark publication "The World Health Report 2000" [1], the ultimate goals of any health system are improved health outcomes, satisfaction of community needs, and financial risk protection. These goals are echoed by Roberts et al [2], who further emphasises that these goals can be achieved only through efficient, effective, accessible, equitable, safe, quality healthcare services. This articulation of health system goals has gone a long way in assisting member countries to craft clear health system goals for their own country.

This thesis acknowledges that health systems make costly and fatal mistakes, which impact negatively on their performance. These health system errors, fall into the realm of patient safety and this acknowledgement already forms a direct link between patient safety and health systems' performance. This relationship has influenced countries to understand that by improving the patient safety and the quality of healthcare services, countries are taking those crucial steps that will culminate in the improvement of health outcomes and satisfaction of the needs of its communities, which will lead to an overall improvement in the performance of their health systems.

The relationship between patient safety, healthcare-quality and health system performance also informed the process of measuring and comparing health system performance that was undertaken by the WHO in 2000. It can be reasonably inferred from the report that was released in 2000 that member countries that were not placing patient safety and the quality of healthcare as high-priority areas and had poor health outcomes did not perform well as those health systems that followed the WHO's directives.

It is therefore not surprising that the 55th conference of the World Health Assembly (WHA) in May 2002 declared that "Patient safety should be prioritized by all member states" [3].The fact that this declaration was made in 2002 and many developed and developing countries have, as a result, placed issues of quality healthcare and patient safety firmly on their agenda of discussions on national health priorities is an achievement worth noting.

There are resource disparities that would place developing countries at a disadvantage in terms of the scope and depth of their efforts to improve their health systems. It is important to note, however, that patient safety and healthcare-quality issues can no longer be ignored by nations, irrespective of whether they are well resourced or not. This research study illuminated to some extent the importance of patient safety and health care quality to the overall performance of national health systems.

Resolution WHA 55.18 of 2002 [3] stands as a declaration which, together with efforts by numerous international and national organisations, research institutes, and committed individuals, has resulted in an increased profile of patient safety issues and healthcare-quality research, campaigns, publications and projects. These in turn have

created room and stimulated further enquiry into issues of patient safety and healthcare quality to the wider international audience.

This research drive has extended to developing countries such as South Africa and has consequently influenced research on determining the effectiveness of a set of quality- and culture interventions in a group of hospitals. In this study a set of healthcare-quality interventions that are centred around an incident and adverse event management system are tested in a developing country setting to determine if they work or not.

The WHO through its WHA has continued to play the leading role in advancing the cause of patient safety and quality health care internationally. In May 2004, the 57th conference of the WHA [4] reviewed the performance of member states in implementing resolution WHA 55.18 and noted the high degree of participation. An international alliance aimed at improving patient safety as a global initiative was proposed, and this signaled the birth of the World Alliance for Patient Safety (WAPS).

WAPS's [5] key mandate is to galvanise expertise, funding and research internationally to address specific issues that would be identified by the WHO as important in advancing the patient safety agenda. At its formation the following six action areas were identified as essential for addressing patient safety:

- Global patient safety challenge 2005-2006: "healthcare-associated infections"

- Patient and consumer involvement

- Developing a patient safety taxonomy

- Research in the field of patient safety

- Solutions to reduce the risks of healthcare and to improve healthcare safety

- Reporting and learning to improve patient safety

The Global Patient Safety Challenge forms a core element of the World Alliance for Patient Safety and focuses on a major area of risk facing all member states. The WAPS usually chooses a theme that extends over two years, to allow member states to plan and implement their initiatives aimed at addressing the identified patient safety issue. In 2005 and 2006 the chosen theme was "healthcare-associated infections". These infections were and are still recognised as a threat to patient safety by all member states and results in increased length of hospital stay, disability and death.

Patient and consumer involvement in patient safety is a very important facet of the WAPS that recognises that these key stakeholders are often the main victims of unsafe health care practices. Patients and their families are frequently at the 'wrong end of the stick' in adverse events and are usually treated to incomplete information, unclear explanations, and are sometimes made to feel that they are responsible for these events. In many instances these patients and consumers need just an acknowledgement by the system that "things have gone wrong" and an apology.

The growing movement of patient safety, suffered from the fact that different researchers, institutions, organisations and countries had different definitions and interpretations for the same concepts, ideas and words. In order to clear this confusion, it became necessary to bring together experts from different organisations and countries to determine the acceptable usage of these words, key concepts and ideas [6,7,8].This has led to the compilation of a common taxonomy, which standardises the language used in patient safety internationally.

Like any new knowledge area, it was very important to identify gaps, mobilise resources, set the agenda for research in order to advance it, and patient safety was no exception. The fact that this area of knowledge expansion affects the developed as well as under-developed countries implies that it is crucial to create a platform for collaboration and knowledge sharing, and this is precisely what the World Alliance for Patient Safety had in mind when it prioritised this action area.

A global initiative such as this also provides a platform for the different member states to share their research findings and experiences from implementing various interventions to address various challenges. In this way member states get to understand what works and what does not work, and each member is allowed to utilise its scarce resources much more efficiently.

The reporting and learning systems are a *sine qua non* in entrenching safe clinical healthcare practices, according to the WHO [9] and the NHS in the UK [10,11] this opinion derives from an understanding that unless one understands the nature, size, types and the root causes of clinical incidents and adverse events, it becomes difficult to implement interventions that are aimed at preventing and managing them. It is for this reason that WAPS has placed the development and implementation of reporting and learning systems as one of the key action areas.

It is important to note that in 2005 the Council for Health Services Accreditation of Southern Africa (COHSASA) [12] played a key role in ensuring that the WAPS holds a regional conference in Durban, specifically devoted to advance the agenda of the implementation of the six action areas described above. This key initiative was, however, not able to persuade the National Department of Health to prioritise patient safety in its healthcare-quality policy initiatives.

This level of disinterest is clearly reflected in the lack of prominence of patient safety in the National Quality Assurance Policy documentation [13], as well in the National Health Act [14] that was passed later in 2007. In fact, the only sign that the South African government through its National Health Ministry is beginning to consider patient safety as a key healthcare quality issue is the level of prominence afforded to patient safety in its first publication of its "National Core Quality Standards" [15], which was released in 2008.

This poor prioritisation of patient safety in the national agenda appears to be one of the areas targeted for change by the new leadership in the Ministry of Health that was established in the middle of 2009. One of the first non-negotiable deliverables for the hospital CEO's as publicly declared by the Minister of Health [16] are the following:

- Clean hospitals

- Patient safety

- Infection control

- Improved staff attitudes

- Improved waiting times

- Continuous drug availability

The first three of these deliverables have a direct relationship with this core subject of this research: "patient safety". It is also important to note that the most predominant use of "patient safety" in South Africa still refers to the physical safety of patients in the hospital setting, as opposed to the wider interpretation of the concept internationally. The wider concept of patient safety refers mainly to the effects of medical errors and unsafe care that lead to patient harm that is unrelated to the patient's medical condition.

The fact that in 2010, at the end of the study and eight years after the passing of resolution WHA 55.18 in 2002 [3], the South African National Ministry of Health was still grappling with the development of a national policy on patient safety is a clear indication of its lethargy in this important area of healthcare quality. This research was therefore also expected to give this effort aimed at developing clear and coherent policies on patient safety for the country an even greater impetus.

1.2 Relationship between patient safety and health system performance – a closer look

The link between quality of healthcare services, patient safety and health system performance is a subject of great interest to many researchers and research institutions [17, 18, 19]. It was therefore inevitable for the author to choose a research project that aimed at exploring this link. This link is a theoretical construct that needs to be well understood by both policy makers and health system managers because such people deal with issues that emanate directly or indirectly from this link on a daily basis. It is therefore hoped that this study will provide some insight into this intricate relationship. It is also hoped that the study will positively influence policy development and implementation in this area.

This study is heavily influenced by the preliminary articles that were reviewed and which to a large extent focused on broad quality and performance issues in hospitals [17,18,19]. The interest in the topic promoted on the author's part a genuine attempt at improving the quality of healthcare services and overall performance of public sector hospitals in the Free State. It is therefore not accidental that this research was based on public sector hospitals.

Although there is currently, on a world-wide scale a greater emphasis on primary healthcare that is district based and focuses on prevention of disease and health promotion, hospitals remain the backbone of any health system. Their importance in the healthcare system is also underscored by the fact that between 60% and 80% of health system resources are consumed by hospitals [20].

Most developing countries have embraced the concept of primary healthcare as an approach that will improve the health of their population in a sustainable manner in the medium- to long term. This approach is also seen as the most cost-effective and efficient manner of delivering healthcare services, especially in an environment where there is severe resource scarcity.

Yet, despite this widespread philosophical acceptance of the primary healthcare approach, we find that expenditure on hospital healthcare exceeds expenditure on primary healthcare clinics by a significant amount. This skewed health expenditure therefore means that improving hospital performance should result in a significant improvement in the efficiency of the health system as a whole. It should however be noted that district hospitals also provide an important healthcare service and that primary healthcare are also provided at this level of hospital.

In democratised countries such as South Africa, there is an increasing interest and involvement of the civilian population in the delivery of social services such as housing, education and healthcare. This places public institutions such as hospitals in a position where they have to begin to justify the huge amounts that are spent on them, in exchange for healthcare delivery to their designated communities. They need to demonstrate a significant value for money to the investors in public healthcare, to justify continued investment in them. Public institutions as we well know do not have profit generation as their primary reason for existence; instead they devote their energies to satisfying the needs of the population as much as possible.

Public institutions have for a long time had funds allocated to them for the delivery of services, without any expectation from them to account as to how effectively and efficiently these have been utilised, nor to account for the quality of these services. There is, however, an increased interest in the performance of these organisations, in the same way as shareholders track the performance of private organisations whose shares they own.

The civic population no longer sees itself as passive consumers of services; they are keen to know if these public services were produced effectively, efficiently and also whether they are of a poor or good quality. Several authors [21,22] have argued that hospital boards should look beyond the financial management of hospitals and focus on issues of quality and patient safety. These authors also propose a number of strategies that can assist the boards to make this important transition.

It is therefore important to understand that the value that communities seek to gain from the investment in public hospitals lies in the improvement of patient safety, improved quality of healthcare services and improved overall performance of hospitals. For this reason it is understandable why there is an increasing public outcry when adverse events emanating from hospitals are revealed in the public domain. The manner in which clinical incidents and adverse events are reported by the media is hardly sympathetic, and is often used to tarnish the image of these public hospitals to their clientele and the public at large.

In South Africa, the introduction and adoption of the Batho-Pele principles and the Patient's Rights Charter [23,24] in the early 1990s as well as the enactment of the Public Finance Management Act in 1999 [25] have further enhanced this approach to a public service that is more accountable and consumer friendly. These initiatives of the public sector have increased the expectations of both the providers and recipients of services. These expectations give additional weighting to the negative reactions that result from reported clinical incidents and adverse events.

The large-scale reforms articulated in the "White Paper for the Transformation of Health Care Services" [26] – with the aim of moving South Africa from its apartheid past to a new democratic dispensation – also emphasised increased access, comprehensiveness, equity, effectiveness, cost-effectiveness and efficiency as an important set of guiding principles. This approach created expectations from communities at large that their lives would change for the better.

The interest in organisational performance is not only confined to the public sector; the private sector has for years looked at ways of measuring the performances of their organisations. These investigations have resulted in many tools for executing this specific task being developed and implemented in a variety of organisations in the private sector. There are, for example, specific tools such as financial ratios analyses, which measure an organisation's financial performance and more general tools such as the balanced score card for measuring various aspects of organisational performance.

An examination of the quarterly and annual reports of public sector hospitals shows that they contain volumes of accounts of what has been achieved in terms of the business plans, as well as an account of the utilisation of the budgets allocated. This reporting exercise in some instances is accompanied by an explanation of the performance variances. The managers of these institutions, who clearly understand that their reward and punishment are based on positive and negative reports produced, respectively, compile these reports.

A need appears to exist for an objective way of measuring the performance of these institutions without relying on these often self-serving reports that are aimed at impressing superiors and other stakeholders.

The public sector has not developed effective tools for measuring organisational performance. Hence there is a scarcity of appropriate tools for measuring organisational performance in the public sector. This scarcity is especially severe in the healthcare sector, particularly hospitals. This problem is not only a problem of the developing countries, but exists worldwide. A group of European nations assembled their best experts to address this problem in a number of workshops under the auspices of the WHO between 1994 and 2003 [27,28], and all these efforts were in search of an appropriate tool for measuring hospital performance.

An interesting but unsurprising finding is that performance measurement in hospitals and quality improvement are so inter-related that it is impossible to mention one without the other. This close relationship between performance measurement and quality improvement emanates from the basic premise that when you start measuring the performance of a hospital, you will discover areas of poor performance and in addressing these; the overall quality of healthcare services will improve. This association between organisational performance and quality also means that any tools that are used to improve the quality of hospital healthcare services will also give you some measure of how well the hospital is performing.

There are numerous approaches described in the literature for measurement and improvement of quality hospital performance. The WHO in 1995 [29,30] sponsored a workshop of the countries that belong to the International Society of Quality Assurance in Health Care, with the intention of examining the different approaches to quality performance and deciding on the applicability of each approach to developing countries in particular. Some of the approaches identified here included:

1. Performance indicators
2. Accreditation
3. Licensing of facilities and service providers
4. Problem solving
5. Performance standards
6. Continuous quality improvement
7. Decentralisation of management

This workshop was not able to reach consensus on the best approach to quality performance and instead recognised that each approach has a contribution to make in the understanding of quality performance in health and that continuous research and contact sessions between the different countries was necessary to improve the overall measurement of quality performance. It was also recognised that no single suitable approach existed, and that each approach has its advantages and shortfalls. A

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suggestion was made that a combination of the various approaches was likely to minimise the effect of the different shortfalls that are peculiar to any one approach.

Shaw et al [31] also introduced some of the more clinically related approaches such as clinical audits, governance and peer reviews to the list set out above, as some of the more useful approaches to the measurement of hospital quality performance. It is important to note that the definition of quality performance differs from country to country, and is largely informed by the various values and priorities of each country. This, to some extent, explains the different approaches to quality performance adopted by these different countries. The lack of a standardised definition of quality also means that for each approach adopted by a country, there needs to be a clear definition of the concepts and terminology on quality-performance measurement.

The performance indicator approach is currently not being applied universally because there are so many indicators to choose from. There are input, process, output and outcome indicators, and it is sometimes difficult to decide which ones are relevant to organisational performance and which ones are not. There is also the difficulty of choosing outcome indicators, when their achievement is at most times not under the direct influence of the hospital management.

Ebrahim [32] suggests that performance indicators are by nature controversial, and this is largely due to the large number of stakeholders, who seem to bring in their vested interests in the use and interpretation of the performance indicators. The fact that there are several different approaches that utilise performance indicators does not help the situation either. The different ideological or schools of thought seem to want to entrench their positions, each time the use of performance indicators is up for consideration.

The health services accreditation approach, whose implementation has been pioneered by organisations such as COHSASA (Council for Healthcare Services Accreditation of Southern Africa) from South Africa [33,34], has the advantage of using internationally accredited standards that are robust and credible. Accreditation is considered by many to be useful and an indispensable approach and, if used with other continuous quality improvement initiatives, is likely to result in improved quality of health care services and overall hospital performance.

According to Shaw [35], the difficulty with the accreditation approach is that the end points of accreditation are hard to define, and vary according to the expectations of the users and the observer. This tends to discourage those individuals and organizations that view accreditation as an end in itself rather than a means to an end. This view is supported by the observation that after each successful evaluation for accreditation, there is a tendency for hospital teams to relax and allow some of the service elements to slide down the quality and performance scale as a result of a lack of motivation. According to the author's experience, accreditation process is by design a labour-intensive process that needs strong institutional leadership to drive and support it. This requires a focused and concerted team effort and sometimes additional resources to comply with the criteria and set standards. This approach may have

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limited success in environments with severe personnel, resource constraints and poor leadership.

The licensing of facilities and service providers is commonly practiced in many countries and is a legal requirement to operate a facility and a professional requirement to enter a specific profession. This approach is very useful as a screening instrument and to give an indication of the capability of the professionals or potential performance of a hospital. It is, however, a poor indication of the actual performance of either the professional service providers or the hospital as an institution.

The problem-solving approach appears to be more practical and applicable in the operational units of a hospital such as a ward, department or cost-centre. It becomes more difficult, however, to apply this approach in order to solve strategic and organizational-wide issues of performance management. This approach may be very useful when applied with other approaches, but not when used alone.

Performance standards, which is one of the approaches supported by the "Batho-Pele principles" [23] offers a more quantitative approach to performance measurement and is widely applied in many organisations. Heideman [36] describes structure, process and outcome standards as forming the basis of quality and performance standards. Performance standards involve developing a set of performance standards specific for hospitals, based on size, package of services and level of care. The performance of a hospital is then measured against these set standards, and similar hospitals can also be compared against one another using this set of standards.

Performance or service standards as they are sometimes called are most suitable when they are referring to organisation-wide performance, because they give the prospective client a sense of what to expect in their interaction with the organisation. These standards are also easier to define on an organisation-wide basis, but become more and more difficult to describe on a department or unit basis.

The major difficulty with this approach lies in the development of the standards, communication and agreement about the standards and the objectivity of the measurement. Ashton [37] even suggests that taxonomy of these standards is necessary to ensure that there is a uniform understanding of them by service providers and all other stakeholders, across the different institutions and countries.

The continuous quality and performance improvement approach enjoys the support of many countries and is based on the premise that no matter how excellent performance is, there is always room for improvement. This philosophy is also the one that drives many important research and quality improvement initiatives in healthcare. It involves regular analyses and testing of the systems to develop new ways and means to improve performance. This however requires highly motivated and patient personnel, who will be prepared for long periods of rigorous inputs with sometimes modest achievements.

Decentralization of management in healthcare is one of the more recently developed health system reform tools aimed at improving organizational performance. This

basically involves appointing executive managers in hospitals and providing them with delegated powers to execute specific management functions. This is supposed to ensure that decision-making is quick; it is effective and is made at the coalface to ensure an efficient performance of the hospital.

This however, has to be balanced against corrupt and counter-productive practices that can affect the system negatively. This can also promote institutional as opposed to systems thinking and approaches which could be detrimental to the whole system.

The effectiveness of the decentralisation of management in improving organisational quality performance has been one of the major concerns of health systems managers for some time. To this extent, Bossert [38] offers an analytical framework to measure the effectiveness of decentralisation. Although this tool was specifically designed to evaluate the effectiveness of system-wide decentralisation, it can be applied to a sub-system such as hospitals. Support for this approach by Omar et al [39] is based on the premise that decentralisation is not an end in itself and has to be measured against how it contributes to equity, efficiency and accessibility.

Chalwa et al [40] have developed a hospital-specific analytical framework. This framework is aimed at describing the main elements of hospital management that are being decentralised. In this article various countries such as Denmark, Holland, France, New Zealand, United Kingdom and Singapore are briefly analysed as examples where decentralisation as a healthcare reform has been implemented.

These countries are proposed as good examples from which developing countries can draw lessons as they decentralise the management in some of their hospitals. As to whether decentralisation improves quality hospital performance in terms of efficiency, access and equity, the jury is still out.

It is important, however, to also consider approaches that have been used in other similar industries and also in the private sector. The innovative work by Kaplan and Norton [41] on the balanced scorecard is seen as revolutionary and a major contributor to organisational success in the private sector. This approach particularly examines the financial-, customer-satisfaction-, internal-business-processes and employee-performance aspects of organisational performance. Out of these measures a balanced score card is developed to measure performance. This approach also links the development of the company's strategy to organisational and individual performance.

The balanced scorecard approach [42,43] was essentially developed for implementation in a profit-making private sector setting, its applicability and suitability for implementation in a non-profit public sector setting is, therefore, an important concern to address. Various authors argue that this tool can be easily adapted to accommodate organisations that are in the public sector, without loss of utility and rigour.

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The major concerns about the scorecard approach, is that it tends to suggest that the dimensions of organisational performance can be simplified into four major domains or perspectives. Brignal [44] has challenged this, and argues that other domains should be considered to ensure that a scorecard is indeed balanced in looking at the totality of organisational performance.

Closely linked to the balanced scorecard approach is another private-sector-process-improvement approach, known as the six-sigma approach. This approach [45], which was developed by Motorola Incorporated in the USA, is based on the premise that too much variation in the production of a service or product is an indicator of poor quality. This approach, which has been successfully implemented in many industries, including health, makes use of a framework that is aimed at improving organisational quality performance, by reducing variation. It also promotes the utilisation of specific six-sigma champions known as the green and black belts to implement these process improvements.

Weigang, Nave et al [46,47] argue that even with a successful performance-improvement tool such as the six-sigma, one has to accept that it is not a universal remedy for all ailing organisations. It has its strengths and weaknesses, and these should be well understood before it is implemented in an organisation.

The question regarding the sustainability of the implementation of the six-sigma intervention, when applied alone, is also posed. Weigang, Nave et al [46,47] also suggest that for long-term sustainability, the six-sigma has to be applied with other tools, such as the lean-management approach if the best results are to be achieved. There is also a concern that by developing specific six-sigma champions to drive the process-improvement initiatives, the rest of the team members may feel alienated.

The lean-management approach as described by Womack et al [48] is another private-sector-generated-process-improvement initiative, which has enjoyed wide success. It is based on the premise that by continuously examining all the steps involved in the process of producing goods or services, one will invariably discover that there some unnecessary and wasteful steps in the process. To improve the quality and overall performance in the process, one therefore needs to identify and eliminate these unnecessary and wasteful steps.

The balanced scorecard-, the six-sigma- and lean-management approaches are recent innovations that have enjoyed considerable success in the private sector. Their track record in the public sector, particularly in a developing country setting, is very limited. There is evidence that they can be successfully applied in a public sector setting and that they can also be adapted to suit the conditions of a developing country this however, needs to be explored further. This uncertainty also means that any quality performance tools, which borrow some parts of these approaches, have to be carefully monitored and evaluated to ensure their applicability and sustainability.

The search for specific quality performance tools indicates that different countries have developed these tools using a variety of elements from the different approaches. An

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example of this variety is the hospital-performance-rating tool used by Mercer [49,50,51,52] for hospitals in the USA, which is based on clinical effectiveness, financial performance and sustainability. This tool utilises a set of eight performance indicators, which include risk-adjusted mortality index, risk-adjusted complications index, severity-adjusted average length of stay, profitability, index of patient activity, long-term growth in equity and return on assets to determine the top one hundred hospitals. Hospitals that are similar in terms of size, rural or urban setting, ambulatory or teaching, are compared to determine the rankings.

The applicability and relevance of this tool is closely related to the national health system of the USA, which is largely dominated by the profit-driven private sector. The strong emphasis on financial performance, profitability and sustainability comes, therefore, as no surprise. It is important to note that almost all the hospitals being assessed for performance are in the private sector. In South Africa such a tool would be more relevant in assessing private hospital performance, and would be of little use in the majority of our hospitals, which are in the public sector.

There are other tools used in the USA, such as the hospital report cards or hospital performance reports that are produced annually for each state. According to Mercer [49,50,51,52], these report cards largely compare hospitals within each state and rate them according to their ability to manage specific clinical conditions, such as acute myocardial infarction and pneumonia. Performance targets are set for each condition and then each hospital's performance is measured against the set target.

This tool is largely developed to assist potential clients of the hospital to determine which hospital they would want to be treated at should they fall ill. It is also meant to give guidance to the medical funders or insurers, regarding which hospitals to contract with on behalf of their clients. This kind of tool would also not be applicable to the majority of hospitals in South Africa, as the majority of our patients do not have the luxury of choice of hospital, as they are indigent.

In the USA, another popular tool that is used for measuring and rewarding hospital performance excellence is the Malcolm Baldridge National Quality Award Programme [53]. This programme is applied across many industries including health and the President of the USA personally gives the awards. These awards are seen as an effort to give the different industries in the USA, a competitive advantage, and are therefore given a high national priority. The criterion used in the programme contains the following seven elements:

1. Leadership
2. Strategic planning
3. Focus on patients, other customers and markets
4. Measurement, analysis and knowledge management
5. Staff focus
6. Process management
7. Organisational performance results

This tool is universally applied to include both private and public sector hospitals. It is therefore not surprising that there is little emphasis on the profit margins, which previous tools seem to emphasise. This tool places heavy emphasis on recent management developments, such as knowledge management, which requires highly developed information systems and expertise. It is this latter reason, which may make its implementation difficult at this point in time in a developing country environment such as the one found in South Africa.

Wagner et al [54] introduce and makes comparisons between the predominant tools for measuring and rewarding quality performance in hospitals in the European setting. These include the European and Dutch Quality Awards as well as the UK Kings Fund accreditation. There is an attempt to develop a quality-performance instrument based on a combination of the different tools. The common elements that are measured in the different tools include:

1. Leadership
2. Policies and strategy
3. People management
4. Resources
5. Processes

These tools are only slightly different from the USA tools and have mainly been applied to the European setting. There has been no indication of how these tools could be adapted and utilised in a developing country.

In the UK the tool in current use is the star rating applied to the National Health System Trusts [55,56,57,58]. This tool was introduced in 2001, and consists of 21 targets against which each hospital is assessed. The targets are made up of nine key, four performance, three clinical and five staff targets. The key targets, which are given the highest weighting, look mainly at the cleanliness, waiting times and financial performance of a hospital.

The performance targets look at some designated waiting times, complaints resolution rates and clinical negligence. Finally the staff targets consider staff retention and absenteeism rates. Hospitals are then given a one, two or three-star rating, based on their performance against the set targets. One star symbolises poor performance and three stars excellent performance. The star rating also determines the degree of autonomy each hospital will be afforded; poor performers are given less autonomy and excellent performers more autonomy.

The publication of the star performance ratings causes a lot of excitement at a managerial-, clinical-, social- and political level in the UK each year. Publication is at that time of the year when patients get to know how well or how badly their hospital's performance is. The fact of the matter though, is that patients have a limited choice of hospitals in the National Health System of the UK. Publication also marks the time when a number of executive managements are congratulated, threatened with dismissal or are dismissed.

There can be no doubt that the star rating system influences the way the executive managements of hospitals make crucial decisions. Clinicians are also put in the spotlight during this time and some have taken this opportunity to resign. In a highly charged social and political environment, such as the one obtaining in South Africa, with wide differences between the rich and the poor, these kinds of ratings could lead to social instability. This could almost be certain, if the poor performing hospitals are those serving the poor black communities and the best performing ones were those serving the mainly, white well-resourced communities.

The above discussions on the various quality- and system-performance measurement or assessment approaches used by different proponents in different countries and settings, chronicles the journey that the author took in a quest to find a niche that could be targeted for use as a research subject. It is, however, also very clear from the discussions above that the subject of quality- and systems-performance measurements or assessment is rather wide and has multiple approaches.

The topical and often emotionally charged issue of the management of clinical incidents and adverse events is part of the improvement of the quality of healthcare services and overall performance of hospitals. The immediacy of the impact of medical errors on the clinical outcomes and the accompanying hysteria and despair that often accompanies the occurrence of these events stimulated the researcher's interest in this field.

The scarcity of rational approaches and policies in the management of these sensitive patient safety issues encouraged the researcher to carry out research in this area in order to develop solutions to these difficult health system challenges. The fact that there is very little published research on patient safety and health care quality in South Africa, has also motivated the author to undertake this study in order to contribute new knowledge in this important area of health care systems.

1.3 Rationale for the study

Even before the study was undertaken the concern of facility managers and executives – including the researcher who was then Deputy Director General (DDG) for the clinical health service of the province at the beginning of the study in 2008 and became the Head of Health in the province in 2010 at the termination of the study – was the poor clinical outcomes that were constantly being reported from Free State hospitals despite efforts aimed at improving the quality of health care services. These poor clinical outcomes were reflected in the discovery of severe adverse events emanating from all the clinical disciplines, as well as the reported high infant, under-five and maternal mortality rates [59,60,61].

It is against this background that the Free State Department of Health sought a programme that would improve its patient safety and health outcomes. When the Advanced Incident Management System (AIMS) was introduced to the management of the Free State Department of Health, it was meant to be an intervention that would

contribute towards improving the overall quality of health care services in the province and improve patient safety.

The researcher was aware that AIMS had been successfully implemented in Australia in different settings [62,63,64], but wanted to determine if it could be successfully implemented in the Free State Department of Health, before recommending that the department should make a substantial investment in an incident reporting system. It was also important to determine if AIMS could be adapted and implemented in a developing country, such as South Africa. The design and the methodology for this study have therefore been influenced by this background.

Key officials in the Free State Department of Health thought that the implementation of AIMS in a developing country setting was going to be faced with a number of challenges and that its success could not be guaranteed. These challenges were based on the reality that South Africa as a developing country is more resource constrained than the developed countries such as Australia, where AIMS had been successfully implemented. At the time when this study was conceived, South Africa's health system was faced with many challenges chief amongst which was the HIV and AIDS epidemic. This meant that any new programme that required investment, would need to justify itself as worth-while when compared to other competing priority programmes.

AIMS at first, appeared to be a costly system that required highly trained and technologically advanced human resource teams. The ability of a developing country to afford the skills and technology was therefore in doubt. Finally, the adaptability of AIMS to a developing country setting became an important consideration that gave rise to the idea of piloting this system in the Free State. This idea of piloting AIMS was one of the most important stimulus for conducting this research at the time.

The primary objective of this study was to determine if AIMS could be successfully implemented in hospitals of a developing country. Intervention was eventually introduced in two phases, for ethical reasons. Phase 1 lasted from randomisation to 9 months and Phase II was from 10 months into the study up to 36 months. Phase II covered the period during which the intervention was also introduced in hospitals that had been allocated to the control group.

The pre-research reporting method (paper based) was kept as the control treatment in this study because of the patient safety challenges experienced by the Free State Department of Health while it was in place, in order to determine if there would be significant differences after the introduction of AIMS, Management and Cultural interventions (AMCu). The main challenge was the poor clinical outcomes that were constantly being reported from our hospitals despite our best efforts aimed at improving the quality of health care services.

The effectiveness of this paper-based system needed to be reviewed, because prior to the implementation of AMCu there was a backlog of more than a hundred cases emanating from clinical incidents that were awaiting disciplinary processes. We were also surprised by cases that were reported through the media or our legal department

because a patient had suffered permanent disability or death as a result of an adverse event. These were cases that in most instances had not even been reported through the paper-based system. There was therefore a need to compare the paper-based system with the system that had been reported to be successful in a developed country to assess its suitability for a developing country. Furthermore the efficacy AIMS as an intervention could best be judged when compared with our existing paper-based system in order for the Free State Department of Health to make an informed investment decision on the new incident reporting system.

The paper based reporting system was maintained in the control sites during the study for the first 9 months, in order to ensure that the comparison between AIMS and the paper based system is possible.

A major outcome of the research was the comparison of the average number of reported incidents between the intervention group and the control group during the first 9 months (Phase I). The outcome for Phase II from 10-36 months was to establish the factors associated with the severe adverse events reported in our hospitals.

Considering that this study was implemented in a dynamic service-provision environment (Figure 1.1), it is critical to ensure that none of the findings are a result of contamination of the controls or of co-interventions that were not part of the study. During the study there were a number of internal and external environmental factors that had a major influence on the ability of the Free State Department of Health to provide quality health care services. These factors have to be considered in the manner that they played themselves out in terms of their sequence, duration and impact. Figure 4.1 provides the key events against which the results from the study had to be interpreted. This series of events reflected in the time line displays activities that started before the commencement of the study. Also, the events stretch throughout and beyond the study period. The purpose of reflecting these events is to provide a context for the interpretation of the results from the study (Figure 1.1).

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AIMS Research Project

No.	Event Name	2007				2008				2009				2010				2011			
		Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
1	Preparatory Phase for AIMS			■																	
2	Baseline COHSASA evaluation				■																
3	AIM Study is implemented at intervention site																				
4	Baseline Safety Climate and Culture Surveys					■															
5	Cost Containment								■	■											
6	AIMS study is implemented at the control sites																				
7	Follow-up Safety Climate and Culture Surveys								■												
8	Baseline Patient Satisfaction Survey									■											
9	Ministerial Report of provincial challenges																				
10	New Political administration																				
11	Announcement of Health 10 point plan																				
12	Free State Health Summit											■									
13	Prioritisation of Health Budgets																				
14	Final Safety climate and Culture Survey												■								
15	Follow up patient Satisfaction Survey													■							
16	Increase of Health Budget by 8%																				
17	AIMS Personnel Evaluation Survey														■						
18	Final COHSASA Evaluation														■						
19	AIMS study ends																				

Figure 1.1: AIMS project schedule

The impact of the intervention was also measured from the perspective of hospital staff and management through an evaluation survey. The study also made use of the Hospital Patient Safety Culture Survey [65], the Safety Climate Survey [66] and the Patient Satisfaction Survey [67]. These surveys are tools that determine the impact of the interventions on the patient safety and overall quality of the services provided by the hospitals.

The study also sought to develop and present a model or a recipe of how the 24 hospitals in the Free State successfully implemented the incident reporting system to achieve its aims. The detailed discussion on how the hospital risk reduction model for the Free State was developed is also described separately in Chapter Seven.

1.4 The research hypothesis

The research hypothesis of this study can be described as: "The introduction of a hospital-based incident management system will improve patient safety and the overall quality of healthcare services in the Free State." The research project is aimed at proving whether this hypothesis is true or not.

The central part of the research is to determine the effectiveness of the implementation of the Advanced Incident Management System (AIMS) [68], which has the following components:

- A computerised, call-centre-based incident reporting system able to capture reported incidents within seven minutes;
- Trained, capacitated and motivated users of the reporting system;
- Dedicated personnel at institutional level who liaise between management and service areas to ensure that incidents are reported and that the specific interventions are implemented;
- Leadership at institutional, district and provincial level who will ensure that prioritized initiatives aimed at addressing incidents are well resourced and supported;
- Organisational structures through which incidents are reported, discussed and corrective measures recommended;
- Structured, prioritised interventions aimed at addressing the identified prioritised incidents;
- Monitoring and evaluation mechanisms; to ensure that recommended interventions are implemented and that they improve the health care processes, quality and performance outputs;
- Resources that are made available to implement the identified interventions; and
- Structures and resources dedicated for the development of a reporting and just culture.

As regard the first point mentioned in the list the computerised, call-centre-based incident reporting system is capable of classifying these incidents by severity, location, time, cause, contributory factors and outcome. This system provides the necessary

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information that informs the prioritised interventions that will need to be implemented to prevent further incidents and to address their negative impacts.

The incident management system needs to be organised, co-ordinated, controlled and resourced to implement the required preventative and corrective interventions to improve the quality of healthcare and overall performance of the hospitals.

To test the hypothesis, several parameters were measured over time. A positive change in these parameters, having considered the possibility of interfering variables, is taken to be an indication that the incident system has improved the quality of health care services and hospital performance. A negative change over time in the parameters is taken as an indication that the incident management system has not improved the quality of healthcare services and overall hospital performance.

The system-based parameters used in the study to test the hypothesis are:

- Reported incidents and adverse events
- Patient safety climate
- Patient safety culture
- Patient satisfaction
- The health care quality as measured by the Council for the Accreditation of Health Services of Southern Africa (COHSASA) [34] evaluation scores.

1.5 Research design and methodology

The study is an intervention study that was conducted in 24 out of 31 hospitals in the Free State, including district, regional and tertiary hospitals, in both urban and rural settings. The main interventions in this study were:

- Implementation of the computerized advanced incident management system (AIMS)
- Implementation of measures aimed at improving health care quality
- Implementation of measures aimed at improving safety climate and culture

The duration of the interventions implemented at the 12 intervention sites was 36 months, broken into two phases. The first phase was the first 9 months, where there was a clear distinction between the intervention and control sites. The second phase was the final 27 months of the study, where there was no distinction between the intervention and control sites.

In the first 9 months the key interventions were implemented at the intervention sites and the control sites were excluded from the intervention. The parameters that were measured during this phase were aimed at determining the differences between the intervention and control sites and to determine if these were statistically significant. The interventions at the control sites were implemented for 9 months to determine their effectiveness. This period was also limited to 9 months for the reason that if the

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interventions implemented at the intervention site are beneficial to patient care, it would be ethically unjustifiable to withhold this benefit to the control sites beyond this point.

In the final 27 months, the intervention was extended to both the intervention and control sites. The parameters that were measured aimed to determine if there were differences in the reported incidents between the different time points at which these parameters are measured across all the study sites. The results of the measurements would then determine if the consistent implementation of the intervention yields specific patterns at all the sites

The specific methodologies for implementing the different interventions are clearly detailed in Chapter 4 of this report.

1.6 Outline of the remainder of the thesis

The chapter that follows (Chapter 2) will cover an extensive literature review. This review will focus on recently published articles, books and other material that provides the theoretical guidance and support to the arguments raised in the research.

Chapter 3 will address the theoretical framework that underpins the study. In this chapter there are several frameworks that are discussed and the relevance of each to the study is clearly illustrated. This chapter also provides the theoretical context for the study, which is useful in the interpretation and application of the results.

Chapter 4 will explain the design and methods that are employed in the research project. This chapter describes in detail the various methods that are used in the different parts of the research. Areas that are covered here include the setting, population, sampling, method, design, measurement, data collection and analysis.

Chapter 5 provides records of all the relevant results and explains the significance of each of the findings. There is intentional restraint in the discussion of the results in this chapter as the full discussions appear in Chapter 6.

Chapter 6 provides a platform for the full discussion of the results recorded in Chapter 5. It is also in this chapter that the limitations and conclusions of the study are presented.

Chapter 7 describes the patient safety risk reduction model which was developed on the basis of successful implementation in 24 hospitals in the Free State.

Chapter 8 presents all the study recommendations in detail

CHAPTER 2: LITERATURE REVIEW

2.1 Introduction

Stelfox et al [70] propose an approach to the review of literature on medical error and patient safety that divides publications into two broad categories; namely those before and after the publication of the "To Err is Human" report [71] that was published by the Institute of Medicine (IOM) in 2000. Stelfox et al [70] also reveal that there was an increase in the articles published from 59 to 164 per 100 000 in MEDLINE after the publication of this article.

This proposed approach underscores the value of this article in placing the issue of medical error and patient safety on the public health agenda. This ground-breaking article indicated that patient safety issues were a serious national problem in the USA with its revelation that between 44 000 and 98 000 lives were lost as a result of medical error that occurs in hospitals and that the total national costs as a result of these deaths were estimated to be between $17 and $29 billion per annum.

The major studies by Brennan et al and Thomas et al [72;73] that were used to extrapolate these figures, together with the publication of the "To Err is Human" report generated much debate and discussions around the accuracy of the fatality statistics within the research and public health domains [74;75]. What cannot be ignored, however, is the unacceptably high number of fatalities and permanent disabilities caused by medical error. The following recommendations that were made by the IOM through this publication set the agenda for patient safety in the USA and to some extent the international public health community:

- Establishing a national focus to create leadership, research, tools and protocols to enhance the knowledge base about safety;
- Identifying and learning from errors through immediate and strong mandatory reporting efforts, as well as the encouragement of voluntary efforts, both with the aim of making sure the system continues to be made safer for patients;
- Raising standards and expectations for improvements in safety through the actions of oversight organisations, group purchasers, and professional groups; and
- Creating safety systems inside health care organizations through the implementation of safe practices at the delivery level. This level is the ultimate target of all the recommendations.

In appraising the sequel to the "To Err is Human" report, "Crossing the Quality Chasm" [76], Berwick [77] indicates that this often less publicised and more comprehensive publication, goes further than its earlier counterpart in paving the way forward with respect to the type and level of interventions that have to be made in order to improve patient safety and overall quality of health care services. Berwick [77] describes the utilisation of the terms "overuse", "misuse", and "underuse" to describe quality defects in health systems that have to be addressed. There is also a clear proposal that in order to improve the overall quality of health care services, all the dimensions of

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organisational performance – effectiveness, efficiency, timeliness, equity, patient centredness and safety – have to be comprehensively addressed.

The approach suggested by Stelfox et al [70] is very useful in providing a historical account of the medical error and patient safety publications while highlighting the important publications, but it does not provide an organised, comprehensive way of dealing with this vast amount of available literature.

To address this shortfall the author classified the available medical error and patient safety literature into defined themes. This classification was meant to provide a comprehensive account of this literature while answering specific questions about the relationships that have been established between different aspects of the health care system and patient safety. These themes, which are inter-related, have been chosen arbitrarily and do not follow any specific order.

The themes that have been chosen for this review include:

- The epidemiology of patient safety
- Introspective articles about patient safety
- Patient safety and links with other high-risk industries
- Patient safety and professional training
- Clinical competence and patient safety
- Patient safety and working conditions for professionals
- Patient safety and the law
- Patient safety and the media
- The economics of patient safety
- Patient safety and health care quality
- Patient safety at the clinical level
- Medication and patient safety
- Healthcare associated infections and patient safety
- Patients and patient safety
- Patient safety reporting systems
- Implementation challenges of patient safety reporting systems
- Patient safety and technology

Another shortfall of the Stelfox [70] approach is that focusing too much attention on the IOM article creates the false impression that serious research on medical error only started in 1999. Leape [78] reminds us that medical error and its acknowledgement dates as far back as the Florence Nightingale era, and that as early as 1964 there were studies indicating that iatrogenic harm was as high as 20% in hospital admissions, 20% of which were fatal

2.2 The epidemiology of patient safety

The articles grouped under this theme attempt to establish the identification, nature, classification, type, and causes of medical error. They also provide details regarding the approaches used by the various researchers in the measurement of adverse events and clinical incidents in organisations and different countries. The authors also quantify adverse events in different countries in order to expose the extent to which medical error and patient safety are international public health problems.

An Australian study on hospital adverse events [79] revealed that up to 16.6% of all hospital admissions were associated with adverse events. More than half of these (51%) were considered to be preventable. This finding contrasts with a finding from an earlier Harvard Medical Practice study that was conducted in the USA [72;73], which reported that 3.7% of all hospital admissions were associated with adverse events, half of these were preventable, and 13.6% of these adverse events led to fatalities.

A USA study conducted by Leape et al [80] indicated that the most common adverse events in hospital settings were adverse drug events (19%), wound infections (14%) and technical complications (13%). Leape et al [80] also found that while a significant number of adverse events were linked with surgery (48%), these were not necessarily as a result of negligence.

The findings are closely related to those of a Canadian study [81], which found that: adverse events were associated with 12.7% of admissions; 4.8% of these were found to be preventable; and 3% of these were fatal. The majority of these adverse events were due to drug treatment, technical complications and hospital-associated infections.

A Spanish study [82] reports that 8.4% of hospital admissions were associated with adverse events and up to 42.8% of these were preventable. Those associated with medication were 37.4%, technical complications 25.5%, and those due to hospital-associated infections were 25.3%. A total of 17.7% of these admissions were also found to have multiple adverse events.

A New Zealand study [83] on the other hand reports that adverse events are associated with 12.9% of admissions, that 35% of these were preventable and 15% of the adverse events became fatalities. A British study [84] found that 10.8% of admissions were associated with adverse events that 11.7% of these adverse events were multiple events and 50% of all adverse events were found to be preventable.

Weingart et al [85] concluded that medical error studies in the USA and Australia are key to the understanding of the epidemiology of medical error, that most medical errors occur with inexperienced physicians or when new procedures are used. Weingart et al [85] also found that complex, urgent and prolonged hospital care and with extremes of age increase the risks of medical error.

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In a study that looked particularly at the epidemiology of adverse events in the elderly [86], it was found that they were more prone to preventable adverse events because of the complexity of the clinical interventions that are often required. It was also found that medication-related adverse events and falls are very common in this age group.

A national patient safety profile based on patient safety indicators in the USA [19] revealed that the majority of non-obstetric adverse events occur more frequently in the elderly as well as in black patients, and that adverse events were in the main more frequent in urban areas.

In another Australian study, Wilson et al [87] found that up to 38.5% of adverse events were attributable to human error and that adverse events due to complications and technical difficulties were only responsible for 34.6% of the adverse events. Wilson et al [87] also found that adverse events due to cognitive failure were associated with a higher degree of preventability than those caused by technical difficulties and complications.

The degree of consistency between all of these international studies confirms the often quoted adverse event rate of one in ten for all admissions, about 20% of these leading to death and severe disability. Wilson et al [87] also confirm the finding that the majority are due to human or cognitive errors and half of all adverse events are regarded as preventable. It is also noteworthy that adverse events are associated with inexperienced clinicians, extreme patient ages and complex clinical procedures.

In an attempt to develop comprehensive strategies to improve overall patient safety on a global scale, it became necessary to develop a common language for the basic terms and concepts involved in patient safety. The establishment of a common terminology has played a major role in ensuring that communication, research and publication on patient safety as well the identification and classification of adverse events are understood in the same way universally.

Tamuz et al [88] warn us that poor use of definitions and classifications of adverse events will lead to poor or incorrect reporting and, therefore, misdirected interventions. These authors further assert that with proper definitions and classifications, there is generally a better understanding of the adverse events and improvement of patient safety in the long run.

The WHO [89] convened a working group consisting of international experts in 2003 to develop a patient safety taxonomy. This was one of the consequences of the World Health Assembly resolution WHA.155.R16 [3] that, among other things, directs the WHO to co-ordinate international efforts aimed at developing patient safety systems. This working group also attempted to develop a common taxonomy for the reporting systems, given the variations that exist from country to country.

Runciman et al [6] describe the effort of the Australian Council for Safety and Quality in Health Care to reach agreement on the preferred terms and definitions for safety and quality concepts. This exercise resulted in an agreement on 149 terms and their definitions. When the World Alliance for Patient Safety (WAPS) was established in

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2004, this group was well represented and formed the basis for its work on the taxonomy of patient safety.

In 2005, the Joint Commission on the Accreditation of Health Organisations (JCAHO) [90] in the USA also proposed a taxonomy for near misses and adverse events in order to create a universal language of patient safety. The JCAHO was chosen to co-ordinate this effort because of the vast amounts of data that it processes through its accreditation programme.

In 2009, the WHO's World Alliance for Patient Safety assembled a group of international experts on patient safety with the sole purpose of establishing the International Classification for Patient Safety [91]. The six principles that were adopted in the development of this classification are:

- Applicability across the full spectrum of health care
- Consistency with other WHO classification systems
- Meanings as close as possible to colloquial use
- Appropriate meanings to be conveyed in relation to patient safety
- Brief and clear and without redundant qualifiers
- Fit for purpose

The result of this effort was a series of terms and definitions that have been used in recent times internationally in all research, discussions and publication on medical errors and patient safety.

In an effort to address the problem of a lack of standardised terms, definitions and classification in errors related to the provision of medication, Bates et al [92] developed a manual for training students and personnel on medication safety. In 2005, the Council of Europe, through its expert group on safe medication practices, developed a glossary of a patient and medication safety [93]. This effort was aimed at removing the confusion that existed between the use of the same terms by regulatory authorities and the patient safety researchers and managers.

These patient safety epidemiology articles which were published between 1999 and 2005 clearly indicate that after the publication of the "To Err is Human" report, many countries embarked on a variety of studies in order to determine the rate of adverse events in patients admitted to hospitals. The publishing of these articles served to bring the nature and extent of adverse events to the attention of the public, funders and policy makers. It is also important to note that most of these studies were conducted in countries that are often referred to as the "developed countries". South Africa is yet to embark on studies of this nature. The absence of published patient safety epidemiological studies that were conducted in South Africa, therefore means, very little is known about the extent and nature of adverse events in hospitalised patients. This study will hopefully stimulate researchers to undertake such studies in South Africa in the near future.

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2.3 Introspective articles on patient safety

In an article "A Tragic death: a time to blame or a time to learn" [94], the authors respond to five key statements that were part of a news article that addressed the broader issues of patient safety. The tragic death of a teenager from tissue incompatibility following a heart-lung transplant owing to a screening error raised huge-scale public outrage because the operation was funded with funds raised through a public campaign. Runciman et al [8] argue that blaming the professionals hinders our learning from such experiences and our efforts to ensure that these are minimised through focused interventions.

Reinertsen [95] suggests that one of the first major steps that can be taken by health professionals, managers and leaders in order to intervene and reduce medical errors is to talk about them. Reinertsen [95] stresses the importance of the non-blame culture and the positive role that leadership can play in health settings to ensure that patient safety is promoted.

Wu [96] asserts that for every adverse event there are at least two victims: the patient that is exposed to harm or near miss and the attending physician. While the victim status of the patient is indisputable, that of the physician is what is being sharply brought into focus by Wu's [96] article. It is argued in the article that the physician is often faced with guilt, dejection and risks of being labelled "incompetent" as a result of these adverse events. Any association with adverse events can have serious consequences of professional scorn, marginalisation and loss of professional self-esteem. Wu [96] therefore appeals that these professionals be treated more sympathetically and provided with the necessary support.

Berwick and Leape [97] challenge the heath sector to look for alternative solutions to patient safety by looking at what other industries such as aviation have done to improve their safety records. These authors argue that the safety record of the aviation industry has improved as the industry has become more sophisticated, whereas experiences in healthcare have shown the opposite trend. Berwick and Leape [97] propose that the blame and punitive culture associated with these adverse events is counterproductive and suggest that the sector should promote a culture that allows clinicians to freely report all incidents irrespective of the outcome, without fear of reprisals, just like in the aviation industry.

The above articles emphasise the complex nature of medical error and adverse events and suggest that the usual knee-jerk reaction of seeking to punish the health professionals that are involved may not be the optimal response. Professionals are mentioned as second victims in the occurrence of medical error and they are urged to report these adverse events in order for everyone to learn from them. This developmental, non-punitive approach that is promoted in these articles is currently not being practised in many countries including South Africa. These articles also lay the foundation for the development of the "just culture" in health care organisations. This culture promotes the reporting of incidents without fear of reprisals, while holding professionals accountable for their actions.

2.4 Patient safety and links with other high risk industries

The scale of medical error and its consequences have been clearly illustrated in the above-mentioned articles. In an attempt to find sustainable interventions to address this major international healthcare challenge, there have been suggestions that healthcare has to look at how other high-risk industries have achieved an improvement of their safety practices.

Given the similarities between aviation and medicine with respect to the high profile given to accidents or adverse events, the high level of professional skill required from surgeons and pilots, the complexity of the operational environment of the operation theatre and cockpit, the ability of healthcare to learn from aviation is a strong likelihood.

The development of incident reporting systems has been influenced by other high-risk industries such as aviation. Harper et al [98] indicate that while it has been easy to adapt reporting systems from aviation to the health sector, there has been significant resistance to the utilisation of these systems for error reporting and estimate that under-reporting may be as high as 96%. This figure is attributable to the perceptions and attitudes of the health care professionals, that reporting is not "safe".

Helmreich [99] has developed a medical error management system based on aviation systems in order to improve incident reporting. The detail and effort required to make this incident reporting system to work, may be seen as an additional bureaucratic burden by professional personnel in the health care setting. Helmreich [99] insists that the sooner organisational and professional cultures accept the inevitability of error and the importance of quality data on error, the better for overall healthcare quality and patient safety.

Gosbee [100] suggests that in order to improve patient safety through efficient equipment, devices, machinery and systems design, we need to apply the human factor engineering approach. In this article the author uses a case study in which a critically ill patient was attached to monitoring equipment that was not properly set and gave incorrect readings of essential clinical patient data – with almost fatal results.

As further support for adoption of human factor engineering in addressing patient safety challenges, Karsh et al [101] argue for the rejection of the two common stereotypical assumptions: one, that healthcare systems are perfectly designed and are let down only by the clinicians; and, two, that healthcare professionals are perfectly designed and most errors are due to system defects.

Sexton et al [102] studied the attitudes of personnel in operating theatres and intensive care units to stress and medical error and compared these to the attitudes of cockpit pilots. The authors found that surgeons and anaesthetists are more likely to deny the influence of fatigue on performance. Another finding was that up to a third of intensive unit personnel did not acknowledge that they made mistakes in their work, and even more agreed that they found it difficult to discuss mistakes that occur in their work environment.

Diagnostic errors are common and can lead to patient harm, irrespective of the skills and competencies of the personnel involved. Singh et al [103] suggest that diagnostic errors can be reduced if the situational awareness model that aviation uses is adopted and appropriately applied to medicine. The basis of this model is that if there is an increased awareness of their immediate space and time environment by physicians, they will be enabled to predict what is likely to happen next, which can be expected to reduce any cognitive -based errors from occurring.

In complex healthcare working environments such as those found in hospital intensive care or neonatal units, teams are often used to provide care for patients. The overall performance of the team has a direct impact on patient safety. In aviation cockpit crew team behaviour is often observed by an expert who notes specific behaviour markers during flights that can lead to errors and these are eliminated through training. Thomas et al [104] studied the behaviour of team members in a neonatal resuscitation unit and argue that if the health care sector adopted some of the team-behaviour analytical tools used in aviation, patient safety can be improved.

The IOM's "To Err is Human" report [71] asserts that while most of the healthcare delivery programmes involve teams, training is still focused on individuals and leaves professionals hopelessly unprepared for what will be required at the coal face of service provision. Hamman [105] argues that medicine has to focus on developing research and training curricula that are aimed at training multi-disciplinary teams on key skills such as communications, collaboration and accountability. This approach will improve team performance and overall patient safety in the same way that aviation has improved its safety record.

Wilson et al [106] note that research reveals that teams by themselves are not always effective and that their performance may become progressively worse in more complex environments. Wilson et al [106] assert, however, that specific industries called" high reliable organisations" such as nuclear power and aviation have been able to strike a healthy balance between effectiveness and safety. The authors argue that these organisations achieve this balance through "high reliable teams", which prioritise, use close loop communication, engage in information exchange, share situation awareness, and make use of backup behaviour.

In a literature review undertaken by Rabol et al [107] to determine whether the multi-disciplinary teams that have been trained in an effort to improve patient safety have succeeded or not. This review reveals that most of these benefits have been recorded at an individual level and that the benefits to patient care at clinical level have been very limited.

Cook et al [108] borrow lessons from engineering and apply these to healthcare systems to address patient safety and quality challenges. These authors argue that when healthcare systems are designed to be loosely coupled to one another they are able to accommodate sudden demand surges within the system without major negative impacts. If they are designed to be more efficient and closely coupled to one

another (in other words, we "go solid") the sudden demand surges will lead to systems collapse with all its consequences for patient safety.

Amalberti et al [109] argue that while the medical industry has much to benefit from through adapting its systems to be in line with the high reliable industries such as nuclear power and aviation to improve patient safety and healthcare quality, there are five barriers that have to be overcome in order to make this alignment a reality. The health sector is advised to do the following to address these organisational, professional and cultural barriers:

- Limit worker discretion
- Reduce worker autonomy
- Move from craftsmanship to equivalent actor mind-set
- Simplify work processes
- Involve senior leadership in driving patient safety strategies

The adoption of systems from other high reliable industries has to take cognisance of some of the research outputs that indicate that safety problems cannot always be solved by complex technological solutions. Vicente [110] describes examples that indicate that to solve some of the cognitive challenges associated with error "less rather than more" technology provides the more sustainable solutions. Vicente [110] argues that patient safety challenges cannot be left to technological solutions, when we know that technological advice is imperfect.

Keller et al [111] describe another best practice from aviation that medicine is encouraged to adopt, and that is the publication by an independent supplier of an industry-specific and aviation-technology-targeted magazine. This magazine focuses on product recalls, hazard alerts, and performance-based issues. Keller et al [111] believe that this magazine has assisted the groups concerned to keep in touch with patient safety practices.

These articles are basically advising the health care sector not to re-invent the wheel in attempting to develop patient safety systems, but to look at the various examples of how other high risk industries have improved their safety records. The barriers to reporting incidents are identified and the health sector cultural issues are specifically exposed in order for them to be addressed. The symbiotic interaction between the health and other high risk industries with a deliberate intention of improving safety is only recorded in a number of developed countries. There is very little evidence that such interactions have happened or are happening in developing countries such as South Africa. These articles are therefore presenting these examples of inter-industry interactions as opportunities for health to improve patient safety, by learning from other high risk industries in a developing country setting. It is important to note that the incident reporting system, whose effectiveness is tested in the study, has its predecessors in the aviation and other high risk industries.

2.5 Adverse events and professional training

Healthcare provision is by nature labour intensive and, as has been discovered, most of the preventable medical errors are due to cognitive under-performance. There is therefore an intuitive logic that supports the training of healthcare professionals as one of the key interventions that will improve patient safety and the overall quality of healthcare services. The articles grouped under this sub-heading are squarely focused on healthcare provider training as a means of improving patient safety.

The 2003 IOM report, "Health Professions Education: a bridge to quality" [112] strongly advocates for the training of healthcare professionals as a means of improving patient safety. Five competencies were specifically identified for development in this publication and these are: patient-centred care; inter-disciplinary teams; evidence-based decision making; use of informatics; and application of quality-improvement methods.

Walton et al [113] under the auspices of the National Patient Safety Foundation have developed a training framework in line with the IOM report's recommended competencies. Walton et al [113] have already indicated that this training framework cannot be implemented by the current silo educational arrangements and that new innovative partnerships between all the stakeholders will be needed for its successful implementation.

A study was conducted by Van Geest et al [114] to assess the factors that physicians and nurses regard as obstacles to patient safety improvement and also what subjects an appropriate curriculum should contain, in order that training needs are addressed. This study revealed that physicians regarded increasing complexity of healthcare, a culture of tolerance and absence of training opportunities as the main barriers against improved patient safety. Apart from confirming that the barriers that the physicians faced also affected them, nurses also paid specific attention to reporting failure, which they regarded as the result of fear of humiliation, punitive processes and the perception that reporting does not result in any change.

According to Leach [115], in the USA the main bodies responsible for graduate medical and speciality training have agreed on six areas of competence that residents have to be assessed on to ensure they are fit to provide healthcare services. These competency areas are: medical knowledge, communication skills, patient care, practice-based learning, professionalism and system-based learning. Leach [115] argues that residents should ensure that their competence in these areas becomes habitual.

The WHO [116] has also developed a patient safety curriculum guide for medical schools. This guide emanates from a clear understanding that patient safety is one of the key challenges facing many member countries. The guide also recognises that a large proportion of preventable medical error is due to cognitive shortfalls, which reinforces the importance of the training of healthcare professionals.

Shojania et al [117], through a case study of an elderly patient with mild pancreatitis who dies as a result of medical error, conclude that poor clinical supervision not only threatens patient safety but denies students of learning opportunities and creates a culture of poor supervision.

In assessing the effectiveness of patient safety training for medical students Modigosky et al [118] concluded that little of what students learn can be sustainable in the first year after training and that some of the practices that had been cultivated, differed from what was taught. This sustainability lapse in training indicates that patient safety training has to be a continuous and repeated process in order to ensure that the acquired skills and knowledge are sustainable.

Medical errors in a teaching hospital environment will invariably involve registrars or residents. Volpp et al [119] capture eight key suggestions made by these trainee professionals with respect to the improvement of patient safety. These suggestions include the installation of appropriate information systems and medical directors taking leadership in patient safety efforts. These suggestions have to be taken seriously as they come from the coalface of healthcare delivery as opposed to the work of researchers and managers.

In an attempt to understand the role that should be played by physicians in patient safety, Goode et al [120] captured the discussions of a conference called by Agency for Healthcare Research and Quality (AHRQ) specifically to address this issue. Goode et al [120] focus on the main levers required for change; these include elimination of barriers to incident reporting, collaboration, incentives and regulation, which they regard as crucial in improving patient safety.

The manner in which the training of health care professionals to deliver quality services is done often undermines the patient safety goals of many health care systems. The apprentice on-the-job type of training exposes a patient to all manners of risk and harm. Ziv et al [121] believe that the answer to this problem is the introduction of simulation-based training for all levels of medical training. Ziv et al [121] argue that apart from reducing experimentation on patients, this approach increases ethical awareness, improves communication and team work, and can improve patient safety in the long run.

The prevention and management of incidents is absent in many curricula used for the training of health care professionals in many countries including South Africa. The training of these professionals is often focused on the technical aspects of health care provision and the development of skills to deal with medical error, patient harm and how these should be managed is often left to the professionals to deal with, on their own as they practice. This lack of training and preparation of professionals on medical error not only increases these incidents, but also denies these professionals the requisite skills for dealing with these incidents when they have occurred. It is hoped that the results of this study will bring the lack of medical error prevention and management skills to that attention of the academic institutions that are responsible for the training of health professionals in South Africa and other countries.

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The inclusion of these skills in the curriculum for the training health care professionals would be an important achievement milestone in the efforts to improve patient safety and overall quality of health care services.

2.6 Clinical competence and patient safety

There is an intuitive relationship that exists between clinical competence and patient safety that has far reaching implications in terms of personal characteristics of service professionals and the ability to train professionals to improve patient safety. On the face of it, one would expect that well trained professionals would be able to provide services in a diligent and competent manner without compromising patient safety and health outcomes. It is also reasonable to assume that the more skilled and experienced professionals would provide a more error free and safe care than those that are still undergoing training.

This view is supported by Martin et al [122], who indicate that competency based instruction was found to increase the skills and competencies of health professionals in invasive procedures. Martin et al [122] also assert that these skills were easily transferable from training to a clinical setting. In a similar study, Johnson et al [123] demonstrated that the clinical skills and competencies of professionals for intubations improved with the increased number and frequency of these procedures.

Ziv et al [121] propose that simulation based medical training is one of the most effective techniques that can be used to increase clinical skills and competencies while improving patient safety and overall health care quality. Gaba [124] insists however that in order for simulation based training to lead to increased competencies and improved patient safety, there are eleven factors that have to be considered and implemented in an integrated manner. This author then demonstrates how this would work using a framework based on these factors.

Nishisaki et al [125] cautions that while there is good evidence that simulation based training has been demonstrated to improve competencies of both individuals and teams, there appears to be a lack of evidence that demonstrates that the team competencies can be transferred to the bedside and also whether that this translates to improved patient safety. This observation suggests that what seemed to be an intuitive relationship between clinical competence due to simulation training and improved patient safety may be difficult to demonstrate after all.

It needs to be remembered that patient safety is a product of competent professionals, processes that are clearly articulated and understood, systems that have been designed to minimize errors and an organizational culture that promotes safe care. The competence or skills of the individual are but one of the factors required for providing safe care.

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2.7 Patient safety and working conditions of professionals

It has already been acknowledged that professionals are in one way or the other involved whenever an adverse event is reported that is due to medical error. The following articles explore the working conditions that professionals are often exposed to and attempt to understand the impact of these conditions on patient safety.

In an attempt to determine the influence that the working conditions of professionals on patient safety, Stone et al [126] discovered that there were lower rates of central line bloodstream infections, ventilator-associated pneumonias, catheter-associated urinary tract infections and bed sores in better staffed intensive care units that have lower overtime rates.

In a study that specifically examined the effects of long working hours on patient safety, Rogers et al [127] indicate that more medical errors and near misses were reported by nursing staff that worked shifts that exceeded 12.5 hrs. These authors also found that nurses often work more that their scheduled working hours and they, therefore, should not be exposed to shifts that exceed 8.5hrs as these are likely to become longer and increase risk for patient safety significantly.

The association between nursing staffing and mortality rates due to adverse events is discussed in detail by Needleman et al [128] after these authors had reviewed several studies. The authors conclude that this association is very strong, but the studies that have been done to date are just the same and are inconclusive in declaring staffing levels as a causative factor in adverse events and deaths.

Hall et al [129] indicate that the nursing staffing models that have a higher ratio of professional nurses as opposed to the other nursing categories experience lower levels of adverse events represented by falls and infection-control deficiencies. Hall et al [129] argue that the training that professional nurses receive makes them more aware of situations in the clinical environment that may lead to patient harm.

The argument that the higher the number of nurses a hospital has, particularly if more of these are professional nurses, the better the patient safety has to be interrogated in the context of limited resources. The affordability of various nursing to patient ratios was investigated at two institutions [130]. The authors's findings indicate that eight patients to one nurse was the most cost-effective ratio but was associated with higher mortalities. The authors also found that decreasing patient to nurse ratios below 4:1 does not significantly reduce mortalities and is only significant if it reduces the average length of stay.

In a study spanning five countries, Aiken et al [131] discovered that there appears to be a good working relationship between nurses and physicians. There are still major problems of work design, supervision and staff satisfaction challenges that need urgent leadership attention across the five countries in order to improve patient safety and quality overall.

In an attempt to determine the effect of the reduction of hours worked by residents on patient safety, Fletcher et al [132] reviewed a number of studies. Their concern in the study was that any benefits to patient safety that come with limiting the resident's working hours may be cancelled by the loss of continuity of care, which is likely to happen as more residents are appointed to provide the services. Fletcher et al's [132] findings based on the issues considered were therefore inconclusive.

Nguyen et al [133] highlight the low number of adverse events reported by physicians and nurses at 1.7% and 4.5% respectively, despite the implementation of user-friendly reporting systems. Nguyen et al [133] are clearly advocating that the curriculum of medical and nursing students should pay particular attention to the value and importance of reporting adverse events in the improvement of patient safety overall.

The various authors in this section draw a direct relationship between the working conditions of health professionals and the health outcomes. They indicate that safe care is a product of reasonable working hours, good staffing levels, better qualified personnel, good inter-professional relationships and good health professional training that emphasises patient safety.

The South African public health system is plagued by chronic shortages of key professional staff leading to long working hours and overtime. The remaining personnel are burdened with huge workloads and they become demotivated, irritated and frustrated. It can be reasonably inferred from these articles that the poor patient safety record in South African public hospitals, can be attributed to the poor working conditions that these health care professionals are often subjected to.

2.8 Patient safety and the law

It is a reality that when families bring their ill loved ones to hospitals for curative intervention and care, there is an overwhelming expectation that the patient will leave the health care centre fully recovered, when this does not happen, they get very upset and often sue the care givers and the hospital for negligence. There exist in many countries a whole set of statutory bodies, legal and other systems to ensure that there is legal recourse to bad and negligent medical care. These systems are often not tuned to the developments in patient safety.

Brennan et al [134] use a case study of a patient that got admitted to a hospital with pneumonia and left the hospital with severe brain damage requiring close, expert and expensive care for the rest of her life, to illustrate the flaws between malpractice and patient safety. These authors conclude that the developments in patient safety have to be used to advocate for a more developmental instead of adversarial approach to form the basis of malpractice systems.

Palmer [135] argues that the systems approach that is advocated through the new patient safety approach is actually undermined by the threats of malpractice law suits and disciplinary action, when in fact there is no evidence that these actions are effective in improving patient safety. Palmer [135] proposes that there is a need for a framework to be developed that ensures that professionals are able to report medical

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error with the view that lessons can be learned from this rather than invoking the big stick of lawsuits and discipline

In the South African scenario Erasmus [136] argues that the latest reports that indicate that there has been a 300-fold increase in the number of complaints by the public about the nursing services (including very serious cases), is a cause for concern. This author argues for introspection by the professionals and the elimination of arrogant and rude behaviour in order to improve patient safety and also to avoid the negative impacts of malpractice.

In an environment where the slightest of medical errors is punished through malpractice lawsuits, there is a tendency of professionals to be pre-occupied by this to a point that patients are often denied key medical interventions owing to the risks of lawsuits attached to them. Pawlson [137] argues that through pro-active risk management, it is possible to improve patient safety whilst at the same time taking sufficient precautions to prevent malpractice lawsuits.

In an effort to achieve a healthy balance between promoting patient safety and ensuring that patients can still appeal to the legal system to get compensation for damages caused to them, Clinton et al [138] make a few practical principle proposals as part of their medical reform. These authors argue that the medical liability system should strive to reduce preventable adverse events; promote open communication between patients and physicians; reduce insurance premiums that physicians pay and ensure that patients are adequately compensated for legitimate medical injuries.

In order to ensure that there are effective working relations between the department of health, the police and health safety executive in the investigation of cases of sudden unexpected deaths in the United Kingdom, the National Health Service has signed a trilateral memorandum of understanding with the Association of Police Chiefs and the Health Safety Executive [139]. This document spells out the roles of the different parties, the protocols to be followed and how all the issues have to be managed in the interests of patient safety.

While the frequency and amounts for which government is sued for the medical errors committed by its health professionals is growing at an alarming rate, this has not reached the extent that is experienced by countries such as the USA. This may be due to the cultural, educational, political and financial barriers that prevent the majority of the users of the public health system in South Africa from taking this legal route, when adverse events have occurred. These barriers have however not stopped leading public figures and community members from calling for "heads to roll", after a publicised adverse event.

The punitive, lawsuit approach may bring some relief to the affected individuals and their families, but further damages the health system by removing these scarce financial resources that are required to provide better quality health care on a sustainable basis. It is therefore important for the health system to make key

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investments in the area of patient safety and medical error prevention in order to keep these important resources within the system.

2.9 Patient safety and the media

The media is one of the main players in the development and maintenance of views and perceptions of members of the public on adverse events, and medical error in particular, and the quality of health care services in general. The outrage, emotion, blame and sensational manner in which a great many adverse events and incidents of medical error are often reported or portrayed in the media often shapes the response of the general public, the funders as well as politicians.

Millenson [140] traces the influence that the media has had in the improvement of patient safety and strongly argues that the media has for a long time been ignored by the health professionals and authorities when it has presented these adverse events to the public. This author states that adverse events, when they have been publicised, have changed the response of the public, professionals and the authorities. Millenson [140] insists that this is the key role that the media has played in the improvement of patient safety.

The media often justifies these reports by declaring that it is representing public interests and that on behalf of the public it is a pressure group that advocates for patient safety and provision of quality health services. In a study aimed at determining whether the publication of hospital performance reports in the media leads to improvement of quality or not, Hibbard et al [141] found that public hospitals were more negative about these hospital performance reports and queried their validity and accuracy more than private hospitals did. These reports, however, have resulted in a significant increase in quality-improvement efforts by all parties.

Publicising the performance results of hospitals is also intended to provide information to the users of these services on provider choice, to the funders on decisions on performance-based resource allocation and to policy makers on evaluative decision making. Werner et al [142], however, argue that the value of these public reports on actual quality improvement has not been quantitatively demonstrated.

The South African public hospitals are often in the media for adverse events that have occurred due to medical error, and these reports are in the majority of cases critical of the quality of health care services that are provided by these hospitals. The health sector can benefit immensely from understanding the root causes of these reported incidents in order learn from them and provide sustainable patient safety interventions, but the manner in which these incidents are often reported, fails to create this learning environment. The reporting of these incidents is more often than not aimed at seeing those health professionals that are involved punished and government made to pay for these medical errors. Government tends to respond to these reports in a guarded and defensive manner, and thereby escalating the already acrimonious situation.

It is hoped that the results of this study will also get the attention of journalists that are serious about reporting on public health issues. The publishing of these results will hopefully provide a different perspective on the management of adverse event due to medical error. The media can therefore play a more positive and responsible role of informing members of the public about the facts around adverse events while holding the health system accountable to the public and deliver safe care.

2.10 The economics of patient safety

The finding that between 44 000 and 98 000 people die each year as a result of adverse events caused by medical error and that this costs the USA between $17 and $29bn each year is the basis for some of the economic concerns around patient safety. Intuitively it means that any significant investment in patient safety efforts that result in the reduction of the number of adverse events will release scarce resources, which can be redirected to other areas of the health system to improve health outcomes.

Corbett-Nolan et al [143] make a very strong case that elimination of wastage within the healthcare system can ensure resources are made available to drive patient safety initiatives and overall quality improvement, and that this by itself is expected to generate further cost savings.

In a comprehensive account of the costing of adverse events, Gray [144] indicates the following:

- The $17 to $29bn per annum costs address only loss of earnings and future lifetime health care costs;
- Adverse events on average increase length of stay from 5.8 to 13.5 days (7.7 days or 132.8%);
- There are additional costs as a result of lab investigations, diagnostic tests, treatment, monitoring and care to be considered

In a more detailed clinical study, Zhan et al [145] found that wound infections resulted in an increase in the average length of stay by 10.89 days, there was a 22% increase in mortality and additional costs of $58 000. Wound dehiscence resulted in an increase in the average length of stay by 9.58 days, and there was a 9.6% increase in mortality and additional costs of $39 000.

In another exercise aimed at calculating the costs attached to adverse events, Encinosa et al [146] estimate that patients that experienced a preventable adverse events paid an additional 52%, 21% and 11%; hospital, physician and out-patient fees, respectively. This study was a private sector study and indicates that adverse event costs are also often unfairly shifted to the patient.

In an attempt to estimate the costs related to drug morbidity and mortality, Ernst et al [147] determined that in 2000, in the USA, these amounted to $177bn. Seventy per cent of these were attributable to hospital admissions and 18% was for long-term care admissions.

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Weeks et al [148] points to the difficulties in attempting to develop a coherent business case for patients' safety, owing to the complexity of estimating the required investments and the timing and quantities of the returns.

The importance of examining the economics of patient safety seeks to provide answers to the question; whether under-resourced developing countries should be making significant investments in patient safety or focus on priority programmes such as those aimed at reducing the incidence of HIV/ AIDS and TB? The bigger question however, is whether those countries can afford not to invest in patient safety initiatives, given the increasing evidence of massive resources that are being redirected from these priority programmes to pay for the lawsuits and other downstream costs due to adverse events and medical error incidents? While these questions have been answered in many developed countries, this debate is expected to emerge in developing countries such as South Africa. The results of this study are expected to persuade the health system authorities to pay attention to this emerging health planning dilemma, and to make informed choices.

2.11 Patient safety and quality

There is very close relationship between patient safety and the quality of health care services. In many ways the issues of patient safety have tended to dominate the discussions on overall healthcare-system quality improvements in recent times. This is evidenced by the declaration by the WHO through the 55th World Health Assembly [3] that patient safety has to be prioritised as an important aspect of healthcare quality-improvement efforts by all member states.

The Agency for Health Care and Research has developed a manual [149] for nurses to provide guidelines to address patient safety and quality healthcare. In this document the authors declare that "patient safety and quality is at the core of health systems".

Legido-Quigly et al [150] in their collective assessment of the approaches and understanding of health care quality in Europe indicate that after efficiency, effectiveness and access, safety is one of the key dimensions of quality that is reflected in numerous definitions by reputable international organisations.

One of the important developments in the improvement of health care quality has been the quality accreditation process carried out by external agencies. In appreciating the role of accreditation as a process and the contribution that these agencies have added to quality improvement, O'Leary [151] challenges healthcare leadership to provide support to these agencies. He argues that this massive responsibility of ensuring that patients receive safe care has to be drive by the facility leadership.

The ever-important principle of "first do no harm" in the provision of healthcare and practice of medicine is one of the clearest indications of the intricate, but inter-twined relationship between patient safety and quality of health care. Miller et al [152] have developed a number of patient safety indicators, with the use of administrative data to assist individuals and institutions to develop tools for anticipating and measuring patient safety.

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The relevance of the articles that confirm the close relationship between patient safety and overall health care quality to this study, is the impact that patient safety initiatives are expected to have in the health outcomes. In this study it is postulated that when a health system improves its patient safety, the improved health care quality is evidenced by reduced morbidity and mortality rates leading to improved health outcomes. This relationship between patient safety and quality is one of the central ideas that have guided this study and this is further developed as a theme in the next chapter.

2.12 Patient safety at the clinical level

In an attempt to understand patient safety characteristics, causes and origins it is useful to examine medical error and adverse events from a clinical or discipline perspective. Reason [153] describes two sets of medical errors – latent and active errors. Latent errors are described as those errors that occur as a result of inherent defects within the health system. An example of this would be an adverse event that occurs because of faulty equipment that was poorly maintained due to lack of budget.

Active errors on the other hand result in adverse events at the coalface and are due to the interaction between the patients and the clinicians. An example of this would be an adverse event that occurs when an inexperienced physician fails to make an appropriate diagnosis. It is these errors that we focus on in this section of this chapter.

Given the complexity of healthcare organisations and the common difficulty of translation theory into practice, Mohr et al [154] suggest the development and implementation of clinical microsystems in order to institutionalise patient safety practices. Clinical microsystems consist of clinicians, support personnel, information and the technology required to provide the service.

In a study aimed at measuring and determining the causes of preventable anaesthetic error, Cooper et al [155] discovered that up to 82% of anaesthetic error was due to human error and that equipment failure was responsible for only 14%. Some of the major contributions to these preventable errors were poor communication, distraction and failure to take precautions.

In an effort to address common preventable anaesthetic errors, Runciman et al [156] developed specific algorithms aimed at capacitating clinicians to deal with any crisis that may present in the operating theatre. These logarithms can easily be remembered through user-friendly mnemonics, which have been tested in clinical situations with good results.

In an observational study aimed at understanding the causes and types of adverse events seen at intensive care units, Valentin et al [157] found that the majority of these were associated with lines, catheters and drains. These were followed by medicine-related adverse events and equipment, airways and alarms.

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In a study whose objective was to determine the effectiveness of using a "Formula One"-based patient handover methodology between the intensive care and surgery units , Catchpole et al [158] found that this approach reduced the number of technical errors from an average 5.42 to 3.15 per patient.

Obstetric errors are so common in many countries that the premium for medical defence insurance for obstetricians has become significantly higher than the premium for other specialities. This has concerned Pearlman [159] to a point that the author has suggested a package of interventions to improve patient safety from an obstetric perspective.

In mitigating medical errors associated with obstetric clinical practice, Cherouny et al [160] developed and presented a number of recommendations aimed at ensuring that there is effective, efficient and safe perinatal care. These recommendations focus on clinical processes, communication, safety improvement and involvement of family in the delivery of babies.

Cairns [161] itemises the common reasons that lead to paediatric deaths and laments that these are largely preventable, but only if the clinicians listened more to parents, recorded clinical and prescription data, monitored patients regularly and communicated better.

In assessing paediatric-related adverse events, Miller et al [162] concluded that the most common adverse events are birth trauma. They also discovered that whenever there is an adverse event, the average length of hospital stay was increased by between 2 and 6 times; mortality increased by between 2 and 18 times and costs increased by between 2 and 20 times..

The surgical discipline is another area where there is a high incidence of medical error and adverse events that lead to disability and death. It is also an area of clinical practice that tends to attract a significant number of lawsuits against the providers of services. In a study by Kable et at [163] aimed at determining the extent of surgical adverse events, the researchers found that in Australia, 21.9% of surgical admissions were associated with adverse events; 83% of these led to temporary disability, 13% to permanent disability and 4% to death. Kable et at [163] also found that 48% of these adverse events were preventable.

In a study by Hundt et al [164] where surgical patients were provided with sufficient preoperative information, adequate post-operative self-management, regular clinical status updates and the correct site, the patient satisfaction rate about the surgery was significantly high.

Vincent et al [165] conclude that good surgical skills combined with good team performance and good equipment will enable a good surgeon to perform a successful high-risk surgical procedure 90% of the time. The improvements to this result can be done through the enhancement of the surgical environment, improved communication, ergonomics and equipment redesign.

Laboratory errors are often at the wrong end of poorly assessed, diagnosed and managed patients and lead to severe or fatal adverse events. These errors can be classified as pre-analytic-, analytic- and post-analytic errors, depending on the stage at which they occur. A specimen-collection error would be an example of a pre-analytic error; an error due to incorrectly mixed reagents would an analytical error; whereas incorrectly transmitted results represent an example of a post-analytic error.

Howanitz [166] found in his study that the pre- and post-analytical errors were significantly higher than the analytical errors and subsequently proposed a set of eight performance indicators to be measured in order to identify laboratory errors and to develop targeted interventions.

In an attempt to measure the extent of anatomical pathology error, Raab et al [167] reported a mean and median laboratory discrepancy frequency of 6.7% and 5.1% respectively. Incorrect classification of tumour type occurred in 48% of cases; incorrect determination of malignancy happened in 21%; 5.3% of these anatomical pathology errors led to significant impacts on patient care.

The above articles give a detailed account of the adverse events studies that have been published in relation to the various clinical areas or disciplines. Their relevance to this study is to emphasise the fact that the majority of adverse events are a product of the interaction between the health system and the patients; that the majority of these adverse events are due to health system failures and medical error by clinicians. The effectiveness and sustainability of patient safety interventions will therefore be determined by how well they have focused on the system failures and medical error.

2.13 Patient safety and medication

Medical errors that are due incorrect medication have been identified in numerous studies as being one of the most common causes of adverse events. This part of this chapter deals with the characteristics, causes and origins of medication errors as well as the interventions suggested by various studies to reduce them effectively.

The reporting of adverse drug events is important for the understanding of their causes in order that interventions can be developed that will prevent or eliminate them. Professional nurses play an important role in the clinical care of patients. It is therefore important to understand the barriers to adverse drug event reporting from their perspective. Wakefield et al [168] have developed a survey tool that can be used to collect and analyse this information in order to gain insights to these barriers to reporting of adverse drug events.

Claasen [169] reminds us that the earliest registers of adverse drug events were created in the 1950s in the USA after the establishment of a link between chloramphenicol use and aplastic anaemia was established. Claasen [169] also states that one of the earliest measures of adverse events in hospitalised patients was measured at 30% and that 3% of hospital admissions were due to adverse drug events.

In a study aimed at determining adverse drug events, Claasen et al [170] found that 2.43 per 100 admissions were associated with adverse drug events and that these led to an additional average increase in the average length of stay of 1.74 days, at an additional cost of $2000 per day. Ernst et al [147] estimated in 2001 that the mean costs of treatment failure per patient was $977; the costs of a new medical problem as a result of an adverse drug event was $1 105 per patient.

In an attempt to diagnose adverse drug events and to measure these through a medical record review, Rozich et al [171] developed an adverse drug event triggers. These triggers give a clear indication that an adverse drug event has occurred, even if this is not recorded as such in the medical record. An example of this is the sudden and unexplained administration of an anti-histaminic drug when this is unrelated to the patient's clinical condition.

Fogarty et al [172] suggest that a significant number of drug administration errors are directly related to organisational factors such as staff shortages, high stress and low morale. The prescription and administration of drugs to the elderly is one of the major causes of drug adverse events. Gurwitz et al [173] have developed a set of eight principles that will serve as a guideline for the improvement in the prevention of adverse drug events in the elderly.

Hennessy [174] indicates that a common mistake that is often committed in addressing adverse drug event interventions is to regard the medication procurement and administration environment as a well-defined system, when in fact it is made up of stakeholders who may have different agendas. Hennessy [174] identifies ten areas that have the potential of producing the highest impact in terms of reducing adverse drug events.

The misinterpretation of medicine prescription and drug labels has been identified as one of the contributory causes to adverse drug events. In a study to illuminate this, Wolf et al [175] determined that in 33% of the tested cases, there was a misinterpretation of prescriptions issued. This was particularly more pronounced in the groups where there is a higher incidence of illiteracy.

It has also been noted that despite the use of technology to improve medication safety, in some instances the coalface implementers, tend to bypass some of the key steps in the medication administration process. Koppel et al [176] describe the causes for process bypass in the utilisation of the Bar Coded Medicine Administration System (BCMAS) as being due to the task, technology, organisation and the patient. These authors argue that meticulous care has to be taken in implementing these technologies to ensure that they deliver the required results.

The above articles that discuss the nature and causes of medication related adverse events are very relevant to this study. The administration and consumption of medication is so common in the health care sector that some community members feel "cheated" if they leave a health facility without any form of medication. The frequency of use of medication in health care also means that the chances of an adverse event

occurring as a result of administration of medication are high. The chances of the occurrence of medication related adverse events are even higher in developed countries, where the tendency of the use and distribution of counterfeit medication is high. The reporting of adverse events related to medication remains unacceptably low, it is therefore hoped that the result of this study will encourage the reporting of these adverse events, in order for all key personnel to learn from them and develop effective medicine related patient safety interventions.

2.14 Health care associated infections and patient safety

In the sections of this chapter that have dealt with the epidemiology of adverse events, it has been clearly articulated that healthcare-associated infections were one of the major causes of adverse events responsible for patient morbidity and mortality in hospital settings. According to Burke [177], between 5% and 10% of all hospital admissions are associated with infections and these affect 2 million patients and are responsible for 90 000 deaths per annum in the USA. Urinary catheter associated, wound site, bloodstream and pneumonias are responsible for 80% of these healthcare-associated infections.

Yokoe et al [178] extensively describe a number of initiatives aimed at reducing health-associated infections that have been successfully implemented by various organisations in the USA. These initiatives largely focus on the surveillance, prevention, and treatment of infections at wound site, urinary catheter, bloodstream and ventilator. These initiatives have effectively reduced morbidity and mortality and are therefore recommended by the authors.

Using a case study to illustrate the importance of implementing patient safety techniques in addressing infection control problems, Gerberding [179] also emphasises the need to implement infection control techniques in addressing patient safety problems. Pronovost et al [180] also describe a successful study carried out in 108 ICUs in the USA, which resulted in a sustainable reduction of 66% in catheter-related bloodstream infections over an 18 month period.

These articles indicate that the prevalence of health associated infections in developed countries such as the USA is between 5% and 10% of all hospital admissions. Given the high prevalence of TB, HIV and AIDS as well as other communicable diseases; resource limitations to procure cleaning materials and other infection control equipment; staff shortages especially trained infection control nurses and cleaners; the prevalence of the health associated infections in developing countries is expected to be even higher. The high prevalence of health associated infections makes an excellent business case for investment in infection control programmes which can also be seen to be patient safety interventions. The ministry of health in South Africa has prioritised infection control for all its hospitals to an extent that it is seen as one of the ministerial non-negotiable priorities.

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2.15 Patients for patient safety

While it is generally accepted that patients are invariably the first victims of adverse events and associated morbidity and mortality, when interventions are designed to address patient safety challenges, these often focus on the professionals, the processes, the systems and the technology. The patient is often forgotten. This section of the chapter focuses on the role of the patient in the development and implementation of interventions aimed at improving patient safety.

In a study aimed at determining the support for patient safety efforts in the USA, following the publication of the "To Err is Human" report, Blendon et al [181] discovered that a significant number of physicians and patients have had a relative of theirs experience an adverse event. There were, however, major differences in the physician and patient perceptions about the effectiveness of the interventions to improve patient safety. It is therefore important to consider the views of all the key stakeholders in designing sustainable patient safety interventions.

Vincent et al [182] assert that patients have to play a key role in the diagnosis of their illness, the effective management of the illness, the choice of an experienced and safe service provider. According to these authors, patients need to ensure that the treatment is properly administered and monitored and detect and report adverse events. This is hardly the passive role that many a patient has often been relegated to by many.

It needs to be said that while the author fully supports the role that Vincent et al [182] describe for patients in order to improve patient safety, the situation on the ground is far removed from this "ideal". In real life patients are treated as passive consumers of health care services and are often expected to be "seen and not heard", by the treating professionals.

While Wensing et al [183] strongly advocate for the incorporation of the views of patients in the management of their illnesses, they also warn that some of the methodologies that are aimed at effectively doing this are flawed. Wensing et al [183] propose a set of interventions that have been found to be useful in several studies for consideration.

In 2003 in the USA, the National Patient Safety Foundation developed a national action agenda [184] in order to ensure that the view and contributions of patients and their families are considered in the development of programmes aimed at medical error prevention and the improvement overall patient safety. This agenda covers education and awareness, patient safety culture, and research and support services.

The establishment of the World Alliance for Patient Safety in 2004 [185] was a clear attempt at ensuring that all member states are encouraged to initiate and establish patient safety programmes aimed at improving quality of care and health outcomes. One of the key action areas of this alliance is patient and consumer involvement, which is characterised by the "speak up" programme, which empowers patients in

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their interaction with the health system to ensure that harm directed at them is minimised.

The above-mentioned articles indicate the centrality of the role of patients in the diagnosis and management of their illnesses. They are also indicating that the patients need to be accorded some respect and responsibility for ensuring their own safety during the process of diagnosis and management of their illnesses. The respect for these fundamental patient rights is in many countries including South Africa absent. Patients are treated as passive consumers of health care services and their contribution to the diagnostic and treatment processes is often ignored. The misinformation, non-communication, non-consultation and failure to involve patients and their families before and after the occurrence of adverse events, are often the main reasons for them resorting to the legal processes to obtain some form of relief.

2.16 Patient safety and reporting systems

The challenge of reporting clinical incidents and adverse events is compounded by the fear of embarrassment and humiliation of the concerned physician as well as the punitive consequences that may visit them upon the discovery of the event [98]. This punitive approach is often encouraged by the politicians, media and the general public who believe that all incidents and adverse events are a result of a negligent and uncaring health system.

Incident and adverse event reporting systems are developed to provide an organised means for capturing all the details surrounding the incident in order to determine which areas of it could have been prevented and to determine where interventions are required. Lawton at al [186] found that professionals, especially doctors, are unlikely to report incidents to a superior and would rather report to a peer. Doctors are also unlikely to report an incident unless there was a protocol violation or a negative outcome.

Pietro et al [187] further illustrate this dilemma of reporting errors by using case studies of urology patients who were incorrectly diagnosed and, therefore, incorrectly managed. Pietro et al [187] make the assertion that health professionals set themselves unreachable standards of perfection and urge them to be modest and to recognise that to err is human.

Different countries have developed reporting systems with different technologies and levels of sophistication, from paper to electronic web-based systems. It is not the intention of this section to do a detailed review of all these systems. A few of these technologies are described below in order to illustrate the development of these systems.

Davis et al [188] give an account of the successful development and implementation of a data-based clinical incident and adverse event system for the military in the USA. These authors found that this streamlined adverse event reporting made the analysis of trends easier.

Tuttle et al [189] indicate in an article published in 2004, an increase in the number of reported incidents and adverse events after the introduction of an electronic reporting system in New York. The nurses reported a significant majority of these (73%) and the physicians only 2%; the reported near misses and unsafe conditions were 16% and only 22% of these led to patient harm.

Nakajima et al [190], on the other hand, reported an improved response and reporting of adverse events and clinical incidents after the introduction of a web-based reporting system, new structural configuration and an educational programme. The implementation of this reporting system resulted in increased awareness of patient safety and improved leadership in dealing with patient safety and quality-improvement issues.

Weinger et al [191] describe a methodology of using audio-visual technology to track clinical incidents and adverse events, which they believe can make a significant contribution to patient safety and overall quality improvement.

These authors indicate the unwillingness of some professionals to report incidents and also report on the various attempts by different countries to develop reporting systems that are supposed to improve the reporting of incidents. One of the key objectives of this study is to determine the effectiveness of an incident reporting system in encouraging the reporting of incidents. It is the first time that an incident reporting system is implemented in South Africa, and therefore another objective is to determine if the incident reporting system works in developing country setting or not. Chapter 3 also has a detailed discussion on why the incident reporting system should be regarded as learning systems.

2.17 Implementation challenges of reporting systems

Voluntary or mandatory?

The primary reason for implementing patient safety reporting systems is to gather as much information about clinical incidents as possible in order to determine their nature and causes; and also to develop appropriate interventions that will help to reduce them and thereby improve patient safety. One of the key questions to consider when implementing these patient safety reporting systems is whether the reporting should be voluntary or mandatory.

Cohen [192] suggests that patient safety reporting systems that are voluntary are more useful and effective in promoting the reporting of incidents than mandatory systems. This increased reporting through the voluntary reporting systems provides information that enables the analysis and deeper understanding of the reported incidents. It is through this understanding that health system managers are able to design and implement effective interventions that will result in improved patient safety.

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Barach et al [193] point out that the major challenges faced by health systems using mandatory reporting systems that makes them less preferable to the voluntary systems, are the barriers to reporting such as; confidentiality, protection for reporters, accountability and feed-back to reporters.

The Australian Incident Monitoring System-Intensive Care Unit (AIMS-ICU) and the ICU Safety Reporting System (ICUSRS) are cited by Wu et al [194] as good examples of systems that are voluntary and confidential by design and in their view are more effective than mandatory systems in improving patient safety.

Fernald et al [195] attribute the successful implementation of a voluntary reporting system in the primary health care setting to the confidential nature of the reporting and argue that confidential reports were far more useful in the understanding of the nature of incidents compared to anonymous reporting.

It should however be noted that there is serious under-reporting of incidents even when voluntary and confidential reporting systems are used. The barriers for the reporting of incidents are clearly articulated in [186, 196, 197,198], and these are not completely eliminated by assurances of confidentiality, anonymity, a just culture and leadership support.

Sheikh et al [199] credit mandatory reporting systems as very effective in holding health professionals accountable for errors that result in patient harm, but indicate that these systems are difficult and expensive to implement and that their value is questionable. Sheikh et al [199] also argue that voluntary reporting systems which are more acceptable to the clinicians, promote reporting and patient safety improvement.

Klevens et al [200] indicate that the introduction of mandatory reporting for specific incidents based on their type, severity and nature may be the only way that authorities can estimate the quantum of a specific patient safety problem. Klevens et al [200] argue that it was only after 7 states in the USA, made the reporting of Health Care Associated Infections (HCAI) mandatory in 2006 that they were able to estimate and measure the extent of this patient safety challenge.

It therefore appears that when reporting systems are voluntary and confidential, there is more reporting of incidents. There are however certain incidents that have to be closely monitored at a regional or national level because of their importance to the entire health system and reporting these should therefore be made mandatory. How this is implemented will determine whether the system succeeds in encouraging the reporting of incidents. In this study, all the incidents that were reported through AIMS were voluntary.

Centralised vs Decentralised ?

In answering the important question of whether the reporting of incidents should be centralised or decentralised, most of the articles appear to place a great deal of importance on the context of the incidents. In a comparison between centralised and local incident reporting by general practitioners, Zwart et al [201] found strong

evidence that localized incident reporting systems were superior to centralized systems and that the former promoted quicker local interventions.

Bigley et al [202] on the other hand insist that a centralized incident command system is most effective and efficient in volatile complex task environments such as emergency medical services and intensive care units. These authors even suggest that in these environments, new flexible organizational structures are what may be needed to improve reporting and management of incidents.

Farley et al [203] suggest that even the most centralized systems can be made to increase incident reporting by additional support such as liability protection.

In the consideration for the implementation of the computerized incident management system in the Free State province during the study, one of the main determinants was the costs. A decentralised, hospital based call-centre might have increased the number of reported incidents per facility, but the costs of implementing this would have been prohibitive and would have rendered the approach non-viable on a generalised basis.

2.18 Patient safety and technology

Several interventions that are aimed at improving patient safety have relied on available or emerging technology and have achieved significant results. Ball et al [204] declare that if sufficient enabling technology was made available at the coalface of healthcare delivery, nurses would spend more quality and productive time on the patient instead of on the mundane tasks that usually occupy them.

In a different publication Ball et al [205] evaluate the added value of technology in improving patient safety. These authors indicate that the computerised patient record can reduce preventable errors related to documentation by up to 90%. They also indicate that the computerised physician order entry system for medicines has reduced medication errors by more than 50%. Ball et al [205] conclude that these technologies are key investments that health systems will need to make in order to improve patient safety.

The British National Health System has developed a comprehensive manual [206] about coding technology and its use in the healthcare system to improve patient safety and overall efficiency. This system links the patient's identification band with the information system that ensures that the patient is given correct medication and undergoes the correct surgical procedure. The system also ensures that there is proper equipment management and pharmaceutical stock management.

Whilst technology-based decision support systems may be useful in improving patient safety on the ground they also have the potential to generate a new set of errors that can threaten patient safety. Coiera et al [207] describe seven types of errors that can be generated by these systems and suggest that these are largely due to the inability of the system to eliminate social, cultural, technological and cognitive variations that are often prevalent in clinical situations.

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Ovretveit et al [208] describe an efficient manner of implementing an electronic patient record in Sweden, and indicate that the success of the patient record depends on effective consultation between the clinicians and the technology specialist, as well as the strong leadership involvement in the project.

These articles discuss the various technological interventions that have been implemented in different countries and settings in order to improve patient safety. The use of technology is often led by well-resourced developed countries and South Africa is unfortunately not one of them. This means that the decision to invest in a technologically advanced incident reporting system needs to be an informed one. One of the key recommendations of this study is to pronounce on the soundness of the decision to invest in the incident management system whose effectiveness is being tested in the study.

The extensive literature review that was presented in this chapter provides a snapshot of the developments in patient safety in the different countries and extensively discusses the challenges that are faced by many countries on patient safety as well the interventions that they are implementing to improve patient safety.

This literature review also provides a theoretical basis for the development of effective and sustainable patient safety interventions. The operational implementation of these interventions and possible challenges are outlined. It is possible to develop output and outcome indicators based on many suggested interventions in order to ensure measurability and evaluation.

The next chapter extensively discusses the theoretical framework for this study which uses the literature review as its basis.

CHAPTER 3: THEORETICAL FRAMEWORK

3.1 Background

In this chapter we explore the soundness of the patient safety theory that drove this research project. The four themes that are central to the understanding of the approach to the study are the pillars forming its theoretical basis. The themes that were identified by the author during the research are:

- Patient safety is a health care quality issue
- Medical error and patient safety are two sides of the same coin
- Balancing systems and individual contribution to medical error is at the heart of a "just culture"
- Reporting systems are learning systems in patient safety

3.2 Patient safety is a health care quality issue

The importance of identifying patient safety as a quality issue implies that improving patient safety improves the quality of health care services and therefore also improves the health outcomes and ultimately the performance of the health care system. Central to relationship between patient safety, quality and health care system performance is also the understanding that reducing the harm that is caused by the health care system to the population in general improves the population's quality of life. There have been many attempts at defining quality in health care, and it is worthwhile to recall a few of these that have been described by Legido-Quigley et al [150] and appear in Table 3.1 below.

The many definitions presented below are reflective of the many different approaches that exist to quality health care. Irrespective of the approach that one takes, there is general agreement that the quality of health care is an important component of the health outcomes of any health system. The approaches set out in Table 3.1 imply that if patients are harmed in the process of health care delivery, the quality of this care should be regarded as poor and is likely to lead to poor health outcomes.

These definitions by the various authors and organisations have a common thread that runs through them, that emphasises the following:

- Patient centredness
- Good health outcomes and
- Knowledgeable and skilled professionals

Table 3.1: Definitions of quality in health care

Author/Organization	Definition
Donabedian (1980)	Quality of care is the kind of care which is expected to maximize an inclusive measure of patient welfare, after one has taken account of the balance of expected gains and losses that attend the process of care in all its parts.
IOM (1990)	Quality of care is the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge.
Department of Health (UK) (1997)	Quality of care is: • Doing the right things (what) • To the people (to whom) • At the right time (when) • And doing things right the first time.
Council of Europe	Quality of care is the degree to which the treatment dispensed increases the patient's chances of achieving the desired results and diminishes the chances of undesirable results having regard to the current state of knowledge.
WHO (20000)	Quality of care is the level of attainment of health systems' intrinsic goals for health improvement and responsiveness to legitimate expectations of the population.

Notes: IOM: Institute of Medicines: WHO: World Health Organization.

Arah et al [209] report that developed countries such as the UK, USA, Canada and Australia consider patient safety to be an important dimension in the assessment of health system performance. The prioritisation of this dimension is clearly illustrated in Table 3.2 below. In a separate comparative study by Legido-Quigly et al [150] about the approaches taken by different leading international institutions to quality of health care, patient safety was identified as a key dimension of quality by four out of six of these. This therefore supports the argument that there is a logical relationship between patient safety, health care quality and health system performance.

This relationship means that any interventions aimed at improving patient safety will also make some contribution towards improving the overall health care quality and performance of that health system.

Table 3.2 Dimensions of health care performance

Dimensions	UK	Canada	Australia	USA	ECHI	Commonwealth Fund	WHO	OECD
Acceptability		✓				✓		
Accessibility	✓	✓	✓	✓ [1]		✓		✓
Appropriateness		✓	✓			✓		
Care environment and amenities[2]	✓							
Competence or		✓						
Capability			✓					
Continuity		✓	✓			✓		
Effectiveness or	✓	✓	✓	✓	✓	✓		✓
Improving health or							✓	
Clinical focus							✓	✓
Expenditure or cost							✓	✓
Efficiency		✓	✓	✓ [3]			✓ [4]	✓
Equity	✓	✓ [5]	✓ [5]	✓ [5]			✓	✓
Governance[2]	✓							
Patient-centeredness or patient focus or responsiveness	✓	✓ [6]	✓	✓			✓	✓
Safety	✓	✓	✓	✓				
Sustainability			✓					
Timeliness	✓ [7]			✓				

This link between quality health care and patient safety suggests that principles and models that are utilised in the analysis of quality in health care apply similarly to issues of patient safety.

One of the basic principles of health care quality that was developed by Donabedian [210] is that health care services can be likened to the productive processes in other sectors where inputs are converted to final goods or services. Donabedian [210] identified structures or inputs, processes and outcomes as the key determinants of the quality of health care services, and we believe that these determinants apply equally to patient safety. This concept is illustrated in Figure 3.1.
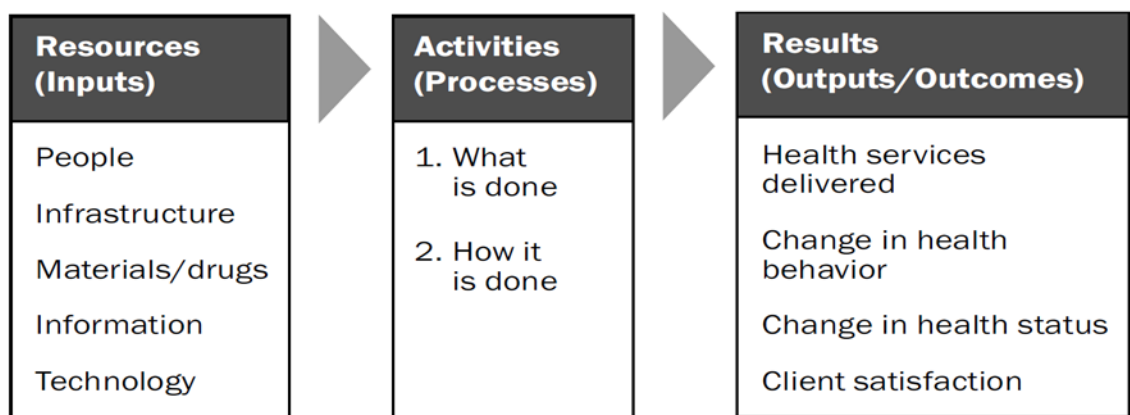
Figure 3.1: Quality improvement integrates content of care and the process of providing care

Adapted from Batalden and Stolz (1993) [211]

"Structures or Inputs" refers to all the required inputs in health care to ensure the production of quality services. These inputs include the quality and quantity of personnel, medication, consumables, funding, technology, equipment and facilities that are necessary to ensure delivery of quality health care services.

"Processes" refers to the policies, procedures, clinical guidelines, protocols and clinical diagnostic criteria required to produce quality health care services. "Outcomes", on the other hand, refers to the results of clinical care such as the case fatalities, post-surgical infections, readmissions and discharges. Clinical incidents and adverse events are by definition also outcomes or products of unsafe patient care. This framework enables the researcher to determine whether the clinical incidents and adverse events were due to problems that occurred at input or process levels and to explain the adverse outcomes.

This particular study, which focuses on adverse events and clinical incidents, could be seen as investigating quality of health care services from an outcome perspective. This approach is aimed at understanding the causes and determinants of unsafe care that

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results in clinical incidents and adverse events. The causes for unsafe care can through rigorous analytical processes be traced back to both the processes and structures.

An important concept that is closely related to health care quality is quality assurance and this is defined by Donabedian [212] as "all arrangements and activities that are meant to safeguard, maintain and promote the quality of care". Ruelas et al [213] define it as "a systematic way of closing the gap between actual performance and the desirable outcomes".

These definitions are describing the process of quality assurance, which should also be understood to mean quality improvement. If quality in health care is understood to be the desired state or destination, then quality improvement is the means to an end or the journey. Massoud et al [214] propose a new paradigm of health care quality that uses continuous quality improvement as a change agent and is grounded on the following principles:

- Focusing on clients
- Understanding work as processes and systems
- Working in teams
- Testing changes and emphasising the use of data

The relevance of this approach to this study is found in the fact that this is a study focused on improving health care services on behalf of the patients or Free State population, who are our clients in this instance. The study is also aimed at understanding the processes and system defects that result in incidents and adverse events. The efforts designed at implementing the necessary interventions are team based and include clinicians, managers, policymakers and, more importantly, the patients themselves.

The study tested a group of interventions centred around an incident reporting system and sought to determine whether these interventions would result in the improvement of patient safety or not. This process was driven by data that was collected on the reported incidents and adverse events, as well as survey results.

Massoud et al's [214] paradigm also suggests that the problems that require solution through this quality improvement approach range from the simple, requiring individual attention, to those that are complex in nature and affect the entire system and, therefore, require a more comprehensive team solution. This is a very useful approach because it also means that the resources deployed for the resolution of these challenges will be allocated more efficiently, instead of using costly solutions to address simple problems. In a resource-constrained environment such as ours in South Africa effective allocation of resources is very relevant.

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Massoud et al [214] also present the essential steps that need to be followed in the implementation of the quality improvement projects (Figure 3.2).

a. Step 1: Identify what needs to be improved
b. Step 2: Analyse what needs to be understood before changes are considered
c. Step 3: Develop options that can possibly provide the required changes
d. Step 4: Test and implement the identified options
e. Step 5: Use the cycle of learning and improvement to drive the solutions and quality improvement
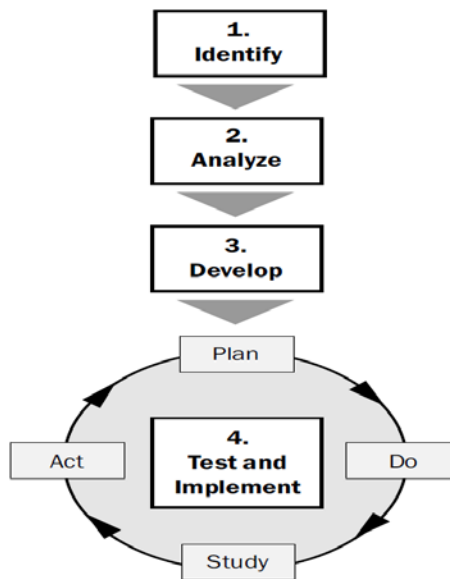
Figure 3.2: Four steps to quality improvement

The learning and improvement cycle was developed by Shewart [215] and adapted for health care quality. This cycle, which is illustrated in Fig 3.3 below, uses the same principle as the cycle called the "quality cycle". In the quality cycle throughout the process of planning and implementing the necessary quality improvement changes, data should be used to monitor and evaluate whether the desired results are being achieved or not. This key information should then, through an iterative process, influence further planning and implementation as the project unfolds. It is this continuous iterative process that is responsible for the continuous nature of the quality improvement process, also known as "CQI" [216].

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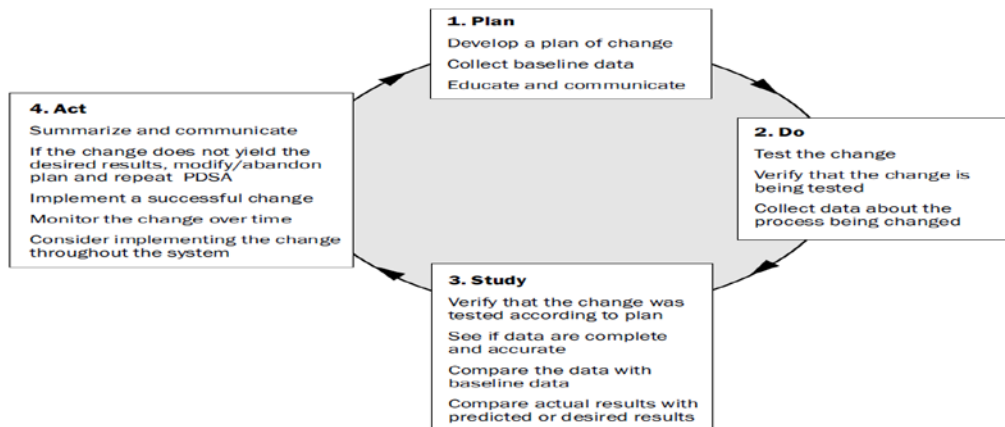
Figure 3.3: Shewhart's cycle for learning and improvement

Brown et al [217] support this new paradigm developed by Massoud et al [214] and attest that it can also be used successfully in developing countries. These authors argue that unless one has a good understanding of the root causes of the situation that is producing sub-optimal health care quality, one cannot develop sustainable interventions. They also insist that interventions have to be assessed prior to their implementation in order to get some idea of the full impact the implementation of the quality improvement project on the entire organisation.

The establishment of the relationship between health care quality and patient safety enables us to utilise established quality tools to explore patient safety issues. It needs to be understood that medical errors and mistakes are important factors in the development of unsafe care. What causes medical errors and mistakes and how these causes relate to patient safety is the major question that is addressed in the next section.

3.3 Medical error and patient safety are two sides of the same coin

This section will address how medical error relates to patient safety. The understanding of human error and its relation to the development of clinical incidents and adverse events has been heavily influenced by human factor specialists. According to Reason [218], one of the most important milestones that has been reached in the collaborations between medical- and human-factor specialists is that the models of causation that have been developed for the aviation, nuclear, petrochemical and other related sectors can be successfully adapted to health care.

In another publication, Reason [219] explains that from a psychological perspective, there are two causally determined types of errors: there are execution errors that include slips, lapses, trips and fumbles; and planning errors, which are also described as mistakes. Execution errors are characterised by adequate plans accompanied by poor actions due to inattention, memory lapses, poor response to changes and related problems. Planning errors or intention failure on the other hand result from a good execution of an inadequate plan.

Planning errors can, according to Reason, [220] be broken down into rule-based- and knowledge-based errors. Rule-based mistakes are usually linked to some procedure, protocol or guidelines, where the failure is mis-application or non-application of a good rule or an adequate application of a bad rule. Knowledge-based mistakes usually involve the formulation of a solution on the spot based on prior knowledge and these errors occur if the plan to solve the problem is inadequate.

Reason [220] further suggests that there has to be a clear distinction between errors and violations, which he describes as deliberate deviations whose actions are intentional but whose outcomes are not. These violations are in turn divided into routine, optimising and situational. The routine violations are mainly where there is cutting of corners; optimising violations where the violation is for "fun" and the situational violations occur when the violation is the only way of getting the job done because the procedures are inadequate.

In describing the aetiology of organisational incidents or accidents, Reason [221] proposes the model that is illustrated in Figure 3.4. This model proposes that this aetiology can be analysed at four different levels: organisational culture; local climate; situation task and at defence- or barrier levels.

a. At an organisational culture level: the vision, mission, structure, policies, communication and budgets of an organisation can have a direct influence on the environment of its units or subunits. The negative sequence in the production of error therefore begins at a strategic level in the organisation and is transmitted down to the work situation and these short-falls at a strategic level creates conditions for both errors and violations of procedures to occur.

b. In the work situation individuals respond to negative organisational impacts by operating under conditions or a climate that forces people to violate procedures, guideline and protocols or to commit errors.

c. The errors or violations that are now committed have a direct impact on the task at hand. These errors and violations results in the transmission of the accident sequence to the area where there is application of safety rules and procedures, which act as barriers to accidents.

d. It is the alteration of the barrier or defence environment that allows the accident sequence to proceed down the line and produce an incident or accident. The occurrence of an incident also means that the individuals at the coalface are recipients of this negative accident sequence, rather than its generators. This sequence of events is important in any attempt to determine the culpability of the production of an accident or incidents.
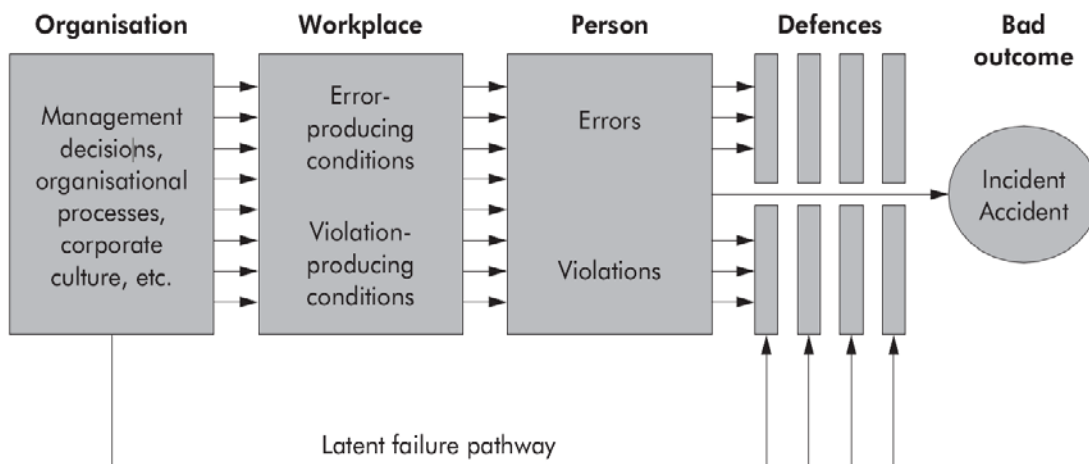
Figure 3.4: Stages in the development of organisational incidents

Reason [219] further argues that certain weaknesses exist in many organisations that allow hazards to be converted into incidents and adverse events. These weaknesses are described as latent and active failures respectively. Active failures are errors and violations that occur as a result of a direct interaction between patients and the health care system at a unit level. Latent failures on the other hand represent errors and violations that occur as a result of the failure by the designers, regulators and managers of the system to prevent the negative accident sequence from spreading down the organisation to the unit level where they occur.

One of the important models that assists in the description of system failures that produce medical errors is the application of Reason's Swiss Cheese Model [218]. This model likens an ideal system as one that is similar to stacks of slices of Swiss cheese whose holes are imperfectly aligned, as seen in Figure 3.5. The holes, on the one hand, represent opportunities for system failure. There are two types of holes: firstly, you have your active failures that are due to slips, mistakes and procedure violations; secondly, you have your latent failures that are due to equipment failure, incorrect protocols, incompetence and lack of skills.

The slices, on the other hand, represent policies, procedures, protocols and guidelines that have been designed to prevent errors and therefore act as defences. This arrangement means that as each error producing opportunity presents itself, it is blocked by the subsequent slice that is not in alignment. This is how an ideal system should be developed in order to ensure that errors do not materialise.

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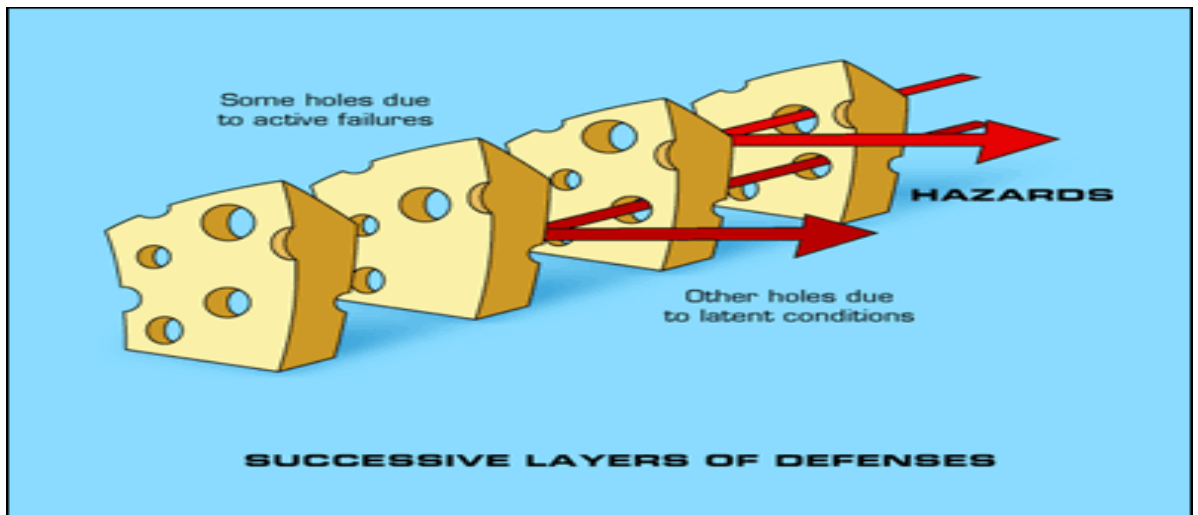
Figure 3.5: An ideal system

In a system that has been deliberately designed to produce disasters and catastrophes, all the holes in the slices are in perfect alignment. Such a situation means that whenever an opportunity for error arises, the system ensures that this is allowed to proceed unhindered to completion as there are no impediments or blocks put in place to deter the process. This unsafe system is represented by Figure 3.6.
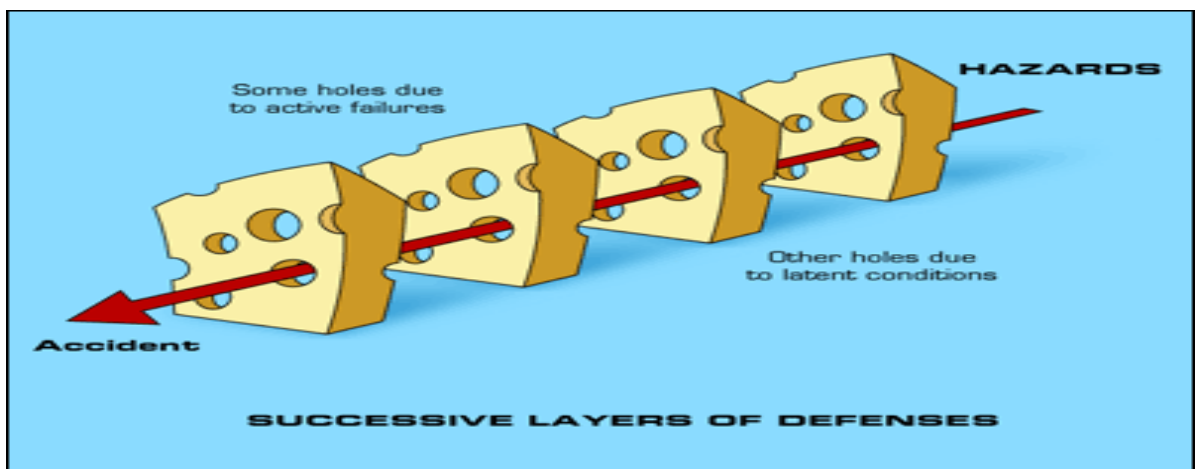
Figure 3.6: An error-prone system

Reason [218] argues therefore that errors occur due to a series of failures in the system to block them and that some of the key strategies to reduce errors must be aimed at putting in place system changes that will act as barriers and block errors from materialising. This model is crucial in the understanding of how medical errors which are sources unsafe care are generated. This model serves as a basis for the systems approach to patient safety improvement.

Brown et al [222] have developed a model that borrows from both Donabedian [210] and Reason [219], which attempts to explain the genesis of incidents and adverse events from an organisational point of view. This model, illustrated in Figure 3.7, provides a framework for developing sustainable interventions and gives

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a clear indication about the areas that are to be targeted by interventions aimed at improving patient safety. It should be noted that the one of the objectives of this study is to determine the effectiveness of patient safety interventions that were targeted at both the management and clinical processes.
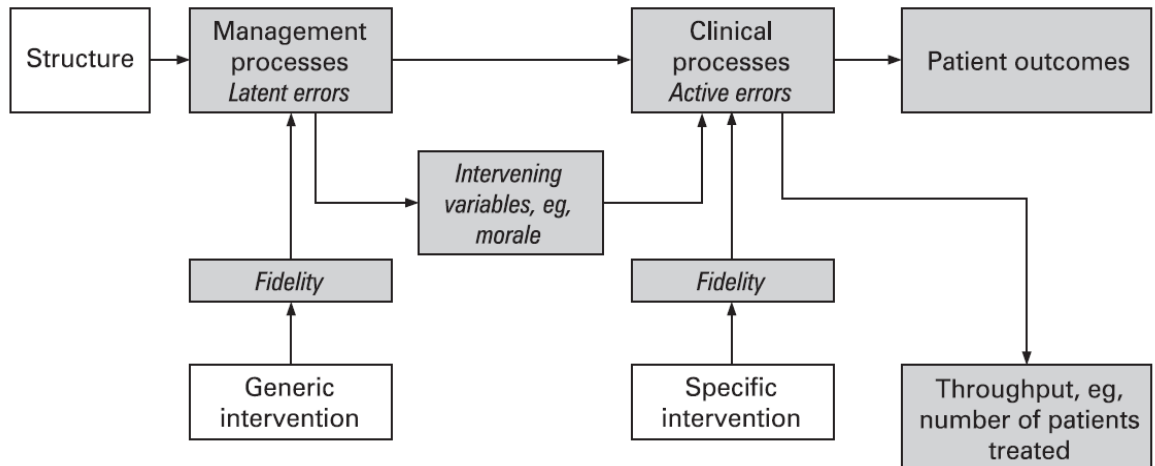
Figure 3.7: Brown et al's model

This model also identifies the structure or inputs, which may also contain elements that are not completely under the influence of the management of the organisation, such as the ministerial mandates, budgets and resources-allocation arrangements.

The model also identifies two key areas of possible interventions: the management processes and the clinical processes. These also happen to be the areas identified by Reason [218] for the occurrence of latent and active errors respectively. Active errors occur in the performance of front-line activities such the clinical assessment, treatment of ill patients and their effects are felt immediately. An example of an active error would be an adverse reaction due to a transfusion with the incompatible blood group. A latent error, on the other hand, occurs in activities that are not directly related to operations, and these lie dormant and only become visible when they are triggered by other factors. An example of this would be the death of a patient in the intensive care unit due to a design fault of the ventilation equipment

According to the designers of the model illustrated in Figure 3.7, the more generic interventions should be directed at the managerial processes that will result in improvement of measurable features, such as staff morale. Specific interventions should, on the other hand, be directed at clinical interventions such as development of clinical guidelines and protocols.

Interventions in these crucial areas of management control will result in sustainable improvement to patient safety and overall health care quality. The relevance of this framework or model to our particular study lies in the fact that our interventions

aimed at reducing clinical incidents and adverse events are targeted at both the managerial as well as the clinical processes.

The implementation of a computerised advanced incident management system can and should be considered a managerial process intervention aimed at improving the reporting of clinical incidents and inculcating a safety culture.

The discussions that occur in adverse events and clinical governance committee meetings are in fact clinical process interventions that often result in the development of specific guidelines, clinical protocols and policies. These interventions are therefore expected to be specific to each case discussed and should not be generalised.

This approach is supported by Battles et al [223], who firstly classified patient safety research into three groups: risk and hazard identification, implementation of interventions to eliminate risks and patient safety hazards and the maintenance of patient safety interventions. Secondly, Battles et al [223] asserted that no one methodology or approach will give you credible results in any of the three types of research on patient safety. This view therefore supports our multi-interventional approach, which cuts across all three research groups mentioned above that are also aimed at reducing medical error and improving patient safety from both a managerial and clinical perspective.

The relevance of this section to the current study is that the implementation of an advanced incident management system is one of the key intervention measures of the current study. It is therefore important to understand the anatomy of adverse events at an organisational-, work-unit- and individual level in order to decide on the appropriate interventions that are applicable at the different levels. It is also important to understand the genesis of incidents from both the individual and systems perspective, as this is important in developing sustainable patient safety interventions.

3.4   Balance between systems and individual contribution to medical error is at the heart of the just culture.

In examining the responses to adverse events, one often comes across differing views about their nature and genesis. At the one extreme there are individuals who believe that adverse events are due to careless, irresponsible, reckless, unprofessional behaviour on the side of service providers. At the other extreme are those that believe that system defects are the source of all adverse events and that humans are hardly ever to blame. The major challenge is to determine the correct position between these two extremes, for the purpose of optimising overall patient safety.

In the first instance, the proposed appropriate intervention is to discipline the involved professionals with the purpose of ensuring that their behaviour towards patients is more professional. In the second case, it is proposed that the responsible

system factors need to be identified and corrected in order to reduce adverse events.

Hickson et al [224] argue that there needs to be a realisation that the systems and the professionals that are in place to produce health care are complex. A disproportionate focus on either the professionals or the systems is inadequate to address the current challenges of patient safety. The focus on systems ignores the reality of untrained, distracted and impaired professionals. The focus on professionals also ignores the negative contribution of the often out-dated and imperfect systems to unsafe care.

Reason [219] proposes that there are distinct differences between errors and violations. These differences provide clear insights into how to deal with each. Reason [219] proposes that errors are a product of information problems (failure to recall, forgetting, ignorance), whereas violations are mainly a product of motivational problems (low morale, poor supervision and lack of incentives for good behaviour). Errors can be explained by what happens to the mind, whereas violations occur within a controlled social context. Errors can be reduced by ensuring there is communication at key areas during the delivery of health care, whereas violations will require motivational as well as disciplinary interventions.

The approach that provides that required balance between systems and individual contribution to patient safety is found in the principles that are embedded in the "just culture". Dekker [225] describes the "just culture" as satisfying the demands for accountability and contributing to learning and improvement. The National Health System (NHS) in the UK[10] describe a "just culture" as not just a total absence of blame but as an atmosphere of trust where people are free to report incidents and there is a clear line that separates acceptable from unacceptable behaviour. The key principles as presented by the Association of Operative Registered Nurses (AORN) [226] in the USA contained in the just culture, therefore, are, (1) the ability to report adverse events without fear of punishment so that others can learn from the adverse events and (2) that professionals are held accountable for their actions.

This approach, that seeks to achieve a balance between an individual- and systems contribution to medical error, between supporting the reporting of adverse events and taking professional accountability, is at the heart of the "just culture". Hickson et al [224] propose the following approach for dealing with professionals that have been involved in a clinical incident. This approach is captured in the self-explanatory accountability pyramid (Figure 3.8).
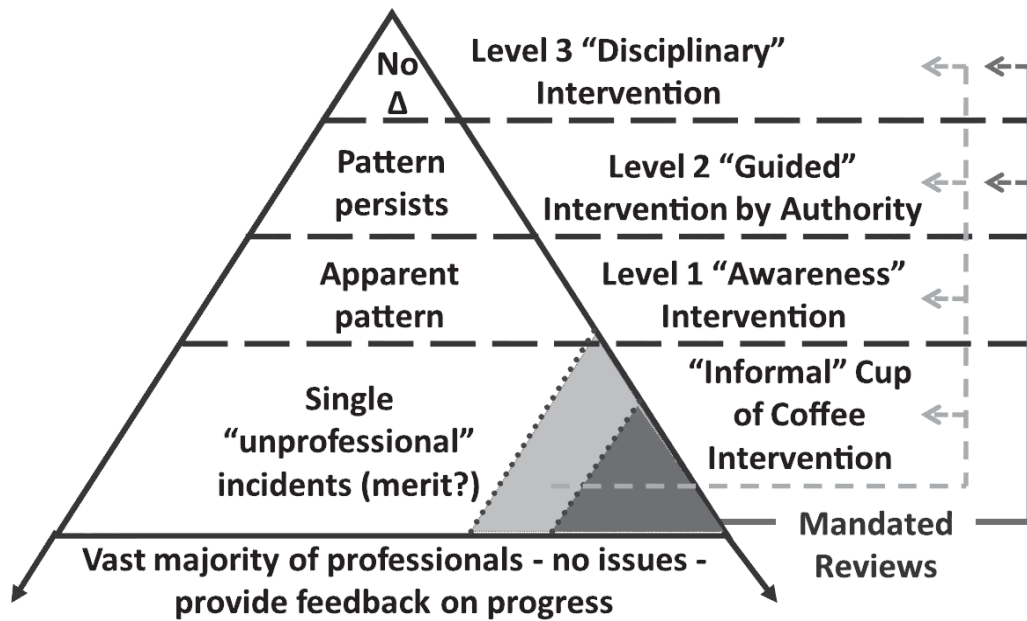
Figure 3.8: The accountability pyramid [Adapted from Hickson et al]

This approach proposes a battery of interventions aimed at correcting unprofessional behaviour based on whether this is an isolated incident or there is a pattern of repetitive incidents. These range from a casual conversation in an isolated incident and serious disciplinary action where there is a persistent pattern of unprofessional behaviour.

The relevance of this to this study lies in the fact that apart from the implementation of the computerised advanced incident management system, there were additional interventions whose aims were to improve the culture of safety in Free State hospitals that were put in place. The success of these interventions was measured by administering safety culture and climate surveys. The balancing of system and individual accountability for patient safety is important for this study, and can be achieved through the implementation of a "just culture".

A "just culture" can however only be implemented in an environment that has a credible reporting system in place, which enables all to learn from other's errors and mistakes.

3.5 A reporting system is a learning system in patient safety

In this section we will discuss the value added by reporting systems in the improvement of patient safety. Reporting systems are often expected to perform certain functions that they were not designed to perform, such as the provision of epidemiological data on incidents and adverse events. It is also sometimes expected that the installation of a reporting system in health facilities will by itself immediately translate to improved patient safety. The fact is, that reporting system are there to capture reported incidents and adverse events. What has not been reported will not make its way into the reporting system. Reporting systems still need people to provide them with the essential and credible data for the system to add any value.

The implementation of a reporting system will not by itself lead to the improvement of patient safety. A process needs to be established of collecting patient safety data, analysing it, investigating incidents, and developing and implementing specific and organisational interventions.

Many countries have developed their own reporting systems and others have used those that were developed in other countries. There are many reporting systems with different levels of sophistication – stretching from the paper-based- to web-based computerised variety. In our study we investigate the impact of implementing an Australian developed web-based advanced incident management system (AIMS) together with other interventions aimed at improving health care quality and patient safety. Irrespective of where they are developed, most of the reporting systems have been adopted from aviation, nuclear, petrochemical and other high-risk industries.

The WHO [9] has developed core principles for developing "ideal" reporting systems and these are:

- They have to improve patient safety by learning from failures;

- Individuals who report incidents must not be punished or suffer reprisals from reporting;

- Reporting is only of value if there is investigation and analysis of incidents, leading to specific and general interventions; and

- Analysis, learning, and dissemination of information should be carried out by experts.

The WHO has also described the characteristics that are essential for a successful reporting system. These are set out in Table 3.3.

Table 3.3: Characteristics of Successful Reporting Systems

Table 3.3: Characteristics of Successful Reporting Systems (7)	
Non Punitive	Reporters are free from fear of relation against themselves or punishment of others as a result of reporting.
Confidential	The identities of patient, reporter, and institution are never revealed.
Independent	The reporting system is independent of any authority with power to punish the reporter or the organization.
Expert analysis	Reports are evaluated by experts who understand the clinical circumstances and are trained to recognize underlying systems cause.
Timely	Reports are analyzed promptly and recommendations are rapidly disseminated to those who need to know, especially when serious hazards are identified.
Systems –oriented	Recommendations focus on changes in systems, process, or products, rather than being targeted at individual performance.
Responsive	The Agency that receives reports is capable of disseminating recommendations. Participating organizations commit to implementing recommendations whenever possible.

The NHS in the UK [10] has developed its own set of characteristics that should be present in an 'ideal' reporting system and these include the following:

- Separation of collection and analysis from disciplinary or regulatory bodies;
- Collection of information on "near misses" as well as actual incidents;
- Rapid, useful, accessible and intelligible feedback to the reporting community;
- Ease of making a report;
- Standardised reporting systems within organisations;
- A working assumption that individuals should be thanked for reporting incidents, rather than automatically blamed for what has gone wrong;
- Mandatory reporting standardised risk assessment – i.e. a common understanding of what factors are important in determining risk; and
- The potential for confidential or de-identified reporting.

This study is about the assessment of the impact of the implementation of a computerised incident reporting and learning system. It is therefore important to understand that the primary reason for implementing a reporting system is to learn from the reported incidents and adverse events. This learning must come from the data that comes with reported incidents and the implementation of the identified interventions.

Learning from reported incidents and adverse events is not an event but a process and therefore cannot occur overnight. This learning has to spread from individuals to teams, from one working unit to the entire section, from facility to facility within a district and between districts in a region; all of this takes time. This dissemination

of patient safety knowledge can be measured over time through patient safety culture and climate surveys and other relevant tools.

In the discussions above, there has been a detailed exploration of the four central theoretical framework themes that are regarded as key for this study. The four central pillars of this framework are the following themes:

- Patient safety is a health care quality issue
- Medical error and patient safety are two sides of the same coin
- Balancing systems and individual contribution to medical error is at the heart of the just culture
- Reporting systems are learning systems in patient safety

This section is important for the understanding of the next chapter on the methodology and design of the study.

This study was designed to determine the success of a set of patient safety interventions centred around an incident reporting system also known as AMCu implementation in a developing country, indicated by an overall increase in the reporting of incidents and adverse events. AIMS together with additional patient safety and quality interventions are collectively known as AMCu; which is derived from AIMS, Management and Cultural interventions. This study is a randomised interventional study of 24 hospitals that were randomly allocated into intervention and control groups. Eventually the intervention ran through two phases. Phase I was from randomisation to 9 months in the study, and Phase II was from 10 months into the study up to 36 months, when the intervention was also introduced in hospitals that were in the control group.

CHAPTER 4: METHODOLOGY AND DESIGN

4.1 Introduction

This chapter describes the aims and objectives of the study and provides a clear description of how the study was conceived, designed and implemented. The implementation of the interventions in this study is complicated by the fact that while the study sought to prove the effectiveness of the main intervention, which is the incident reporting system (AIMS)[68], other enabling activities tend to confuse the picture. These enabling activities are referred to in this chapter as secondary interventions and include all the preparatory processes leading to the implementation of the main intervention.

The Advanced Incident Management System (AIMS), developed by Patient Safety International (PSI), the commercial wing of the Australian Patient Safety Foundation, is a computerised system for the collection, classification and analysis of incidents that occur during the process of delivering health care services. It is a product of 20 years of research and development in a clinical environment, and had been implemented in Australia and other countries for about 10 years at the time when this study began in 2008.

AIMS is a versatile management tool that uses a single point of entry for information drawn from multiple sources, and this information is utilised to support managerial planning and decision making. It takes advantage of a centralised call centre that co-ordinates information and data from various sources, which makes it less costly than setting up such a system at each institution. This system is able to capture, classify and grade clinical incidents, adverse events and near misses and empowers management to play an active role in reducing these in order to improve patient safety.

AIMS's main advantage over other systems is its ability to record incidents live within seven minutes, therefore eliminating delays and duplications. This enables health care providers and hospital management to intervene before the incident leads to patient harm. It also provides security and safe storage of information, which is a distinct advantage over a manual paper system. It makes use of well-structured classification systems that ensure that information received about an incident, adverse event or near miss is placed in a category that is linked to specific associated factors.

The AIMS programme was implemented in the 12 intervention hospitals in the current study, and 9 months later in the control sites as well. When serious incidents were reported, these were recorded on the AIMS system and steps were immediately taken by the hospital staff to alleviate the situation and initiate steps to prevent further harm, and the recurrence of similar incidents.

The AIMS programme also contains an incident management sub-section. The required process is that the management of serious incidents is recorded in this sub-section over the time period required to address the particular problem. Entry of the

data into this section of the AIMS database allows for the monitoring of intervention steps during the remedial period, and later analysis of the success of the intervention. It also provides a facility that can be used to analyse the success of the interventions to address deficiencies and later to collate and analyse similar interventions in order to determine their frequency and impact.

Where interventions for a specific incident type are found to be successful these lessons are used to address similar deficiencies occurring in other sample hospitals. In this way, beneficial procedures resulting from lessons in the intervention hospitals in the current study were applied to the control group of hospitals after the nine-month period.

Regular monthly meetings were organised by the Deputy Director General responsible for clinical health services to discuss specific reported adverse events. The adverse events that were presented were the most severe; those that were likely to result in litigation and those that occurred frequently. This meeting which was regarded as a learning platform, was attended by hospital CEO's and Heads of Clinical Services; District Managers and key executives. The decisions that were taken at the meeting were communicated to all the institutions including those that were involved in the specific adverse events.

The expectations were that there would be an initial increase in the reported incidents due to the implementation of AIMS and the presence of an enabling reporting environment. The implementation of effective patient safety interventions would follow, after there was a full understanding of the nature and causes of these incidents. If the implementation of these interventions was successful, then the more severe incidents would decrease in number.

The secondary interventions were for the purpose of this study regarded as additional patient safety and quality interventions that were implemented along with AIMS. Collectively, the interventions applied are referred to as AMCu (an acronym for: Advanced Incident Management System; Managerial interventions to improve patient safety and health care quality; Culture and climate of Safety improvement interventions).

In other words AIMS is a subset of and is contained in AMCu, and they are not the same thing. AMCu and AIMS in this study are also not used interchangeably because they refer to different interventions.

4.2. Aims

This study had two key aims:

1. To determine whether a set of patient safety interventions (AMCu) centred around a computerised incident reporting system (AIMS) could be successfully implemented in a developing country setting.

2. To develop a hospital patient safety risk reduction model based on the existing quality frameworks and the study results for the Free State province.

4.3 Objectives

The objectives of the study were formulated to address the aims and are best articulated through the following key questions:

1. Can AIMS can be successfully implemented and maintained at an operational level in a developing country setting?
2. Does AIMS provide insight into the risks associated with reported incidents and adverse events that inform health system managers about sustainable policy and clinical interventions?

3. Does AMCu improve health care quality outcomes?

4. Stemming from question 3 as set out above, the sub-questions that follow represent a breakdown of the health care quality outcome issues raised:
   a. Does the implementation of AMCu improve the safety climate?
   b. Does the implementation of AMCu improve patient safety culture?
   c. Does the implementation of AMCu improve patient satisfaction?
   d. Does the implementation of AMCu improve quality as measured by the Council for the Accreditation of Health Services of Southern Africa (COHSASA) reporting system?

This chapter has two major sections, in line with the important features of each phase of the study. Each section is as far as possible structured in such a manner that it covers the methodology, design, population, sampling, data collection, measurement, data analysis and ethical considerations. The first section has AIMS and the paper based incident reporting as its key features and the second section has the safety climate survey, hospital safety culture survey, patient satisfaction survey and the COHSASA accreditation evaluation.

The logic of pairing AIMS with the paper-based reporting system emanates from the fact that the first two questions of our objectives are strictly focused on examining the effectiveness of AIMS and comparing it with the paper based system in the first 9 months of the study. In this section the presentation of the paper-based system is done to provide sufficient information for its comparison with AIMS, because strictly speaking it is not a study intervention.

The grouping of the safety climate, hospital safety culture, patient satisfaction surveys together with the COHSASA evaluation is based on the fact that the last question regarding the ability of AMCu to improve quality outcomes is based on these items. It will also be noted that the safety climate and the hospital safety culture surveys are

also paired because they were implemented on the same dates at the different hospitals. They are separated from the patient satisfaction survey and the COHSASA evaluation because these were implemented at different times and there are no similarities in their methodologies. In the second section the discussions on the ethical considerations is a common one for all the features that are covered there. The first section covers the discussion from 4.5 to 4.6.2 and the second section from 4.7 to 4.10.

Section A

4.4 AIMS [Advanced Incident Management System]

4.4.1 AIMS: Methodology

The methodology of this study was influenced by the interventions that were part of it. The primary intervention in the study is the implementation of the computerised incident reporting system (AIMS). It is this intervention that was implemented at the beginning of the research project in January 2008, exclusively at the intervention sites. This exclusive implementation at the intervention sites was stopped after 9 months in September 2008, before the same intervention was extended to all the study sites. The extension to all other study sites occurred for an additional 27 months, from October 2008 to December 2010. This early switch to expose all sites to the intervention was decided after the preliminary results were already indicating the benefits of the implementation of AIMS, and for ethical reasons we could not continue to deprive the control sites of these benefits.

In the first 9 months, the intention was to compare the effectiveness of the incident reporting system between the control and the intervention sites. The incident reporting system was implemented at the intervention sites, whereas at the control sites, the pre-research paper-based system was maintained. The comparison between the intervention and control sites was restricted to the first 9 months of intervention at the intervention sites. Beyond that point the overall response of the study sites to AIMS in terms of the nature and causes of reported incidents was examined, with the intention of developing effective management interventions.

The parameters that were compared between the control and the intervention sites in the first 9 months were the reported incidents. The proof of the effectiveness of the intervention was demonstrated by the increased number of reported incidents at the intervention sites compared to the control sites. The methodology as described above is illustrated by Figure 4.1 below as a step design.
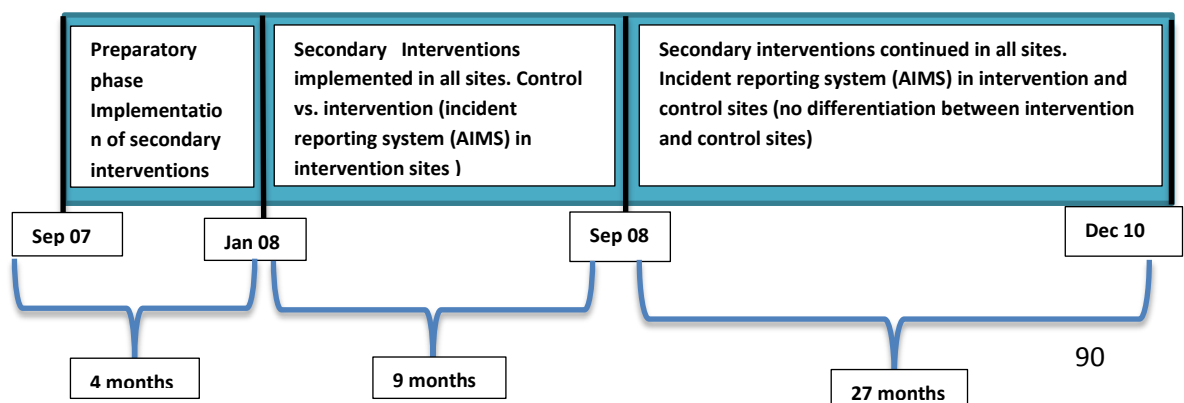
Fig 4.1: Methodology diagram

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Some of the important methodological challenges in this study are based on the fact that the research is occurring in a dynamic environment and the researcher does not have full control of all the variables, as he would have in an experimental study.

Co-intervention refers to an instance where during the implementation of a designated intervention in a study, another intervention appears in the study environment that interferes with the measured impact of the original intervention in a negative or positive manner. There was sufficient attention and focus directed at this study during the design and implementation phases to ensure that there were no co-interventions. Apart from the enabling activities, which have also been named "secondary interventions", there were no unexpected interventions that influenced this study. It has already been mentioned that the enabling activities or secondary interventions were deliberately implemented in preparation of and in support of the implementation of the incident reporting system

Contamination refers to a situation where during the implementation of the intervention at the intervention sites; there is failure to completely exclude the control sites from the intervention, which leads to a false response from the control sites to the intervention. There was a clear intention during the design, planning and implementation of the research project to prevent this contamination. During the first 9 months, there were no incidents collected from the control sites using the incident reporting system. The control sites used only the pre-research paper-based system to report their incidents.

4.4.2 AIMS: Study design

The study was designed as an intervention study in which a set of patient safety and quality improvement interventions built around AIMS were implemented in a group of 24 hospitals in the Free State over a period of 36 months. Twenty-four hospitals were randomly allocated through a computerised sampling process to two groups – the intervention group and the control group. Each of the 24 study sites had an equal chance of belonging to either the intervention group or the control group. This resulted in a two-arm study design with the intervention and the control groups containing 12 hospitals each. This separation between the control and intervention sites was limited only to the first 9 months of the study. The study design is illustrated in Figure 4.2.

Figure 4.2: The study design
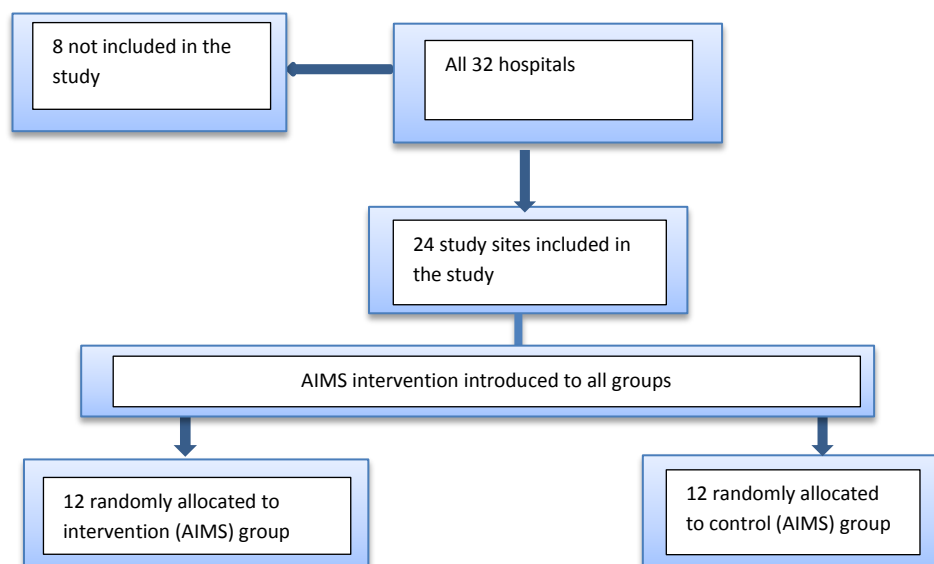
4.4.3 AIMS: Study population and setting

The study was conducted in public hospitals in the Free State Province, South Africa. The study population was therefore defined as the entire public district, regional and tertiary hospitals that were functional in the Free State Province from January 2008 to December 2010. Incidents were reported from all 24 public hospitals included in the study. The first incident was reported on 2 January 2008 and the final incident was reported on 31 December 2010.

4.4.4 AIMS: Sampling

A total of 24 Free State public hospitals were included in the study. Twelve hospitals were selected as the intervention group and the other 12 were selected as the control group. All incidents reported from January 2008 to December 2010 in the 24 hospitals were included in the analysis. The incidents were recorded consecutively as they were reported. Each of the reported incidents was allocated a computer-generated unique identification random number. In some cases the incident was reported more than once. However, such incidents were counted once during the analysis.

The next crucial step in the sampling was the determination of the control and intervention hospitals. This process of cluster randomisation was done using a computer program which considered the hospital name, level of care, region or location and number of beds in the process. During this process hospitals were stratified with respect to a group of hospitals in a defined geographic area (also known as the "complex") that they were part of and according to the level of care they provided. Selection resulted in the inclusion of:

For district hospitals:

- Complex 1: 6 out of 7 hospitals

- Complex 2: 6 out of 9 hospitals

- Complex 3: 6 out of 7 hospitals

- Complex 4: both (2) hospitals

For regional and tertiary hospitals:

- Four out of 5 hospitals

The hospitals in each stratum were randomly selected into 2 groups, resulting in intervention and control groups of 12 hospitals each. The randomisation process attempted to match the 2 groups according to bed numbers and the levels of care provided by the hospitals. This matching process is illustrated in table 4.1 below. The challenges of this randomisation process are discussed in detail in the study limitation section in Chapter 6.

Table 4.1: Matching control and intervention site beds

Level of Care	Hospital	Total Beds	Level of Care	Hospital	Total Beds
		Control group		**Intervention group**	
Level 1			**Level 1**		
	Thebe	71		Botshabelo	135
	Mantsopa	26		Itemoheng	55
	E Ross	110		Dr JS Moroka	180
	Katleho	78		Parys	50
	National	177		Stoffel Coetzee	23
	Embekweni	25		Phutuloha	31
	Mafube	29		Thusanong	86
	Mohau	28		JD Newberry	42
	Phekolong	85		Winburg	55
Sub Tot		**629**			**657**
Level 2			**Level 2**		
	Boitumelo	312		Dihlabeng	140
	Manapo	270		Pelonomi	620
	FSPC	760		Universitas	627
Sub Tot		**1 342**			**1 387**
Total		**1971**			**2044**

4.4.5 AIMS: Sample size estimation

The Free State has 1 tertiary hospital, 1 specialised hospital, 5 regional hospitals, and 25 district hospitals: a total of 32 hospitals. Owing to this low number and in order to ensure that the study yielded credible results that were representative of the entire province, 24 of the 32 hospitals in the province were included in the sample of the study.

The following assumptions were made in the determination of the sample size:

- The introduction of the interventions at the intervention hospitals would involve the entire hospital and a cluster randomisation design was therefore deemed the most appropriate.
- The study hypothesis is that the introduction of the interventions would initially increase the overall number of reported incidents and that there would then be a reduction in the rate of severe incidents that were reported.
- Type I error of 5% (two sided)
- Type II error of 20% (80% power)
- Intra-class correlation coefficient: 0.01
- A total of 100 incidents would be reported per hospital
- The rate of adverse event reporting in the Free State was expected to be about 18% in the intervention group and higher than the reported 10% for developed countries [72,73,79,80,81]. In the control group the rate of severe adverse event reporting was expected to be about 24%. We wanted to show that the

severe adverse event reporting rate was decreased by at least 6% over a period of 9 months after the introduction of AIMS.

Therefore the following hypothesis and alternative hypothesis were to be tested:

H_O: P1-P2=δ H_1:P1-P2 $\neq\delta$

The required sample size per group was estimated using the following formula:

Where P_1 is the expected adverse events reporting rate in control group i.e P_1=18%

P_2 is the expected adverse events reporting rate in the intervention group i.e P_2= 12%;

$\delta = P_1-P_2$ is the difference to be detected i.e δ=6%;

ϕ is intra-class correlation coefficient i.e ϕ =0.01

$f(\alpha;\beta)$ is the squared of the sum of the upper tail β point and the upper tail $\alpha/2$ point of the standard normal distribution

From the given Tables $f(\alpha;\beta)$= 7.85$\approx$ 8.0; α=0.05; and β=0.10 for a two tailed test.

$$N^*= \frac{\{P_1(100-P_1)+P_2(100-P_2)\} \times f(\alpha;\beta)}{(P_1-P_2)^2} \quad [227,228]$$

N={N* X IF}/100

Therefore

$$N^*=\frac{\{18*82)+(12*88)\} \times 8.0}{(18-12)^2} =562.667$$

Inflation Factor (IF) = 1 + (100-1) X 0.01= 1.99 and

 N = 562.667 X 1.99 = 1119.707 /100=11.19707 $\approx$ 12

In rounded figures the sample size for each of the two independent samples was 12 hospitals. Therefore, the sample size that was required to have the specified power to detect the expected significant reduction in the adverse event rate was 24 hospitals. This provided for 12 intervention and 12 control hospitals.

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4.4.6 AIMS: Data collection

AIMS data collection happens through telephonic reporting by the health care worker, clinician, patient or any other person present during the incident to a centralised call centre. When an AIMS call is answered, the person answering the incoming call identifies herself by mentioning the name and by using the following sentence: "AIMS good day how can I help you"? The caller is then identified and a telephone number obtained. The name of the hospital as well as the ward the person is calling from (in case the call is dropped) .The information is collected using the following questions:

Are you **calling** about a patient?

If yes, Please give me the details of the patient?

What happened?

What did you do immediately after the incident occurred?

What was the outcome for the patient?

Who was notified?

What is your designation?

What was the likelihood for this to happen?

What are the consequences of the incident?

A similar set of questions is asked if the incident does not involve the patient.

Incidents reported are immediately sent back via e-mail to the hospital for further management. The process can therefore be perceived as a triangle. The process of incident reporting and further management is depicted in Figure 4.3

FREE STATE HOSPITAL

INCIDENT HAPPENED

COHSASA CALL CENTRE

RECEIVES REPORTED INCIDENTS

INCIDENTS DATABASE AT COHSASA

THE INCIDENT IS AUTOMATICALY REPORTED BACK TO HOSPITAL FOR FURTHER MANAGENT
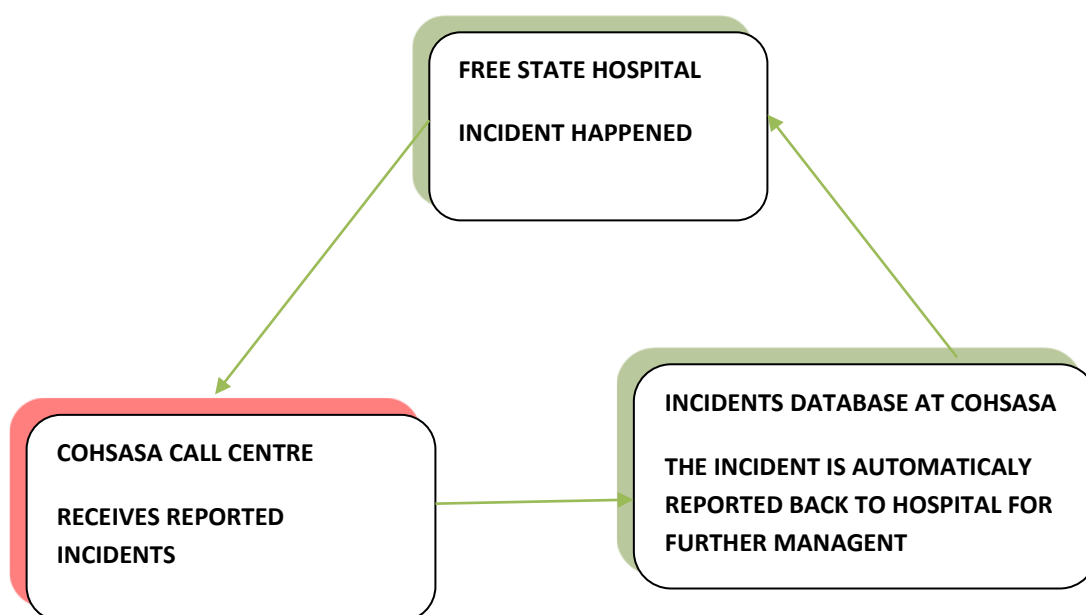
Figure 4.3 : Incident reporting process in AIMS

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The possibility of measurement error was limited in the Free State study because the calls were received by one AIMS trained person throughout the study period. The AIMS expert went through the training described below.

- When the province commenced with the AIMS programme, staff from PSI in Australia came to South Africa to train the local personnel. The local AIMS expert received additional training for 2 weeks.
- When the version of AIMS was upgraded, additional training was provided 9 months later from PSI
- For the first year the trained expert could only capture calls and the minimum data set required for classification. This data set was then sent to Australia for classification
- After a year the expert had to do 8 web-based exams on line and had to pass all of them before she could classify incidents. After this PSI still did random checks on the classification on a daily basis, then weekly and then monthly until it was satisfied with the local expert's expertise.
- Further analysis and sub-classification of the reported incidents were also performed by the researcher and the team, which has extensive experience in patient safety culture – as previously described.

Nobody in the COHSASA office other than the experts are qualified to classify incidents. Incident data is captured from primary reporters (doctors, nurses, allied workers and management) via a call centre located off site in the COHSASA offices. This approach was selected because of the following advantages associated with using a call centre:

1. There would only be a single point of entry for all hospital departments via the telephone system staffed with skilled and experienced call centre operators

2. Hospital staff would be guided through a series of simple questions by highly trained interviewers to provide detailed data specific to the incident. A cascading questioning process would be used taking, on average, only 7 to 10 minutes to capture data, and thus reducing the need for staff to supply time-consuming written reports.

3. Reporting facilities would not need to acquire and maintain complicated paper or computer systems and software nor the staff to run them.

4. There is cost effectiveness in using one call centre for all hospitals

The call centre is staffed by nurses trained to capture the incident data required by the AIMS system, according to the severity of the incident. All incidents captured would be classified according to the AIMS – Healthcare Incident Types (HITS) classification. Participating facilities are notified by e-mail as soon as incidents are reported. Facility safety managers are trained to respond to notifications by reviewing the report and notifying the relevant facility and with it investigate why the incident occurred.

Telephonic or SMS notifications are escalated to the organisational leadership, when there is a severe or life-threatening incident or adverse event. The call centre also provides participating facilities with weekly summary reports of all incidents reported by the hospital during the previous week. These include:

- Multi-column summary of incidents
- Most frequent incident types

4.4.7 AIMS: Measurements

When an incident occurred at a hospital, any person present during the incident could call the toll free AIMS call centre to report it. The trained person (AIMS expert) would answer the call and record all the information reported. Detailed information on the patient was obtained during the time of incident reporting by the trained AIMS expert. This included the demographic information of the patient – for example, patient name, hospital name, service point (ward) and admission number, date of birth, relevant diagnosis age, gender, and the date and time the incident occurred. A detailed description of what happened, any contributing factors, what the incident reporters did immediately after the incident had occurred was recorded in the system. The AIMS expert would ask what the outcome for the patient was, which person (authority) was notified, and what the designation of the caller was.

Figure 4.4 summarises the data elements collected when incidents occur in healthcare facilities. The figure also explains the methodology used in this study for analysing clinical incidents with the purpose of determining the underlying systemic factors leading to incidents. The figure also shows the link between these factors and the different health outcomes.
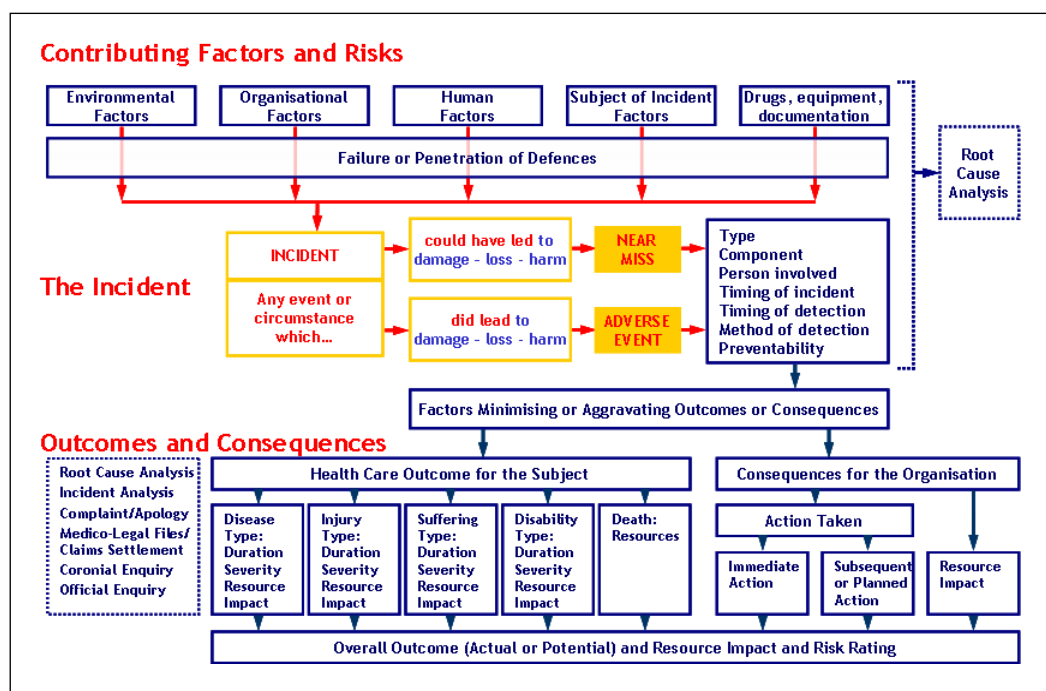
Figure 4.4: Possible measurements. Source: COHSASA. 2006[34]

The analysis of the incidents was done by the researcher, a health care quality expert, and a cardiothoracic surgeon who between themselves had more than 80 years of experience as doctors and had a passion for patient safety and health care quality. The list of all reported incidents was submitted to this expert team that classified these into incident types, based on whether there was harm or not, as adverse events, hazards, near misses and occupational injuries. This team further classified the incidents into systems error (where the incident was a product of the failure of the different parts of the system to work together to produce safe care), duty of care error (where the source of the incident was unclear but was related to the provision of care and included all cases that needed an in-depth investigation) and human error (where the incident occurred as a result of a human commission or omission error).

The systems error incidents were further classified as due to personnel, management, equipment, facility, transport, or organisation. Further classification of the duty of care incidents into the categories related to the ethical conduct of the health professionals was possible only after an in-depth analysis of the incident, with tools such as the root cause analysis. This classification and analysis of these duty of care incidents, is beyond the scope of this study.

The reported incidents were further regrouped as maternal, child and other. Year and month of reporting were also collected and whether the incident was reported from the control group or the intervention group. The classification and analysis of the incidents was based on the narrative of the report, as well as additional supporting evidence that was provided by the health care practitioners.

In summary, all the reported incidents, irrespective of where they were reported from were classified into the following broad categories and subcategories in line with the proposals by Chang et al [90], as illustrated in Figure 4.5.
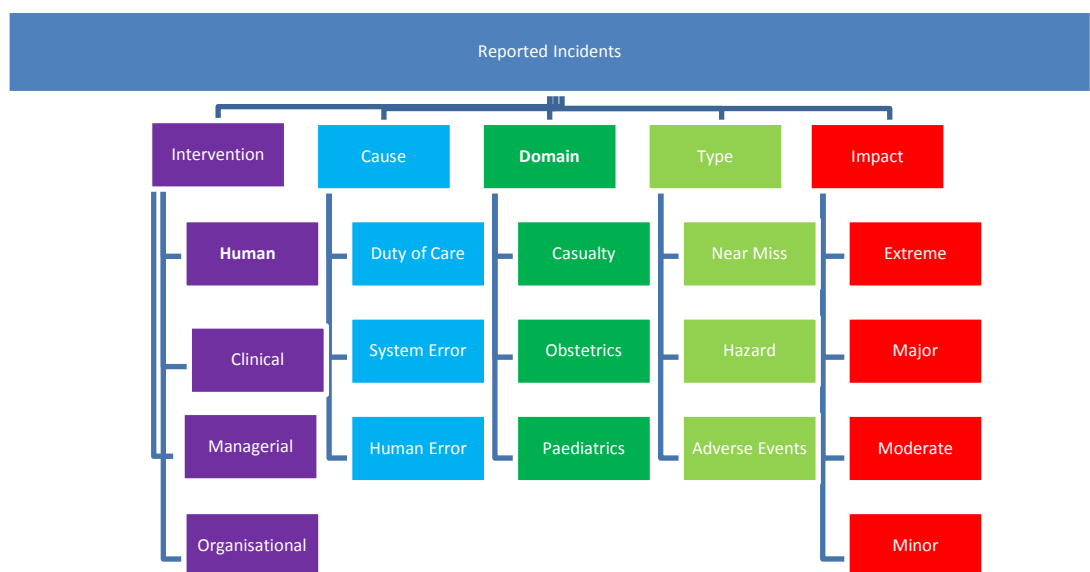
Fig. 4.5: Classification of reported incident

4.4.8 AIMS: Data analysis

During the implementation of AIMS in this study, and as data about clinical incidents and adverse events became available, interim analysis was carried out to determine any patterns or trends noted over time. This was done using graphs and frequency tables to achieve this objective. These measurement tools were expected to provide deeper insights regarding the nature of the clinical incidents and adverse events. Expectations were that these graphs would initially indicate an increasing number of incidents reported, with a concomitant decrease in the number of serious reported incidents.

At the end of the study data was analysed using descriptive statistics such as the percentages and frequencies as well as graphical presentations. The monthly numbers of incidents reported were measured using the counts and percentages. The effect of AIMS was assessed using the median number of incidents reported per month in the intervention sites compared to the median number of incidents reported in the hospitals in the control groups using Kruskal Wallis test [229]. The reporting rates from the two groups were compared using a t-test.

The relationship between the incidents reported in the hospitals included in the intervention group and those reported in the hospitals in the control group after the introduction of AMCu from 15 months to 54 months was established. The comparison of median number of incidents reported in the control and intervention groups was hampered by the large number of incidents reported in the hospitals in the intervention group relative to incidents reported in the control group. Therefore, the imputed numbers were then compared with the actual numbers reported in the hospitals in the control group using a Wilcoxon chi-squared test.

Adverse events were regarded as those classified according to the Safety Assessment Coding(SAC) [230] as SAC 1; SAC 2; SAC 3 and SAC 4, where:

- SAC 1 refers to extreme incidents that result in permanent disability or death
- SAC 2 refers to major incidents that result in temporary disability
- SAC 3 refers to moderate incidents
- SAC 4 refers to minor incidents

Any associations between the incident severity and month of occurrence were established using chi-square test.

The rate of adverse event reporting was defined as:

The number of adverse events reported during the first 9 months x 100

The total number of incidents reported for both groups.

The risk factors associated with severe incidents were determined using log binomial regression models adjusting for clustering effects at the hospital. The cost containment was adjusted for, with the use of dummy variables as follows:

Before: January 2008 to September 2008;

During: October 2008 to March 2009 and

After: April 2009 to December 2010.

Data analysis was grouped in groups of 9 months namely:

January 2008 to September 2008

October 2008 to June 2009

July 2009 to March 2010

April 2009 to December 2010

The grouping of the data for analytical purposes was done in an effort to assess the reporting patterns after every 9 months.

Associations between the type of incidents reported and 9-month intervals were identified using chi-square tests.

4.4.9 AIMS: Ethical considerations

During the preparatory and the research phases of the study, there was a conscious effort to ensure that there was consistency in the application of the main bioethical principles of:

- Respect for autonomy: respect for the decision making of an independent person
- Non-maleficence: do no harm
- Beneficence: balancing benefits against risks and costs
- Justice: distributing the benefits, risks and costs fairly

As described by Beauchamp et al [231], it needs to be said that the reporting of incidents using AIMS is voluntary and this is in recognition of the fact that that the autonomy of individuals has to be respected. The Free State Department of Health has through various educational and policy initiatives encouraged its health professionals to report incidents, but reporting has never been made mandatory.

When an individual is reporting an incident to the call centre, he or she does not have to reveal his or her identity, and this is done to protect these individuals from reprisals from their own supervisors. While it is important to know the identity of a patient for investigative purposes, once the investigation is complete, this identity is removed from the case file. These are specific measures that are used to protect health professionals and patients from any intended or unintended harm.

Access to the incident reporting system is limited to a few individuals as it is password controlled and it is graded access and depends on your seniority in the department of

health. The CEO of a hospital can only gain access to his or her hospital's information, whereas a district manager has access to the information about all the hospitals in that district. The data repository of all the reported incidents is kept off site from the Free State Department of Health and is therefore not accessible for disciplinary purposes.

The private and societal benefits that emanate from this study cannot easily be measured. The fact that through this research project, the patient safety and overall quality of the health care services in the Free State was likely to improve means that the population of the Free State was expected to directly or indirectly benefit from it.

Cannistra [232] and Bassler et al [233] propose that one of the indications for the early termination of a clinical trial on ethical grounds is evidence of a either significant benefit or harm to the intervention group. The significant benefit in this instance therefore means that researchers had an obligation to maintain ethically allowed norms and standards and not to deprive the control sites of the beneficial effects of the intervention for a period longer than necessary.

During the AIMS study it was planned that the reporting rates would determine whether to continue with paper-based reporting or not. It was pre-determined that if there were significant benefits accruing to the intervention sites, the intervention would be extended to the control sites. Continuing to report using the paper-based system beyond this point would have been in violation of the ethical principles of beneficence and non-maleficence. This study has been approved by the Ethics Committee in the Faculty of Health Sciences at the University of Pretoria.

4.5 Survey of personnel perceptions on AIMS

4.5.1 Methodology:

The purpose of administering the survey of personnel perceptions on AIMS was to determine the perceptions, attitudes and beliefs of the end-users on its usefulness and effectiveness. This survey was also meant to provide part of the answer to the question as to whether AIMS can be successfully implemented in a developing country or not. An in-house questionnaire was developed for the purpose of conducting this survey.

4.5.2 Population:

This survey was directed at the health personnel at both the control and intervention sites whose daily responsibilities included the reporting, analysis and management of reported incidents. The population therefore included the facility quality co-ordinators, heads of nursing, heads of clinical services, hospital chief executive officers, district executive managers, the provincial quality assurance team, nursing personnel and doctors.

4.5.3 Sample:

The targeted personnel were members of the facility, district and provincial adverse events and clinical governance committees. This was done to ensure that only officials

that have some knowledge and experience on using AIMS were the main respondents. Seven hundred questionnaires were distributed using the data-base of the adverse events and clinical governance committees members only.

4.5.4 Data Collection:

The distribution of the questionnaires was done through the secretariats of the adverse events and clinical governance committees and the instructions that were directed at each participant indicated that participation in the survey was voluntary. The completed questionnaires were sent back to the provincial quality assurance team, who had volunteered to participate in the co-ordination of the administration of this survey. Five hundred and ten of 700 questionnaires were returned, a 70% response rate. This questionnaire was administered in June 2010, 30 months into the study. The time chosen to conduct the survey was meant to ensure that even those officials belonging to the control sites would have had sufficient exposure to AIMS to assess its utility.

4.5.5 Measurement:

The information gathered using this questionnaire included background of the participants such as their work area, experience and position at the facility, district or provincial level. There were also questions directed at specific focus-areas such as familiarity with AIMS, an approval rating, opinion on feed-back reports and a comparison with the paper based system.

4.5.6 Data analysis:

The perceptions of personnel on AIMS are presented using graphs, percentages and frequencies. A 3-point Likert scale of "agree"; "not sure" to "disagree" was used to measure the responses.

4.6 Paper-based reporting system

4.6.1 Paper-based reporting system: Data collection

The reporting of incidents and adverse events using the paper-based system relied on incidents that occurred at ward or unit level being reported to the unit manager, who in turn reported to the Head of Nursing, Head of Clinical Services and ultimately the Chief Executive Officer of the Hospital or District Manager. The paper-based system produced results that were difficult to analyse and was not user friendly.

The reporting of these incidents was dependent on several factors. Firstly, most incidents that were reported were those that were so severe that they had resulted in permanent disability or death. These were also the incidents that would have been reported through the media or legal department because of their severity. In other words many incidents that were reported using this system were those that could not be hidden from the public eye due to their nature and severity.

The rest of the incidents that were reported are those that the CEO or District Manager thought were interesting and required inputs on their management from his or her peers from other institution. The policy was, however, clear that serious incidents needed to be reported to the Head of Clinical Services (HOCS), Head of Nurses (HON), CEO within a specified period. The near misses and hazards were not seen to be important enough to be reported. The non-reporting of an incident or adverse event was seen more as an aggravation factor during the disciplinary process rather than an act of misconduct by itself.

Given the situation described above, a number of serious incidents and adverse events are thought to have gone unreported. Even those that were reported at a unit, ward or institutional level stood little chance of being reported at the highest level of the organisation unless sanctioned by the CEO, for fear of punitive action that comes with the disciplinary process. The near misses and hazards remained unreported and, consequently, there was minimal learning from the incidents and adverse events. This also means that there was little conscious effort that was directed at specifically preventing adverse events.

The investigative processes that followed the reporting of incidents and adverse events was mainly conducted by labour relations officers and each incident was treated as a punishable act of misconduct. The highly subjective process was not standardised and created additional problems for all the parties involved. Officials could be charged differently for the same "offence", and different punishments are meted out for the similar offences. The provincial structure responsible for the management of incident and adverse events behaved more like a tribunal whose role was to attempt to create evenness in the manner in which these disciplinary cases are handled and less attention was paid to the nature and causes of the incidents and adverse events.

The investigative processes were also not focused on determining the root causes of incidents and adverse events from a systems perspective. This meant that after the investigations and disciplinary actions, there were still no corrections to the real causes of incidents. The introduction of AMCu in the current study brought with it a new set of investigative tools such as root cause analysis, decision trees and others. These tools provided the department with an opportunity to train many officials (both nurses and doctors) in the techniques and use of these systems investigation tools.

4.6.2 Paper-based reporting system: Structures for the management of incidents and adverse events

Prior to the implementation of AMCu, the following structures were in place to manage incidents and adverse events:

- Institutional unusual incident committee
- District unusual incident committee
- Provincial unusual incident committee

The institutional unusual incident committee was chaired by the hospital CEO, and met once a month, received and considered reported incidents and adverse events from

the HOCS or HON. New incidents would be tabled and approval given for their investigation, progress on the old incidents would also be presented for noting and endorsement. A decision would then be taken as to which cases would be escalated to the district unusual incident committee. The decision regarding which adverse events could be escalated to the organisation's leadership was by default given to the hospital CEO.

The cases that would be escalated to the district or provincial unusual incidents committees were mainly those where investigations had been started but were not completed. These incidents also included those where disciplinary sanctions had been recommended and therefore the endorsement by the higher structure was sought. This also meant that those CEOs, who were not comfortable in implementing the recommended sanctions, would use this endorsement as approval for the sanctions to be implemented.

The district unusual incident committees were also referring their incidents to the provincial unusual incidents committee for noting, for approval of recommended sanctions or for advice and inputs from the larger collective. These committees spent very little time in the determination of the causes of incidents and adverse events, let alone the in-depth root cause analysis required to complete the investigations of incidents using the systems approach. The district committees were all chaired by the district managers and the provincial committee was chaired by a "manager", with an interest in reported incidents, who also had the required clinical background (mostly a medical officer in management).

The provincial unusual incident committee was tasked to finalise all the incidents that were presented to it and develop policies that would assist the department to manage incidents and adverse events more effectively. This task, however, became impossible because: at all the committees there was an increasing backlog of unprocessed disciplinary cases. The reason for the backlog was that there was insufficient personnel and time to investigate and conduct disciplinary cases of all the incidents that had been reported. The introduction of AMCu shifted investigations to the more severe incidents and adverse events, and also shifted the focus to include the systems defects that cause incidents.

One of the key interventions that were part of AMCu was the restructuring of these committees and the re-definition of their roles and responsibilities. The following main changes were effected:

- Reporting was done through a call centre and not only through the committees;
- Reporting provided for anonymity;
- All CEOs and District Managers were made compulsory members of the committees at facility, district and provincial level;
- HOCS were also made compulsory members of these committees

- To reflect the change in the manner in which incidents were to be managed, the committees were renamed the Adverse Events and Clinical Governance Committees;
- Investigations were focused on systems and human factors instead of misconduct by professionals;
- Clinical teams were in charge of investigations that used recognised system investigation tools such as Root Cause Analysis [234] and Incident Decision Tree Analysis [235];
- Recommendations of the provincial adverse event and clinical governance committee served on the executive committee of the Free State department of Health and were used for prioritisation, planning and decision-making at that level.

The recommendations that emanate from the provincial adverse event and clinical governance committee have identified personnel shortages, unskilled personnel, equipment malfunctions, medicine shortages, process bottle-necks and other problems. It became easier at a strategic level to develop focused interventions because that is where the decisions to allocate resources to address the challenges and to measure the impact of the interventions occurred.

Section B

4.7. Safety climate and hospital patient safety culture surveys

4.7.1 Methodology and Design for the safety climate and hospital safety culture surveys secondary interventions

The differences between safety climate and hospital safety culture are for the purpose of this study based on the organisational level under study. Safety climate refers to the patient safety practices, traditions and way of doing things at a ward or unit level, whereas the hospital safety culture refers to the entire hospital as an organisation. All the evaluations were carried out with the use of cross-sectional surveys conducted among health care workers. The hospital safety culture survey was done with the use of a questionnaire [**Appendix A**] that was developed by the Agency for Healthcare Research and Quality in the USA. The survey seeks to determine the perceptions of the personnel in health facilities about patient safety at different levels of operations. This self-administered questionnaire elicited the personnel's perceptions about safety issues at unit, hospital and management levels.

The safety climate questionnaire was developed under the auspices of the Institute for Healthcare Improvement (IHI) and has been tested and validated in the USA and Europe [**Appendix B**]. It was used to measure the perceptions of frontline personnel about safety in their administrative or clinical areas. It also seeks to determine the perceptions about the management's commitment to patient safety.

The methodology for the administration of the questionnaire is described by the researcher and was followed without any attempts to adapt it to the South African environment, because the questions were relevant and clear with respect to the key

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patient safety features that they focused on. These questionnaires were applied at different time periods in order to determine improvement or deterioration of the safety culture in a hospital environment. The design for all the evaluations were cross-sectional surveys conducted among health care workers.

4.7.2 Population for the safety climate and hospital safety culture surveys

The population for both the climate and culture survey was defined as all the clinical and administrative heath care workers employed in the participating hospital during the month of the surveys.

4.7.3 Sampling for the safety climate and hospital safety culture surveys

The CEO of each hospital provided consent for the carrying out of the study and provided a contact person for co-ordinating the administration of the questionnaire. The contact person was then provided with between 100 and 150 questionnaires, which were distributed amongst various categories of personnel for completion. The personnel then filled in the questionnaire as directed and returned them to the co-ordinator, who then passed these on to the provincial co-ordinator, who finally passed them on to the external service provider. No deliberate effort was put into the selection of the personnel to complete this questionnaire; all this was done on a voluntary basis. There was no volunteer bias detected in the 24 study hospitals, where the only participants in the survey were the ones that have volunteered to do so.

4.7.4 Sample size estimation for the safety climate and hospital safety culture surveys

In both surveys sample size was determined by taking into consideration the size of the hospital. In this case the size of the hospital was measured by the number of employees. The number of employees that were provided with questionnaire to complete at each hospital was determined by the size of the hospital. The smaller hospitals were provided with 100 questionnaires as these hospitals had a maximum of 100 employees and the larger hospitals were provided with 150 questionnaires (one tenth of the largest hospitals). This convenient way of estimating the sample size was considered because of budgetary constraints.

The sample size was estimated using the following assumptions:

- Hospitals operate on a two-shift basis
- The largest hospital in the province has about 1 500 personnel
- The smallest hospital in the province has less than 100 personnel
- Hospital personnel such as cleaners, gardeners, general workers and security were excluded from the study
- The main groups that were included in the study were the clinical and administrative staff

Therefore a total of 5515 questionnaires were sent to the co-ordinators for the survey

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4.7.5 Data collection from safety climate and hospital safety culture surveys

The questionnaires were self-administered by hospital personnel and required individuals to answer a set of prepared questions and then to submit the completed questionnaire to the co-ordinators. The questionnaire packages were accompanied by a set of instructions, and assurances that participants would be protected from all forms of harm and were free to withdraw from the study at any time. Data was collected from consenting clinical and administration personnel.

The questionnaires were administered in March 2008, November 2008 and November 2009 for both the culture and climate surveys. Therefore, the surveys were conducted three times. The increase in the hospital safety culture and the safety climate scores were used as an indicator of an improvement of patient safety practices in these hospitals between the different time periods.

4.7.6 Measurements for safety climate and hospital safety culture surveys

Information collected during the culture and climate surveys included background information such as years of experience, work category, hospital, work area, support from management and colleagues, supervisor and management opinion regarding patient safety, communication channels, frequency of event reporting and patient safety grade, handling of medical errors, and actions of leadership regarding patient safety, guidelines and policies. This information was grouped into the following domains: management and leadership support, patient safety practices, communication, reporting of incidents and adverse events, patient safety grading and teamwork.

4.7.7 Data analysis for safety climate and hospital safety culture surveys

The hospital culture survey on patient safety instrument consisted of 12 safety culture dimensions and two outcomes (number of events reported and hospital patient safety grading). The dimensions measured the perceptions of the respondents regarding the safety of the patients in their unit and their overall perception of the safety of the patients in the hospital. Each dimension had 3 to 5 questions using a 5-point Likert scale agreement from "strongly disagree" to "strongly agree", as well as frequency scale ranging from "never" to "always." The two outcome measures consisted of single-item responses about the number of events reported in the past 12 months and the overall patient safety grading of the hospital.

Individual responses to each question were classified as positive if the actual response was "agree" or "strongly agree" as well as "most of the time" or "always" in positively worded questions. All negatively worded questions were reverse coded during the analysis. Dimensional scores were computed for each respondent by taking the number of positive responses for each dimension, dividing it by the number of questions in the same dimension and multiplying by 100. These dimensional score could therefore range from 0 to 100 and a low value represents perception of a less developed patient safety culture.

The safety climate survey tool on the other hand consisted of 19 patient safety questions. These questions were aimed at determining the climate of patient safety in a hospital setting and each response was linked to a 5 point Linkert scale agreement. In all the questions except question number 18, a score of 1 represented "disagree strongly" and a score of 5 represented "agree strongly". In question number 18, a score of 1 represented "agree strongly" and 5 represented "disagree strongly". There is a formula that is clearly described in the methodology to convert the individual response scores into safety climate scores out of a 100. The safety climate scores ranged from 0 to 100, where 100 represents the most developed patient safety climate.

The dimensional and safety climate scores were summarised using descriptive statistics (i.e. frequencies, means, and standard deviations). The descriptive statistical measures were computed for all the dimensions and safety climate scores and these were compared over time as well as by intervention groups. Two sample t-tests were used to compare the average dimensional scores between the two treatment groups and analysis of variance was used for the comparison of the average dimensions over time across the levels of care. The level of significance considered in this study is 5%. All the statistical analysis was performed using STATA 10. (STATA Corp. 2007) [236]

4.8 Patient satisfaction survey

4.8.1 Design for patient satisfaction survey

All the evaluations were cross-sectional surveys conducted among patients visiting the hospitals. The patient satisfaction survey was conducted using a questionnaire that was developed by the Agency for Healthcare Research and Quality in the USA **[Appendix C]**. This questionnaire was designed to determine the perceptions of satisfaction about hospital care from patients.

This questionnaire is also seen as an assessment tool of broad quality in health care and not specific to patient safety. In this particular study this questionnaire was not administered at the beginning of the study but in February 2009. The survey was again repeated a year later in February 2010 and this was to determine if there will be a difference in responses between the two periods. An increase in the patient satisfaction between the first and the second period was an indication that the implementation of AMCu had resulted in improved satisfaction and, therefore, in the improved overall quality of the health care service.

4.8.2 Population for patient satisfaction survey

The population for the patient satisfaction survey was defined as all the patients that were seen in each of the participating hospitals during the month of the survey.

4.8.3 Sampling for patient satisfaction survey

Patients that were seen or discharged from hospital during the survey month were included in the study. The size of the hospital and the patient activities determined the size of the sample for the study. The Patient Day Equivalent (PDE), which is an aggregated measure of out, day and in-patient activities, was used as a determinant of the sample size. The out-patients and those that have been discharged are more likely to give an objective opinion as compared to the in-patients who would still be dependent on staff for further care, and therefore unlikely to make negative comments about the quality of the care received.

4.8.4 Sample size estimation for patient satisfaction survey

It was decided that 10% of the previous quarter's PDE would constitute the sample. It was also decided that 80% of the sample should be out-patients and patients that had been discharged from the hospital. This decision was made to ensure that the patients chosen to be part of the sample could provide a more objective opinion about staff without fear of reprisals.

4.8.5 Data collection for patient satisfaction survey

The questionnaire used for this evaluation was specifically designed for administration by mail and telephone. The extent of the use of cell phones in South Africa is so vast that even the illiterate, the unemployed and the poor have this device. We therefore exploited this fact in the administration of this survey and targeted patients that had just been seen by a health professional or had been discharged from hospital to include in the sample for a telephonic interview. The interview was adapted to include Southern Sotho, Tswana and Afrikaans, as these are the dominant languages in the Free State Province. The questionnaire was also adapted so that it reflected South African occupational groups better. Therefore, data was collected with the use of telephonic interviews by a trained research assistant. The telephonic interviews were conducted by one person, which reduced any possible errors in the interpretation of the questionnaire responses.

4.8.6 Measurements for patient satisfaction surveys

The patient satisfaction survey investigated how the patient got to the hospital, the waiting time before being admitted, his or her experience of the admission process at the hospital, processes with respect to time in hospital, the physical environment of the hospital, the way the hospital responded to his or her needs, processes during discharge, overall hospital experience and, finally, requested the patient's demographic information

This questionnaire had 27 questions that needed to be answered and these focused on determining perceptions of satisfaction with health care services in the following areas: nursing care, doctor care, hospital environment, experiences in hospital, discharge process, overall rating and personal data.

4.8.7 Data analysis of patient satisfaction survey

The perceptions of patients were presented using graphs, percentages and frequencies.

Different dimensions were created on the basis of the themes of the questions. The averages of the created dimensions for 2009 and 2010 were compared through the use of a t-test.

4.9 COHSASA standards compliance evaluation

The methodology for the COHSASA standards compliance evaluation is treated separately because it is different from the other survey evaluations that are discussed above. The Free State has 32 hospitals. Twenty-five of these are district (or Level 1) hospitals, 5 are regional (or Level 2) hospitals, 1 is a tertiary (or Level 3) hospital and 1 is a psychiatric hospital. All of these hospitals were enrolled into the COHSASA facilitated accreditation programme as part of our strategy to improve the quality of health care services provided. The outcome of the performance of the Free State hospitals in this accreditation programme has been varied:

- Some hospitals received accreditation outright and have maintained that status.
- Some hospitals have received accreditation, but have struggled to maintain that status.
- Some have struggled to achieve accreditation and, instead, obtained 'focused' accreditation before obtaining full accreditation.
- Some have struggled to achieve the focused/ partial accreditation

4.9.1 Design and methodology for COHSASA

This data was collected with the use of the tools that have been developed by COHSASA and accredited internationally. The task was performed by a team from COHSASA, which was supported by a well-trained provincial quality assurance team. This data was also collected prior to the implementation of the interventions at the end of 2007 and again at the end of the study during the December 2010, The data that was collected made it possible to do a trend analysis and a comparison of the intervention sites with the control sites as well as a comparison between hospitals in the same category.

4.9.2 Population

It has been indicated that at the beginning of this study, all 32 hospitals in the Free State had been enrolled in the COHSASA facility accreditation programme. All the hospitals in the province therefore constituted the population for this measure.

4.9.3 Sampling and data collection

Each hospital in the sample has a trained data-capturer that has a lap top with 3G connectivity. These individuals served as a link between the facility and COHSASA, and their main responsibility was to ensure that they captured a pre-determined set of data with the use of a provided template and transmitted this to COHSASA via the Internet. This data included measures of the various service elements that were part of the facility evaluation criteria.

4.9.4 Measurements

The measurements and calculation of the COHSASA evaluation scores is developed on a hierarchical basis and follows the 4 levels of scoring. Firstly, there are the criteria scores that determine whether there is compliance with pre-set criteria. The aggregated criteria scores will then be measured against a performance indicator. Aggregated performance indicator scores are then measured against a service element norm which is also pre-set. Finally, an overall facility score, which is what is used as an evaluation score is an aggregation of service element scores. A detailed analysis of the COHSASA data is captured as **(Appendix D)**.

4.9.5 Data analysis for COHSASA

The COHSASA scores were presented graphically and the average scores at baseline and the evaluation stage were compared. The compliance status of the service elements measured in each hospital at baseline and the evaluation period were compared with the use of t-tests.

4.10 Ethical considerations for all the surveys and the COHSASA accreditation evaluation

For the climate survey and culture survey, the participants were asked to sign an informed consent form. The consent form stated that participation was voluntary and that the participant had the freedom to withdraw at any stage. Participants were assured that their anonymity would be maintained and that they were to receive feedback. Participants were also assured that their participation would not interfere with the delivery of health care services to them. The hospital CEOs also gave permission for the patient related information about in their hospitals to be accessed by the researchers in order that the various reported incidents could be classified and analysed. An agreement was signed by the researcher and the Free State department of Health that all the data on reported incidents belongs to the Free State Department of Health. The agreement also stated that no publication based on this data could be published without the knowledge and support of the Department of Health.

When the various surveys had been completed feedback and specific recommendations were given to the hospitals for them to implement. These sessions were very important in terms of developing effective interventions that would improve patient safety. There were no identified instances of contamination or co-interventions in the administration of the various surveys, as these were carried out at the same

time in the whole province and did not permit managers to discuss the questions and responses.

CHAPTER 5: RESULTS

5.1 Background:

The overall objective of this study is to determine whether a collective set of quality and safety culture improvement measures (known as AMCu) built around an advanced incident management system (AIMS) [68] can be successfully implemented in a developing country setting. In this chapter the results of the research study are presented without any detailed discussion as this is covered extensively in Chapter 6.

The results in this chapter are presented as answers to key questions that are directly linked to the aims and objectives of the study. The following key questions provide a structure for presenting the results in a logical and easy-to-follow manner:

5.1.1   Can AIMS be successfully implemented and maintained at an operational level in   a developing country setting?

5.1.2   Does AIMS provide insights about the risks associated with reported incidents and adverse events that inform health system managers about sustainable policy and clinical interventions?

5.1.3   Does AMCu improve health care quality outcomes?

5.1.4   This question is further divided into the following sub-questions:
   a.   Does the implementation of AMCu improve safety climate?
   b.   Does the implementation of AMCu improve patient safety culture?
   c.   Does the implementation of AMCu improve patient satisfaction?
   d.   Does the implementation of AMCu improve quality as measured by the COHSASA evaluation scores?

It is important that each set of results should be matched against the specific key question in order for each argument to be taken to its logical conclusion. The manner in which the results are presented in this chapter can be broadly divided into 2 main sections. Section A, is mainly focused on presenting all the results that are related to the implementation of the AIMS. This section therefore includes all the results that are related to the reported incidents through the computerised reporting system and therefore covers questions 5.1.1 and 5.1.2 as posed above. This section also deals with all the results of reported incidents at both the control and intervention sites for the entire duration of the study. The results that are reported under 5.3 to 5.36 are therefore part of this section.

Section B on the other hand, includes the results of the safety climate, safety culture, patient satisfaction and the COHSASA quality evaluations. This section provides answers to question 5.1.3 and all the sub-questions from (a to d) and therefore includes all the results that are reported from 5.4 to 5.5.

The separation of the results into these 2 distinct sections is aligned with the manner in which the various interventions were dealt with in the design and methodology presented in Chapter 4. This separation was deliberately done to ensure that the

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reader is able to follow the results as they are presented and also be able to link these with the discussions in Chapter 4.

SECTION A: AIMS Results

5.2 Can AIMS be successfully implemented and maintained at an operational level in a developing country setting?

In order to answer this question in a comprehensive and successful manner, it was decided that the following parameters needed to be examined:

- Nature and number of reported incidents and adverse events at the control and intervention sites in the first nine months;

- Nature and number of reported incidents and adverse events at all sites in the last twenty seven months of the research; and

- Perceptions of staff on AIMS

5.2.1: Reported incidents during control period in the first 9 months

A comparison of the monthly incident reporting rate between the control and intervention sites from January to September 2008 is presented in Table 5.1. The Free State Department of Health's then paper-based mechanism of reporting incidents and adverse events was maintained at the control sites for the first 9 months of the study. During the first 9 months period only 3 incidents were reported in the control (paper-based) sites compared to 706 incidents reported in the AMCu intervention sites (Table 5.1).

The large and significant difference ($p < 0.05$) in the number of reported incidents and adverse events reported justified the early inclusion of the intervention at the control sites.

Table 5.1: Comparison of the number of incidents reported during the first 9 months between the treatment groups (January to September 2008)

Months	Control sites (n=3)		Intervention sites (n=706)		Total (n=709)	
	Freq	%	Freq	%	Freq	%
January	0	0.0	56	7.9	56	7.9
February	0	0.0	72	10.2	72	10.2
March	0	0.0	68	9.6	68	9.6
April	1	33.3	62	8.8	63	8.9
May	0	0.0	68	9.6	68	9.6
June	0	0.0	71	10.1	71	10.0
July	1	33.3	107	15.2	108	12.2
August	0	0.0	100	14.2	100	14.1
September	1	33.3	102	14.5	103	14.5
Total	3		706		709	

The reported incidents were also converted to reporting rates per 100 000 Patient Day Equivalents (PDEs) for both the control and intervention sites for the first 9 months of the study. This conversion provides a common denominator that allows for comparison between the small and the large hospitals that are included in the sample. The use of PDE's further allows for establishment of the link between reported incidents with the activity of patients in the hospitals. The use of the PDEs also makes it easier to analyse these incidents by month.

The monthly distribution of the incidents per 100 000 PDEs reported during the first 9 months is shown in Figure 5.1 for both control and intervention sites. Fewer incidents were reported in control site during the first 9 months even after the conversion to the PDEs. The monthly reporting rates per 100 000 PDEs in the control sites ranged from 0 incidents per 100 000 PDEs to 2 incidents per 100 000 PDEs during the first nine months. However, the reporting rates per 100 000 PDEs in the intervention sites improved after the conversion. This reporting rate ranged from 95 incidents per 100 000 PDEs in January 2008 to 172 incidents per 100 000 PDEs in July 2008. Overall the results indicate a steady increase in the incident reporting rate per 100 000 PDEs in the intervention hospitals from April to June 2008, which reached a peak in July 2008. This rate is much higher compared to the reporting rate in the hospitals from the control sites.

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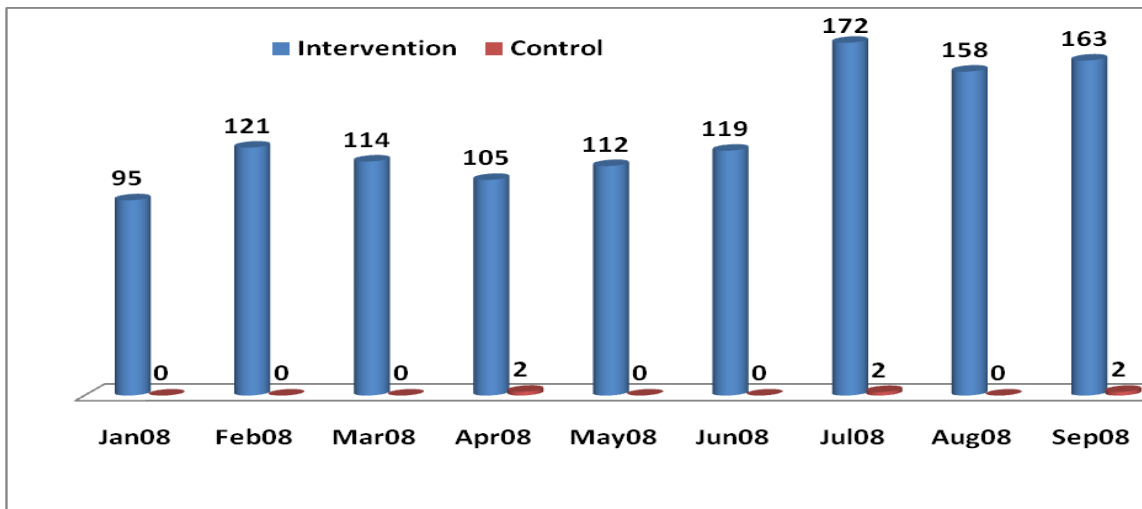
Figure 5.1: Number of reported incidents per 100 000 PDEs in the two groups during the first nine months

The study findings were also categorised into 9-month intervals, which was done for the purpose of assessing incident reporting patterns, as well as establishing the types of incidents reported over time when the intervention was introduced at all the sites in the study. The number of incidents reported at the intervention sites for each 9-month interval was almost the same, whereas fewer incidents were reported at the control sites for each of the 9-month intervals (Table 5.2).

A similar number of incidents were also reported for each of the last three 9- month intervals at the control sites and the largest number (342) of incidents was reported during the third 9-month interval.

This difference in reporting between intervention sites and control sites for the first 9 months of the study makes it very clear (Table 5.2) that AIMS encourages incident reporting more than the paper-based system does. This increased reporting of incidents observed at the intervention sites is also observed in the total number of incidents reported in the first 9 months compared to those reported in the follow-up months.

Table 5.2: The distribution of incidents reported in nine-month intervals

Time	Control (N=940)		Intervention (N=2 658)		Total (N=3 598)	
	n	%	n	%	n	%
Jan 2008 to Sep 2008	3	0.32	706	26.56	709	19.71
Oct 2008 to Jun 2009	298	31.70	698	26.26	996	27.68
Jul 2009 to Mar 2010	342	36.38	634	23.85	976	27.13
Apr 2010 to Dec 2010	297	31.60	620	23.33	917	25.49

5.2.2 Reported incidents beyond the first 9 months

The analysis of the reported incidents over the period of study indicated the following key findings:

- That the average number of reported incidents at all sites increased from 79 in the first 9-month period to more than 100 in each of the subsequent three 9-month periods. See Table 5.3
- There is a decrease in the average number of reported incidents at all sites between the second 9-month and the last two 9-month periods. See Table 5.3
- The percentage average number of reported incidents per 9-month period fluctuated between 19.7% and 27% during the period of study. See Figure 5.2
- The monthly distribution of the reported incidents per 100 000 PDEs, demonstrates a seasonality with peaks in November and troughs in December throughout the study period. See Figure 5.3
- The total number of reported incidents per 100 000 PDE's remain consistently high, with a range between 45 and 82 incidents in the period beyond the first nine months. This is illustrated in Fig 5.3

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Table 5.3: Descriptive statistics over the four nine-month periods

Time	Mean ± sd	Median	IQR	Range
Jan 2008 to Sep 2008	78.77 ± 19.36	71	100-68	108-56
Oct 2008 to Jun 2009	110.67 ± 31.54	116	135-116	144-52
Jul 2009 to Mar 2010	108.44 ± 15.73	108	120-104	126-75
Apr 2010 to Dec 2010	101.89 ± 26.47	108	115-81	130-78

IQR- Interquartile range
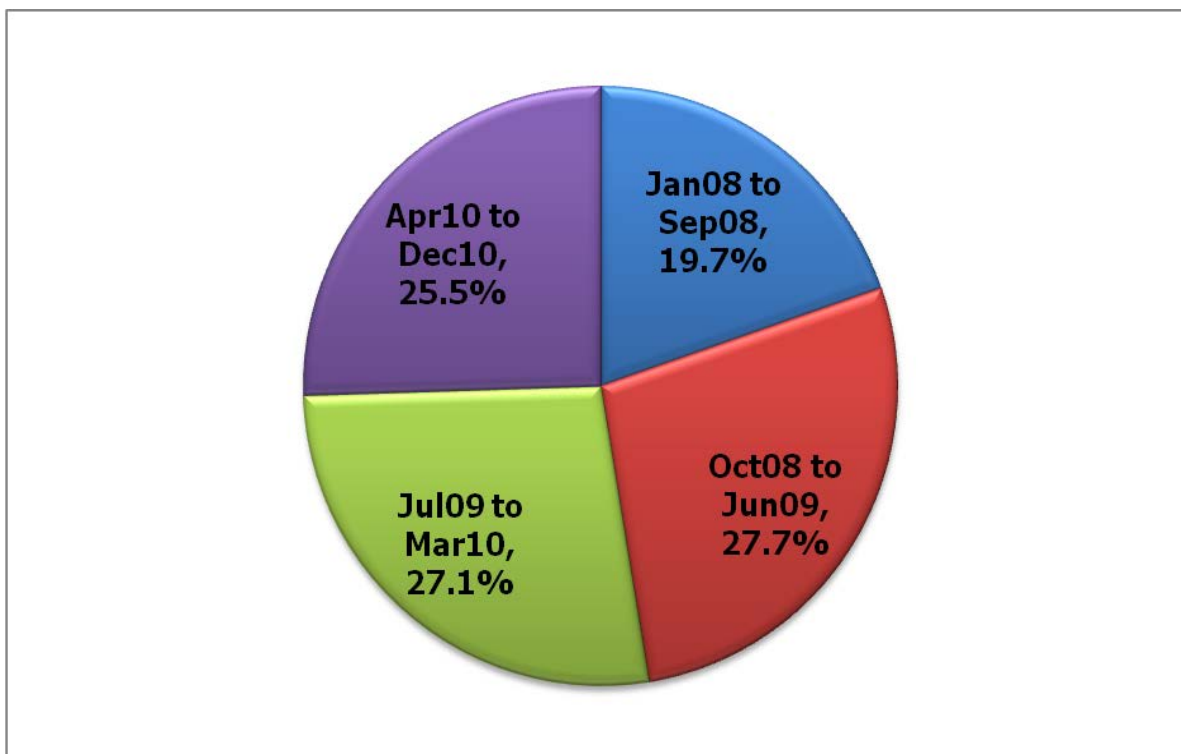
Figure 5.2: Reported incidents in each of the nine months interval
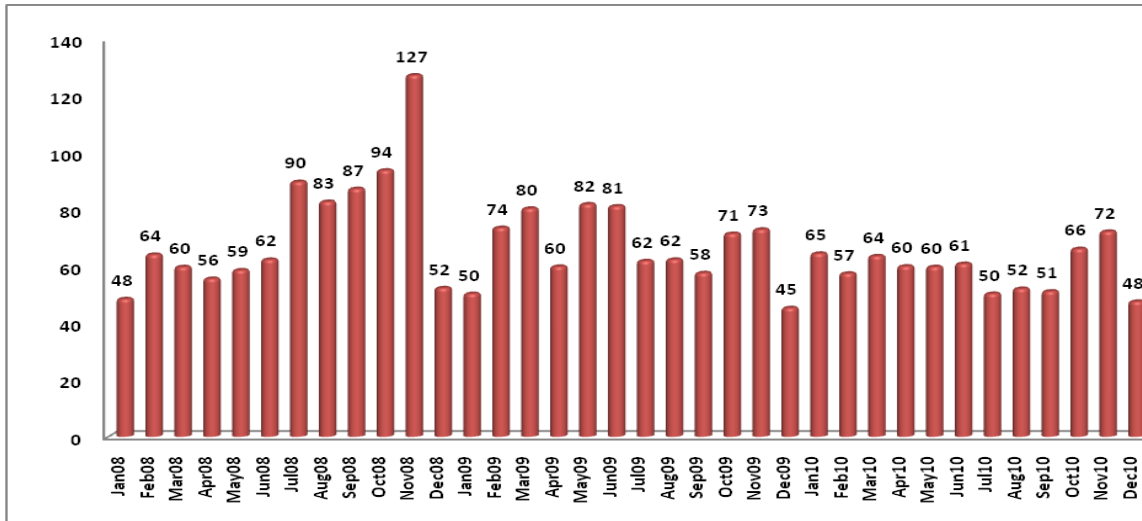
Figure 5.3: Monthly incidents reporting rates for the entire study period for all hospital.

It should be noted that adverse events are those incidents that resulted in patient harm either on a temporary or permanent basis and includes deaths. Near-misses are those incidents where an intervention was implemented after the onset of an incident and harm to the patient was prevented as a result. Hazards are those circumstances that if left unattended, will result in the occurrence of a serious incident. Occupational incidents are those incidents that affected health care personnel in their course of delivering health care and did not involve the patient as a victim.

In an attempt to further understand the nature and trends of the reported incidents from all sites during the study period the following analysis was done:

- The reported adverse events were considered separately from the reported incidents.
- The basis of comparison was the reported adverse events and incidents per hospital versus per month
- The period of comparison of reported incidents and adverse events was four 9-months and three 12-month periods

The detailed analysis, methodology and calculations for the Averages, Medians and Inter-quartile ranges are detailed in **(Appendix E).**This comparison was meant to assess whether the observed patterns of reported incidents and adverse events supports the expectation that there will be an initial increase in their numbers, based on the assumption that this would be due to the newly created reporting platform and non-punitive environment created by the implementation of AIMS. The key findings of this analysis indicated the following:

- The differences in the reported incidents and adverse events per hospital were statistically insignificant whether the period of analysis was per 9 –month or per 12-month period ($p > 0.05$)
- The differences in the reported incidents and adverse events per month were statistically significant ($p < 0.05$) whether the period of analysis was per 9-

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month or per 12-month period. The level of significance was more marked for reported adverse events compared to the reported incident

5.2.3 Personnel perceptions of AIMS

This section provides an assessment of the attitudes towards and beliefs of personnel about the usefulness and effectiveness of AIMS as an incident reporting system. This section is also aimed at providing part of the answer to the question whether AIMS can be successfully implemented in a developing country setting. It is also meant to provide the general perception of health care workers of AIMS compared to the paper-based system. A total of 510 out of 700 health care workers – responded to the survey, giving a response rate of 73%; with 394 (77.2%) indicating that they were familiar with AIMS (Figure 5.4). This survey was conducted in all 24 study hospitals and there was no effort made to differentiate hospitals as either control or intervention sites. All the results presented in this section are based on 394 respondents who were familiar with AIMS.

This survey was done in June 2010, 30 months into the study (Figure 4.3 shows this study time line) and the timing of this survey pre-supposes that the majority of health care practitioners will have known about the existence of AIMS and would be able to evaluate it in relation to the paper-based system they had been using all along.

	Familiar with the incident and adverse event management system known as AIMS
■ Agree (n=394)	77.2
■ Not sure(n=80)	15.7
■ Disagree(n=36)	7.1
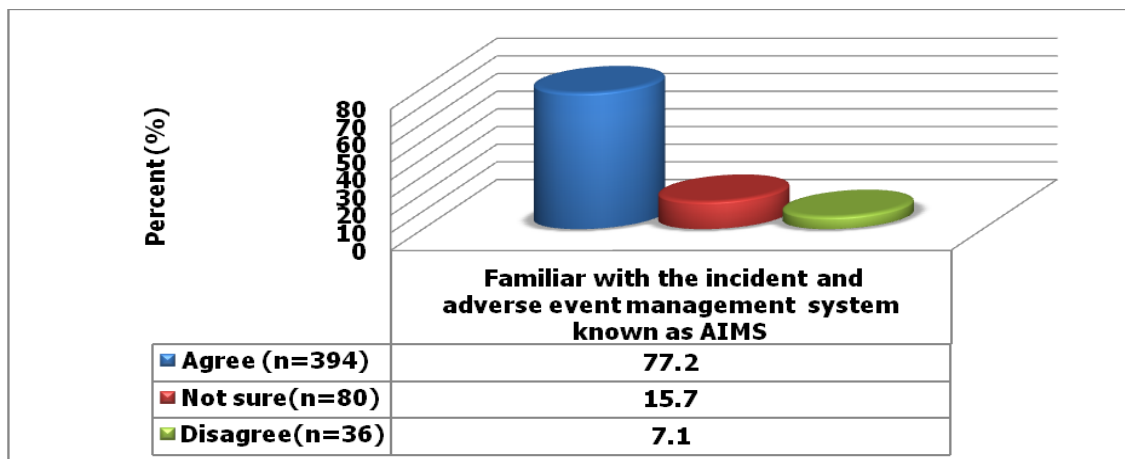
Figure 5.4: Familiarity with AIMS

The survey that was conducted at all study hospitals to determine the attitude and beliefs of personnel about AIMS indicated the following:

- Approximately 70% of 394 respondents indicated that they would recommend AIMS to other hospitals or other provinces (Figure 5.5).
- The overall approval of AIMS was indicated by nearly 62% of the 394 health care workers. About 59% indicated that management was prompt in addressing issues raised through AIMS.
- Two-thirds of the health care workers who were familiar with AIMS agreed that access and support from the AIMS call centre was easy and available (Figure 5.6).

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- Nearly 54% believed that support for AIMS from a standard compliance unit was easily available.
- Just below half (48.7%) of the respondents indicated that they were happy with the feedback received from cases reported on AIMS.
- Only 45% of the health care workers agreed that there was marked improvement in patient safety since AIMS started compared to only 15% who disagreed.
- Nearly 52% of the 394 health care workers indicated that AIMS provided more value for money compared to the paper-based system and more than 63% indicated that AIMS was more effective in supporting the management of incidents or promoting safety culture or at classifying incidents
- Approximately 71% of the respondents indicated that AIMS was more user friendly than the paper-based system and nearly 86% believed that AIMS was more effective at reporting incidents and adverse events than the paper-based system.
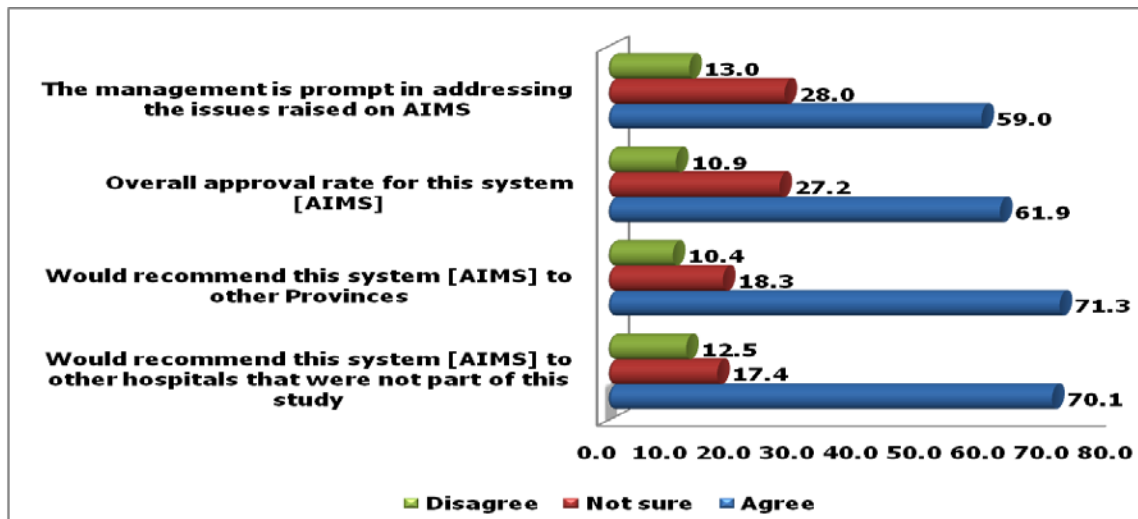
Figure 5.5: Perception of health care workers regarding AIMS approval
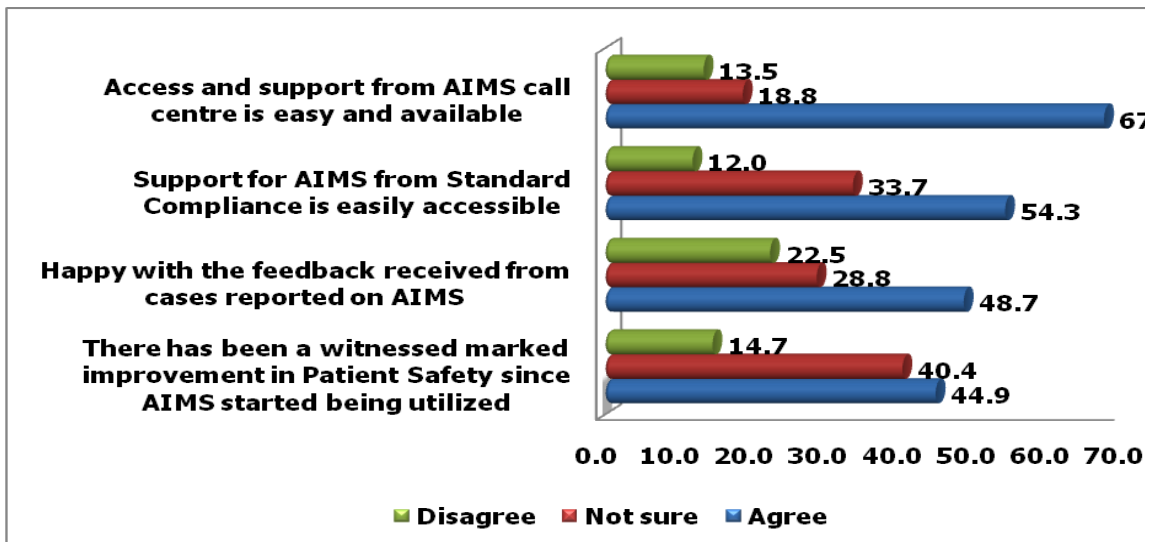
Figure 5.6: Perception of health care workers on feedback reports from AIMS
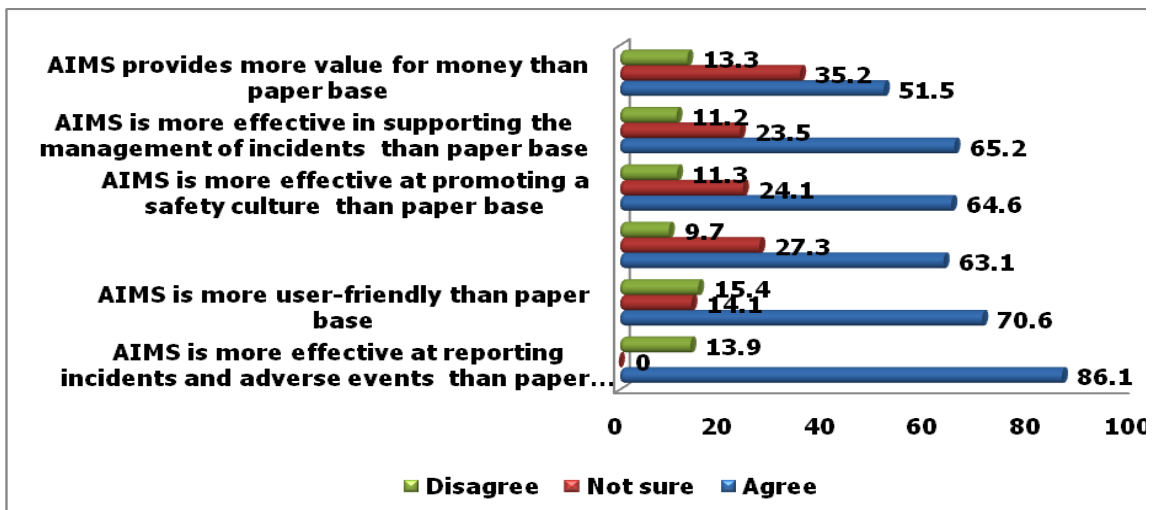
Figure 5.7: Perception of health care workers on added advantages of AIMS compared to paper-based system

5.3 Does AIMS provide insights about the risks associated with reported incidents and adverse events that inform health system managers about sustainable policy and clinical interventions?

The ability of AIMS to support the classification of reported incidents into various categories enables health system managers to develop specific insights about the risks associated with them. The classified reported incidents are a rich source of useful information that after careful analysis, provides valuable clues and insights regarding their causes, type and nature. This information about the reported incidents can then be used by the health system managers to develop sustainable policy and clinical interventions in order to improve patient safety.

In order to illustrate the point that was made above, a selected set of characteristics are presented below that indicates the type, nature and factors associated with the reported incidents. The detailed discussion on how this information can be used to develop sustainable clinical and policy interventions is presented in the next chapter.

5.3.1 Characteristics of the type of reported incidents

Figure 5.8 shows the distribution of the incident types that were reported during the study period, and indicates the results of their classification as adverse events, hazards, near misses and occupational injuries as defined earlier in this chapter. More than half (57%) of the reported incidents were regarded as adverse events, about one third (36%) were regarded as hazards, approximately 4% were classified as near misses and the rest were classified as occupational injuries (3%). This also indicates that out of a 100 reported incidents, 57 of these are likely to be adverse events.
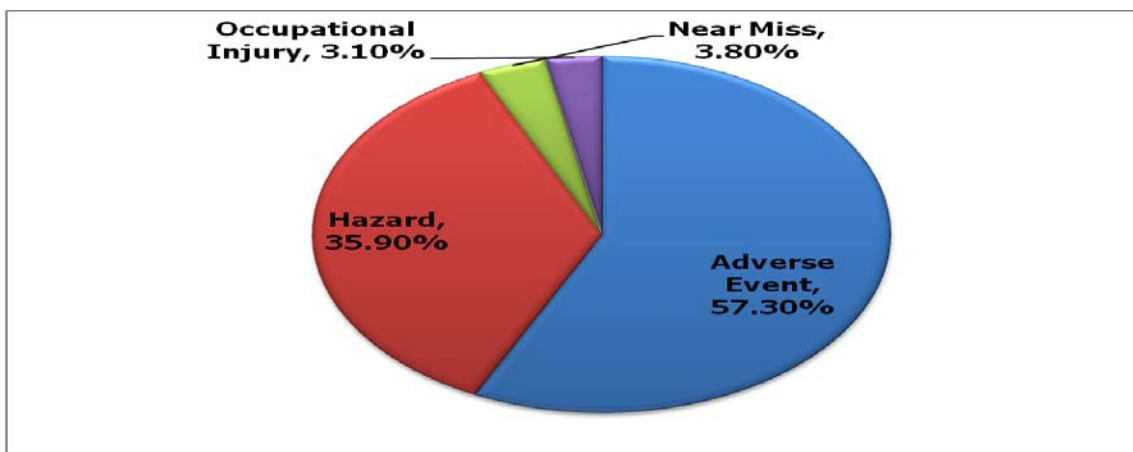
Figure 5.8: Reported incident types

The monthly reporting rates within the nine-month intervals for each of the classified incident types per 100 000 PDEs are depicted in Figure 5.9. The highest reporting rates were experienced during the second nine-month interval for all the classified incident types. The reporting rates stabilised from the third to the fourth nine-month intervals.
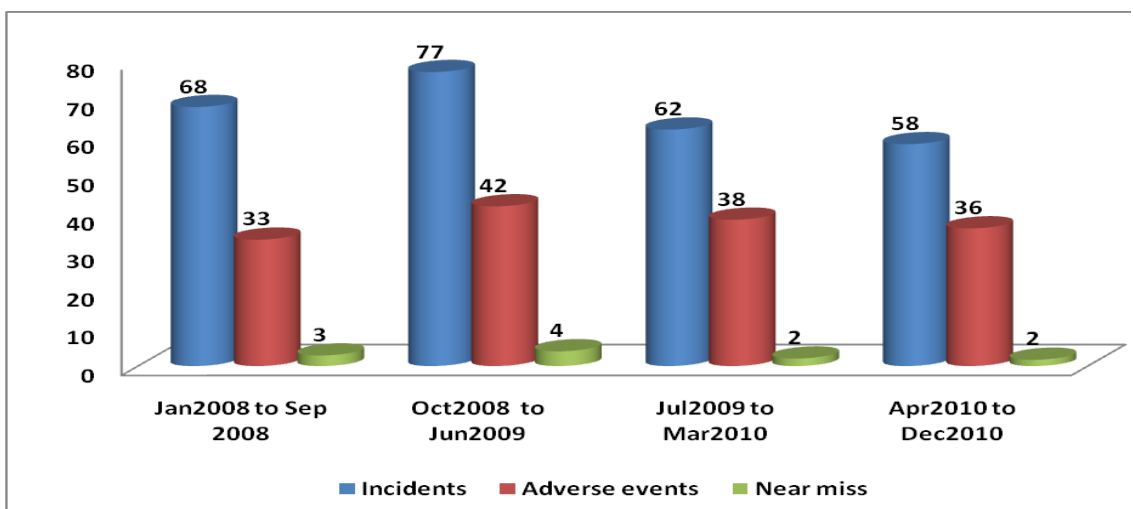
Figure 5.9: A comparison of nine month interval reporting rates per 100 000 PDE

5.3.2: Characteristics of reported incidents based on setting [clinical vs non clinical]

Figure 5.10 displays the classification of reported incidents between clinical and non-clinical. More than half (58%) of the reported incidents were classified as resulting from clinical management processes and 42% from non-clinical processes. This is a clear indication that the majority of reported incidents are clinical in nature and that any interventions that will succeed in reducing these would result in the improvement of clinical outcomes. This observation suggests that as management is focusing on creating a safety culture within the hospitals it is very important to address both clinical- and non-clinical management processes.
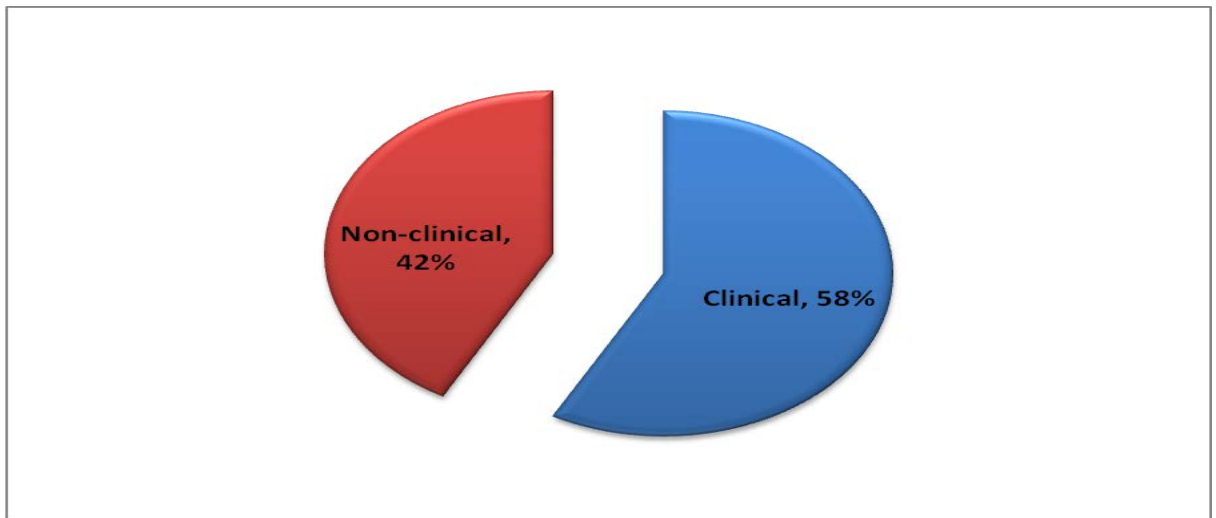
Figure 5.10: Major classification of reported incidents

5.3.3: Characteristics of reported incidents and their associated factors

During the classification process it was possible for the expert team to isolate factors that were closely associated with the reported incidents. These factors were further classified into human; duty of care incidents and system factors and these are presented in Fig 5.11. Systems error contributed to nearly half of all the incidents reported during the study period, about one third were classified as duty of care incidents and only 18% were classified as human error.

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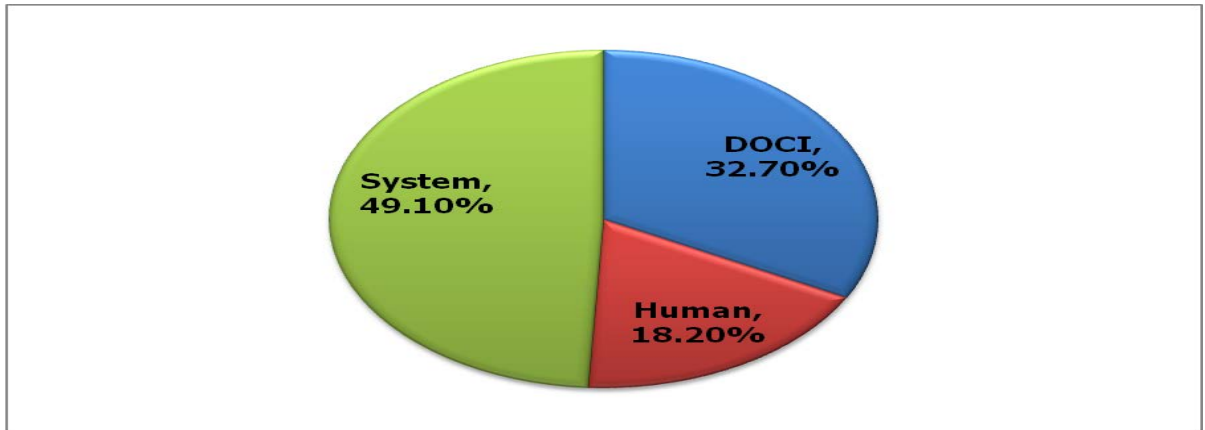
Figure 5.11 Associated factors as classified by the expert team

The results in Table 5.4 suggest that system errors contributed to more than 45% of the incidents reported in each year, with duty of care contributing nearly one third each year. There was a statistically significant (p=0.001) association between incident classification and year of reporting.

Table 5.4: The distribution of associated factors over the years of study

Classification Factors	Year of reporting						p-value
	2008 (n=1021)		2009(n=1333)		2010(n=1244)		
	Freq	%	Freq	%	Freq	%	
DOCI	362	34.46	439	32.93	377	30.31	<0.001*
Human error	93	9.11	265	19.88	295	23.71	
Systems error	566	55.44	629	47.19	572	45.98	

*Chi-square Test

Figure 5.12 indicates that the majority of the reported incidents were classified as being associated with systems error for each of the four 9-months interval, followed by those classified as duty of care incidents. Reported incidents that were classified as associated with human error increased over time whereas those classified as duty of care and system error decreased with time.

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	Jan08-Sep08	Oct08-Jun09	Jul09-Mar10	Apr10-Dec10
System Error	55.99	52.11	44.26	45.69
DOCI	36.39	33.23	31.56	30.64
Human Error	7.62	14.66	24.18	23.66
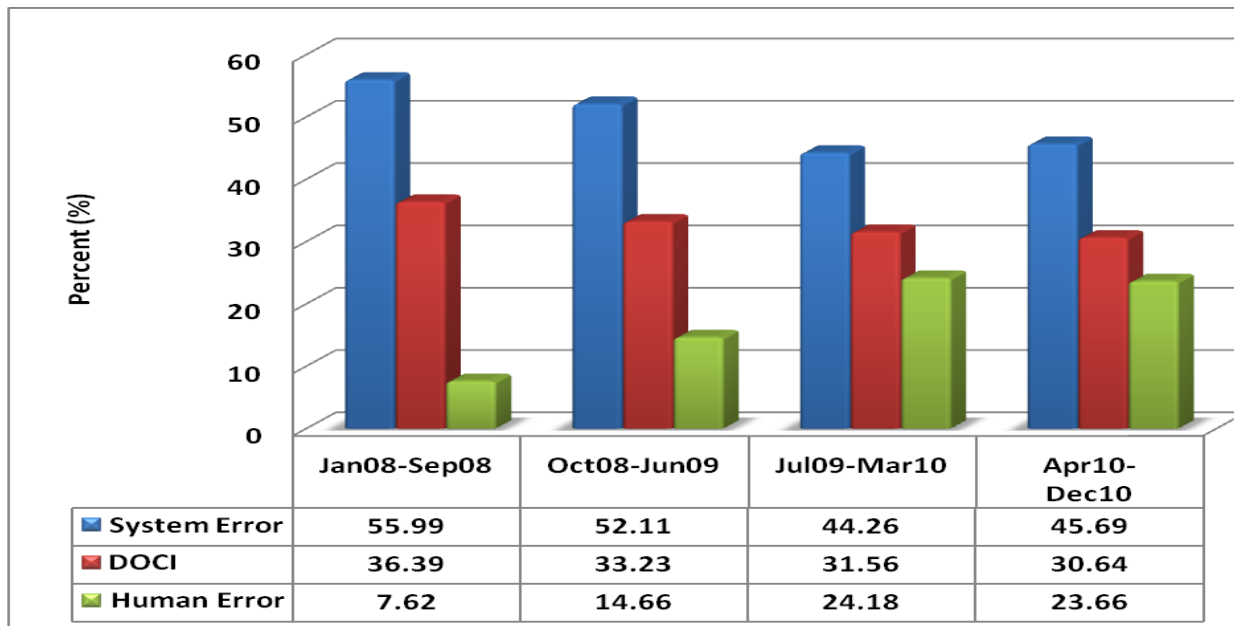
Figure 5.12: Factors associated with the reported incidents

5.3.3.1: Characteristics of reported system incidents

The types of system errors associated with the reported incidents during each nine-month interval are presented in Figure 5.13. Most of the system errors identified as associated with the reported incidents during the study period are regarded as personnel issues, followed by management issues and then equipment. The incidents associated with personnel issues increased over time with a slight decrease in those associated with management- and equipment-related issues.

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	Jan08-Sep08	Oct08-Jun09	Jul09-Mar10	Apr10-Dec10
■ Personnel	32.2	38.5	41.7	41.5
■ Management	23.7	18.9	22.0	22.4
■ Equipment	16.4	11.8	12.0	13.1
■ Facility	12.3	10.6	13.4	16.0
■ Transport	7.1	15.0	10.2	6.9
■ Organisational	1.5	3.7	0.2	0.0
■ Other	6.8	1.5	0.5	0.0
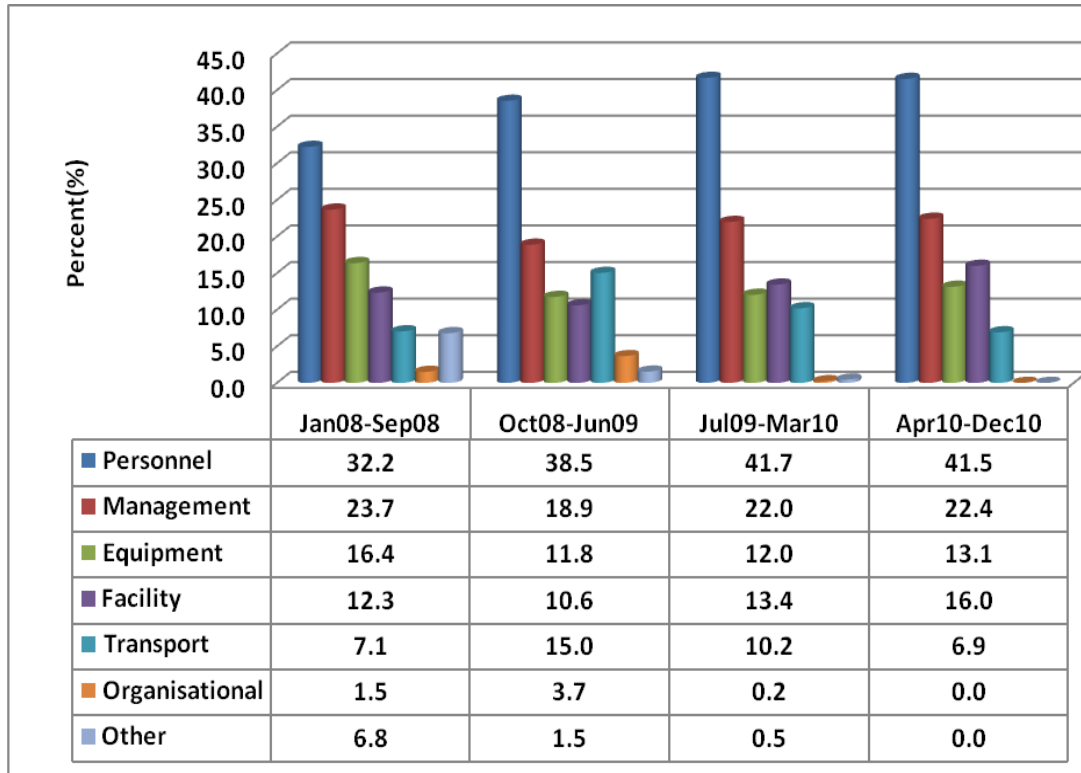
Figure 5.13: Reported incidents associated with system errors

5.3.4: Characteristics of reported incidents by type and severity

The classification of the reported incidents in terms of the Severity Assessment Code (SAC) demonstrates their degree of severity. The most severe reported incidents were investigated to determine if there was a relationship between the increase in the number of most severe incidents over time and the introduction of AMCu.

The distribution of the SAC classification of all reported incidents is presented in Figure 5.14. Nearly one quarter of the incidents reported during the study period constitute the most severe SAC (1 &2) incidents. More than half of the reported incidents were classified as SAC 3 and approximately 19% were classified as SAC 4.
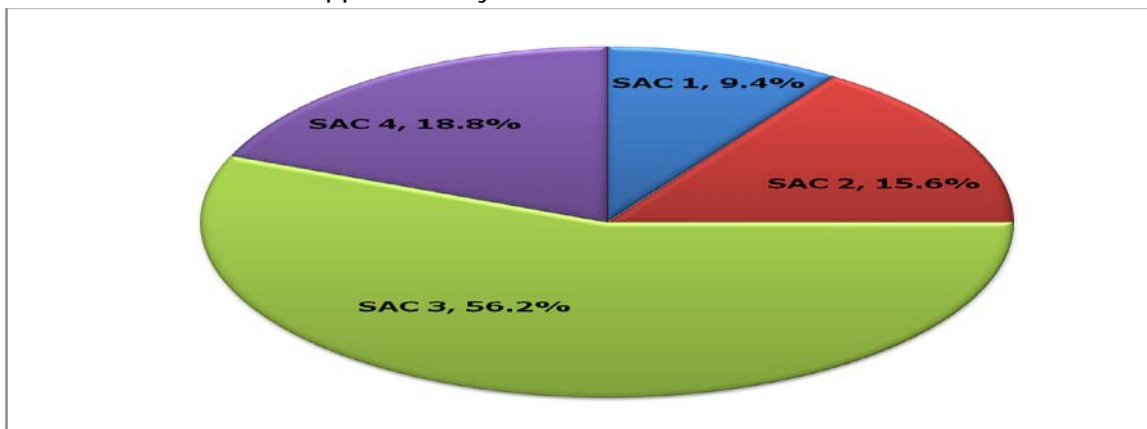
Figure 5.14: The distribution of SAC classification of the reported incidents

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The SAC classification over time is shown in Figure 5.15. More than 50% of the reported incidents were classified as SAC 3 at each of the 9-months intervals. Although less than 20% of the reported incidents were classified as SAC 2 or SAC 1, there was an increase in the percentage of reported SAC 1 and SAC 2 incidents over time. There is an observed decrease of the SAC 3 and SAC 4 incidents over the time period.

	Jan08–Sep08	Oct08–Jun09	Jul09–Mar10	Apr10–Dec10
SAC 1	6.1	8.7	11.1	11.0
SAC 2	14.1	13.0	15.6	19.6
SAC 3	54.0	58.5	56.3	55.4
SAC 4	25.8	19.8	17.1	14.0
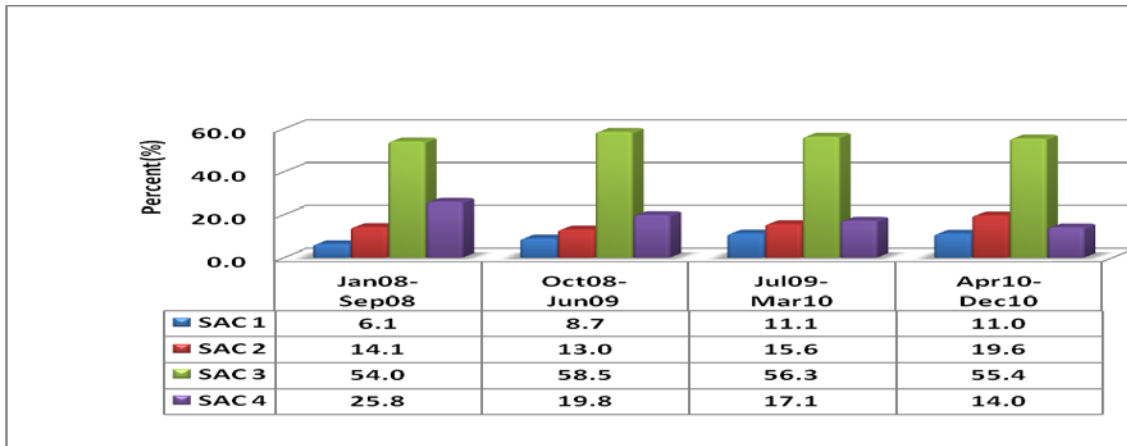
Figure 5.15: The distribution of the most severe incidents over time

The distribution of SAC 1 and SAC 2 across the incident type over the four nine-month intervals is presented in Figure 5.16. The results reveal that higher proportions of SAC 1 and SAC 2 incidents are reported from the incident type classified as adverse events followed by those classified as hazards over the four time points. All the incident types show an overall increase in the proportion of SAC 1 and SAC 2 reported incidents across the four nine-month intervals.

	Jan2008–sep2008	Oct2008–Jun2009	Jul2009–Mar2010	Apr2010–Dec2010
Adverse event	30.6	31.8	34.4	35.0
Hazard	11.6	11.3	14.8	24.8
Near Miss	0.0	2.0	16.1	19.2
Occupational injury	0.0	4.9	3.3	13.0
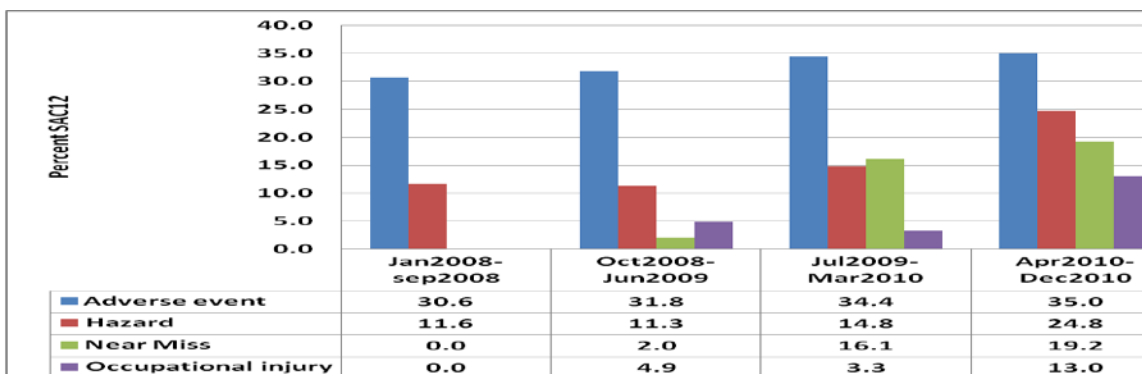
Figure 5.16: The distribution of SAC 1 and 2 categories across the type of incidents over time

The distribution of SAC 1 and 2 in each category of the associated factors reported for each of the four nine-month intervals is presented in Figure 5.17. More than one third of the SAC 1 & 2 categories were reported in the duty of care category followed by the systems error category for each of the nine-month categories. Very few SAC 1 and 2 categories were reported from the human error category.

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There is also an overall increase in the proportion of SAC 1 and 2 categories among the reported incidents in each category of associated factors examined over the four nine-month intervals.

	Jan2008-sep2008	Oct2008-Jun2009	Jul2009-Mar2010	Apr2010-Dec2010
■ DOCI	36.1	39.3	50.3	47.3
■ Human	0.0	6.2	3.0	7.4
■ System	12.6	14.8	22.7	31.5
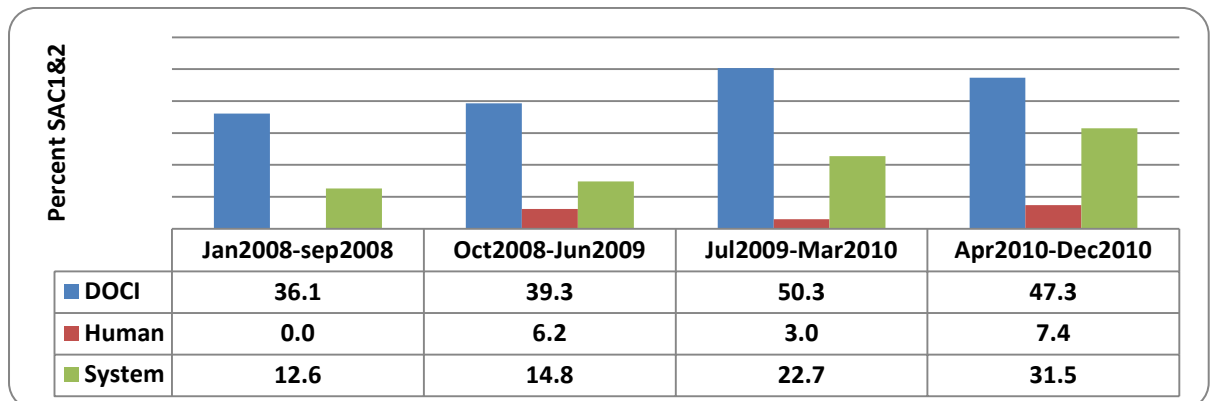
Figure 5.17: The distribution of SAC 1 and 2 across the categories of associated factors over time

The distribution of SAC 1 and 2 categories reported from each clinical discipline in each of the four time points is shown in Figure 5.18. The most severe incidents were reported from maternity for all the time points followed by those reported from paediatrics.

	Jan2008-sep2008	Oct2008-Jun2009	Jul2009-Mar2010	Apr2010-Dec2010
■ Maternity	42.9	57.1	72.9	75.4
■ Paediatrics	25.9	32.8	51.6	45.2
■ Other	17.1	15.5	18.7	26.3
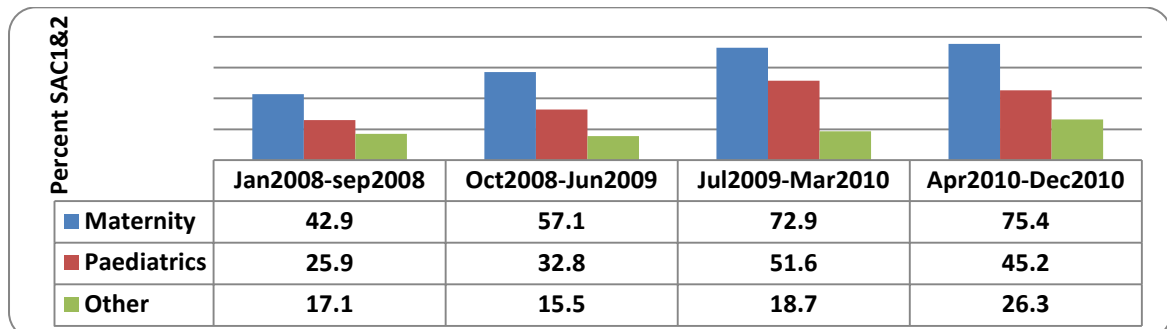
Figure 5.18: The distribution of SAC 1 and 2 categories across clinical discipline over time

Figure 5.19 shows the distribution of SAC 1 and 2 categories across the categories of systems errror for each of the four time periods. The greatest number of reported severe incidents in the first three nine-month intervals can be attributable to organisational, transport and management factors respectively. In the last period, the majority of the reported severe incidents were linked to transport (51%), management issues (40%) and then equipment problems (29%). All 100% of the incidents reported between July 2009 and March 2010 associated with organisational causes were severe.

Percent SAC12	Jan2008-sep2008	Oct2008-Jun2009	Jul2009-Mar2010	Apr2010-Dec2010
■ Equipment	20.0	6.6	11.5	29.1
■ Facility	16.3	9.1	8.6	22.4
■ Management	7.5	21.4	28.4	40.4
■ Organisational	33.3	36.8	100.0	0.0
■ Personal	9.4	13.0	17.8	27.6
■ transport	17.9	16.7	61.4	51.7
■ Other	11.1	12.5	0.0	0.0
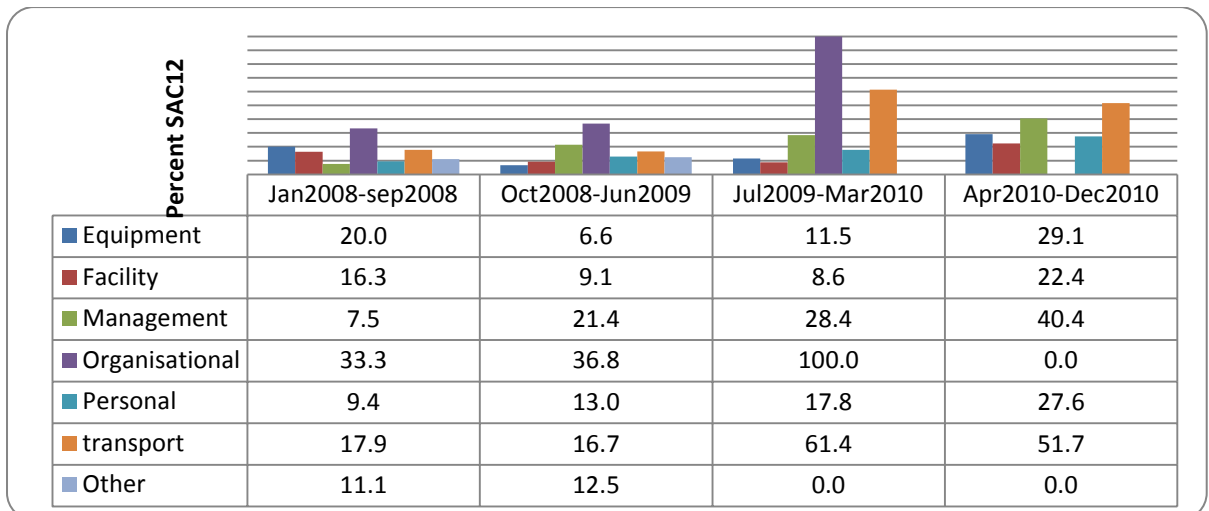
Figure 5.19: The distribution of SAC 1 and 2 categories across the categories of systems error over time

Figure 5.20 presents the distribution of severity of all incidents reported during the years of the study. It is clear from these results that the proportion of SAC 1 and SAC 2 incidents, which are also the most severe, actually increased between 2008 and 2009.

The moderate to mild SAC 3 incidents, which constitutes the majority of reported incidents during this period, show a marginal increase between 2008 and 2009 and a marginal decrease between 2009 and 2010. There was a decrease in the proportion of SAC 4 incidents between 2008 and 2010.

Percent (%)	2008	2009	2010
■ SAC 1	6.37	10.8	10.45
■ SAC 2	13.81	14.18	18.57
■ SAC 3	55.53	57.69	55.23
■ SAC 4	24.29	17.33	15.76
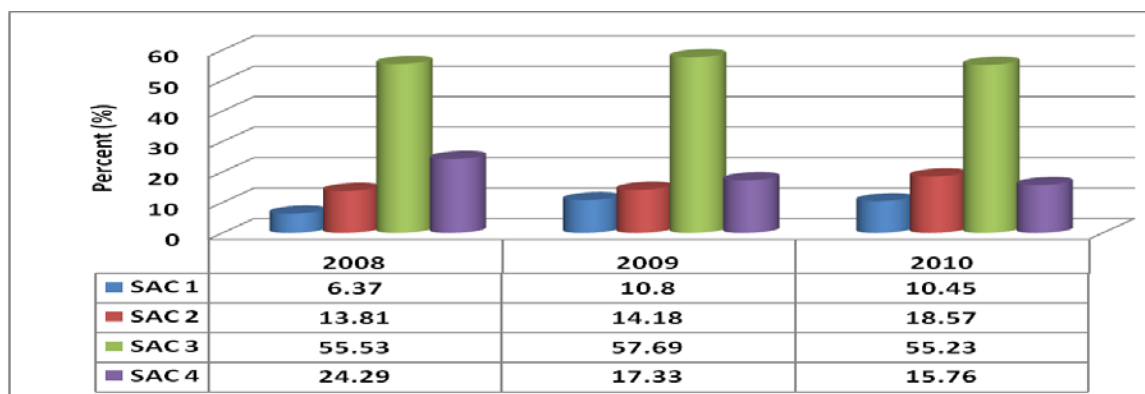
Figure 5.20: Yearly distribution of the severity of reported incidents

The trend in proportion of combined SAC 1 and SAC 2 severe incidents is presented in Figure 5.21. There in an increase in the proportion of the reported combined severe incidents throughout the study period, whereas the reported combined SAC 3 & SAC 4 incidents decreased between 2008 and 2010.
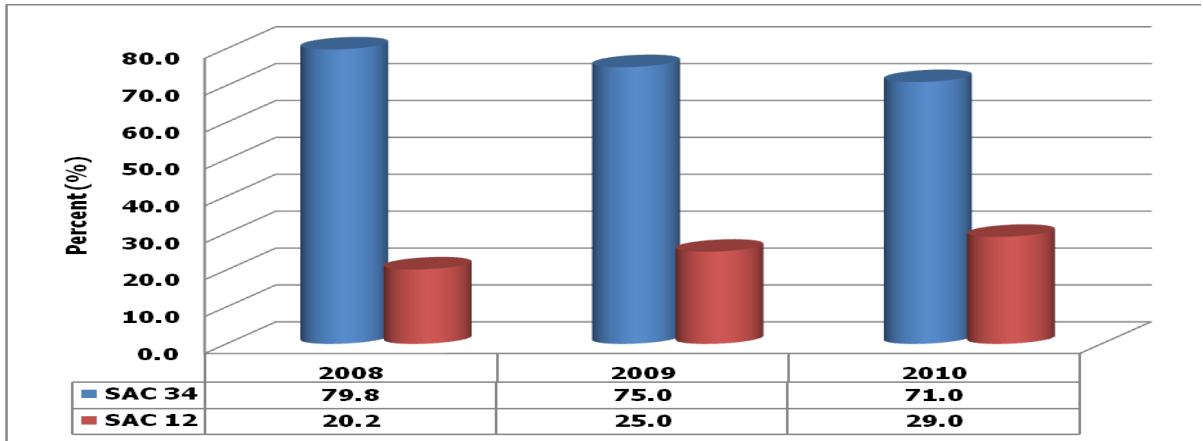
Figure 5.21: Distribution of SAC classification during each of the three years of study

	2008	2009	2010
■ SAC 34	79.8	75.0	71.0
■ SAC 12	20.2	25.0	29.0

The distribution of SAC 1 and SAC 2 incidents reported for each of the nine-month interval is important because the reduction of the most severe incidents is one of the key goals of patient safety. An examination of the proportion of SAC 1 and SAC 2 reported incidents are presented in Figure 5.22. The results indicate that there is an increase in the proportion of the reported combined SAC 1 and SAC 2 over the nine-month intervals. This variable (combined SAC 1 & SAC 2) was used as an outcome variable in order to identify the risk factors associated with most severe incidents.

	Jan08 to Sep08	Oct08 to Jun09	Jul09 to Mar10	Apr10 to Dec10
■ SAC 12	20.2	21.7	26.6	30.6
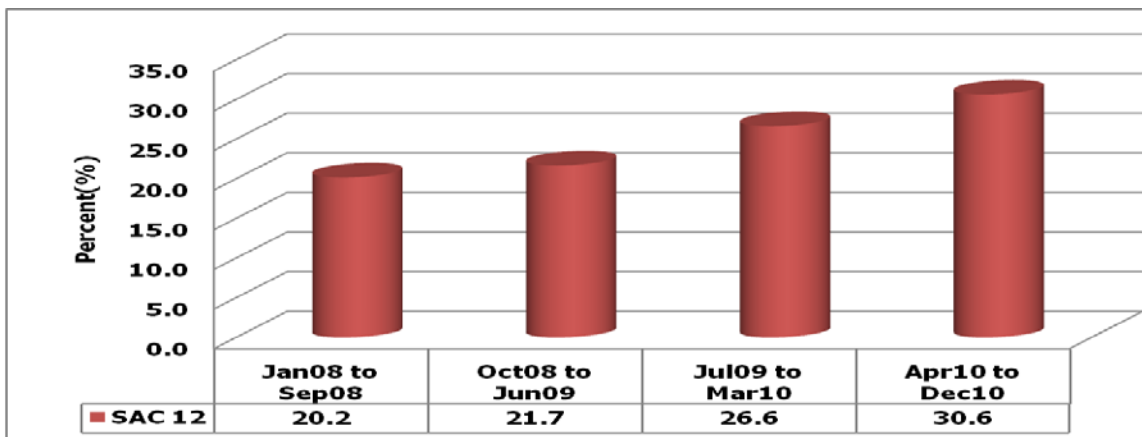
Figure 5.22: The distribution of most severe incidents across the nine months interval

5.3.5: Seasonal characteristics of reported incidents

It has already been indicated that there appears to be a seasonal pattern of reported incidents and adverse events. The number of incidents reported per month for the entire study period is presented in Figure 5.23. A lesser number of incidents were reported in the December months following the peaks in November throughout the study period, meaning that November month carries a higher risk of patient safety incidents compared to the December months. However, the pattern of incident reporting needs to be further observed in order to establish all possible risky periods.

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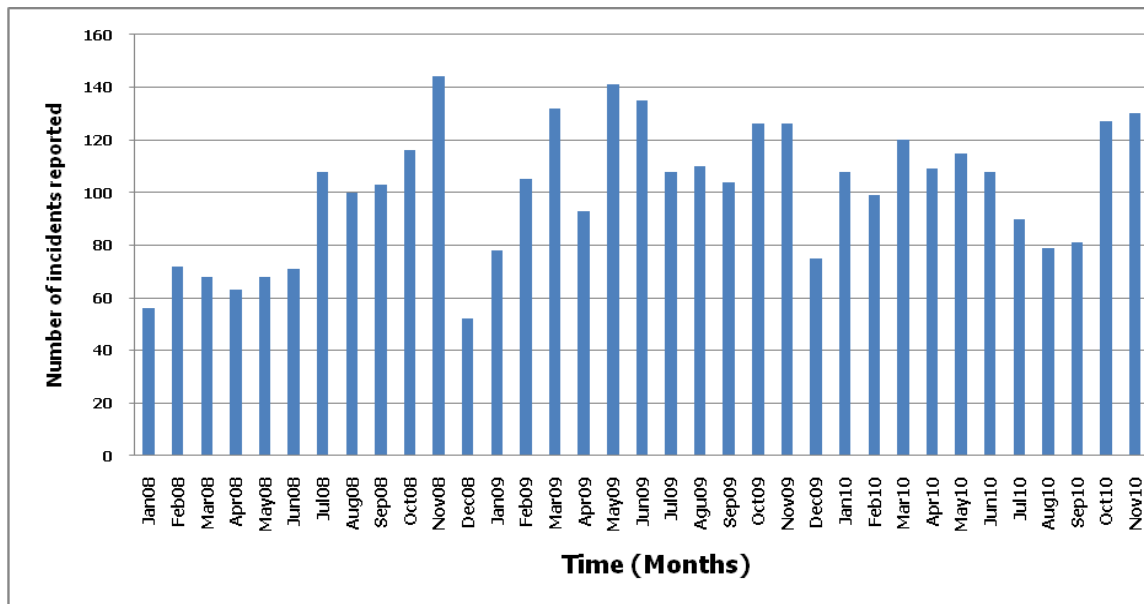
Figure 5.23: The number of incidents reported per month

5.3.6: Response of reported incidents to cost-containment

The occasion for high risk of incidents and adverse events occurrence happened when the Free State Department of Health introduced cost-containment measures from September 2008 to March 2009 as a response to the budgetary pressures that it found itself exposed to. This cost-containment response resulted in serious interruptions to the provision of health care services. These measures included the admission and referral of only emergency cases, the discharge of stable patients and the postponement of elective surgery. These service restrictions resulted in fewer activities in the hospitals and, therefore, fewer reported incidents during this period. The cost-containment measures were lifted from April 2009 and service rendering returned to normal. However, when these service restrictions were lifted there was an increase in reported incidents between April and June 2009 (Figure 5.23 above). This increase might have been that patients who were previously denied care were now presenting as complicated cases or emergencies.

The proportion (16.8%) of incidents reported before cost containment was less than the proportion (20.3%) of incidents reported during cost containment, and even less than those reported after (62.9%) cost containment (Table 5.5).

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Table 5.5: The distribution of the reported incidents across the cost-containment period: control and intervention sites

Cost containment	Control sites (n=940)		Intervention sites (n=2658)		Total (n=3598)	
Before (Jan to Aug 2008) 8mths	2	0.21%	604	22.72%	606	16.84%
During 7mths (Sep2008 to Mar 2009)	187	19.89%	543	20.43%	730	20.29%
After 21 months (April 2009 to Dec 2010)	751	79.89%	1 511	56.85%	2 262	62.87%

Section B:

This second and final section of the results explores the impact or outcomes of the implementation of the collective set of interventions known as AMCu. Impacts are in many instances difficult to assess and measure due, sometimes, to the amount of time that has to elapse in order for one to fully appreciate the quantum of the impact. In this instance, the outcome measures were used to determine the effectiveness of the AMCu intervention.

This section of the results addresses itself to the original questions 5.1.3 and 5.1.4, as posed in the introductory part of this chapter and therefore focuses on all the survey results as well the COHSASA evaluation scores. The separation between section A and B conveniently made to separate the reported incident results from the rest. The following results are therefore important for this section:

a. Results of safety climate surveys
b. Results of safety culture surveys
c. Results of patient satisfaction surveys
d. Results of COHSASA quality surveys duplication with below

5.4: Does AMCu improve patient safety outcomes?

This question will be addressed by addressing the following specific questions

a. Does the implementation of AMCu improve safety climate?

b. Does the implementation of AMCu improve patient safety culture?

c. Does the implementation of AMCu improve patient satisfaction?

d. Does the implementation of AMCu improve health care quality as measured using COHSASA scores?

5.4.1 Effect of AMCu on patient safety climate

In order to determine the effects of AMCu on patient safety climate, we examined the mean scores of the key domains as defined and measured at three time points using the Safety Climate Survey. The means for March 2008, November 2008 and November 2009 are compared as firstly aggregated scores (for all sites) and also as disaggregated scores for the control and the delayed control or intervention sites. This disaggregation was done to determine whether the safety climate, which is a process and takes root in organisations over time, will change at different rates between the control and intervention sites.

5.4.1.1. The patient safety climate survey assessment

A total of 3510 questionnaires were completed over at the three time points with 1647 being completed in March 2008, 1038 were completed in November 2008 and 825 were completed in November 2009.There is at this stage no explanation for differences in the response rates at the different time points. Of the 3510 questionnaires completed at all the three time points 932 (26.6%) were completed by the same personnel at least two time points. The difference in numbers reported for each question is due to the fact that the non-response for a particular question, were not in the final tally of responses.

5.4.1.2. Demographic Information

More than one third of the participants in the patient safety climate survey were 45 years or older, followed by those who were between 40 and 44 years at each of the three time points. Just over 20% of the participants had experience of 3 to 7 years or 13 to 20 years in the position they held. (Table 5.6).

Table 5.6: The distribution of age and experience in position

	2008Mar		2008Nov		2009Nov	
Age group		**n=1535**		**n=963**		**n=756**
Younger than 30 year	256	16.68	177	18.38	138	18.25
30 to 34 years	198	12.90	130	13.50	78	10.32
35 to 39 years	226	14.72	118	12.25	86	11.38
40 to 44 years	304	19.80	192	19.94	143	18.92
45 or over	551	35.90	346	35.93	311	41.14
Experience in post		**n=1538**		**n=967**		**n=706**
Less than 6 months	108	7.02	30	3.10	18	2.55
6 to 11 months	61	3.97	72	7.45	76	10.76
1 to 2 years	220	14.30	152	15.72	91	12.89
3 to 7 years	342	22.24	203	20.99	166	23.51
8 to 12 years	176	11.44	114	11.79	77	10.91
13 to 20 years	330	21.46	223	23.06	145	20.54
21 years or over	301	19.57	173	17.89	133	18.84

The distribution of the experience of the participants in the organisation and speciality is presented in Table 5.7. Nearly one quarter of the participants indicated that they had 3 to 7 years' experience in their area of speciality at each time in point. Only approximately 18% had speciality experience of 13 to 20 years. Experience of over 20 years was cited by 20.9% of participants in March 2008, 19.7% of the participants in November 2008 and 23.6% of the participants in November 2009.

Table 5.7: Distribution of experience in organisation and speciality

	2008mar		2008nov		2009nov	
Experience in specialty	**Freq**	**n=1189**	**Freq**	**n=740**	**Freq**	**n=533**
Less than 6 months	93	7.82	50	6.76	24	4.50
6 to 11 months	47	3.95	55	7.43	51	9.57
1 to 2 years	176	14.80	115	15.54	71	13.32
3 to 7 years	284	23.89	185	25.00	126	23.64
8 to 12 years	154	12.95	78	10.54	70	13.13
13 to 20 years	235	19.76	130	17.57	91	17.07
21 years or Over	200	16.82	127	17.16	100	18.76
Organisational experience		**n=1427**		**n=897**		**n=711**
Less than 6 months	107	7.50	34	3.79	20	2.81
6 to 11 months	67	4.70	80	8.92	84	11.81
1 to 2 years	168	11.77	135	15.05	76	10.69
3 to 7 years	299	20.95	187	20.85	139	19.55
8 to 12 years	160	11.21	87	9.70	84	11.81
13 to 20 years	327	22.92	197	21.96	140	19.69
20 years or more	299	20.95	177	19.73	168	23.63

5.4.1.3 Patient safety climate survey results

The distribution of the responses used to measure the safety culture in the clinical area is presented in Figure 5.24. More than half of the participants at each of the three time points agreed that the culture of their clinical area made it easy to learn from the mistakes of others and that medical errors were handled appropriately in that clinical area. However, nearly 40% of the participants disagreed that they would feel safe being treated there as a patient.
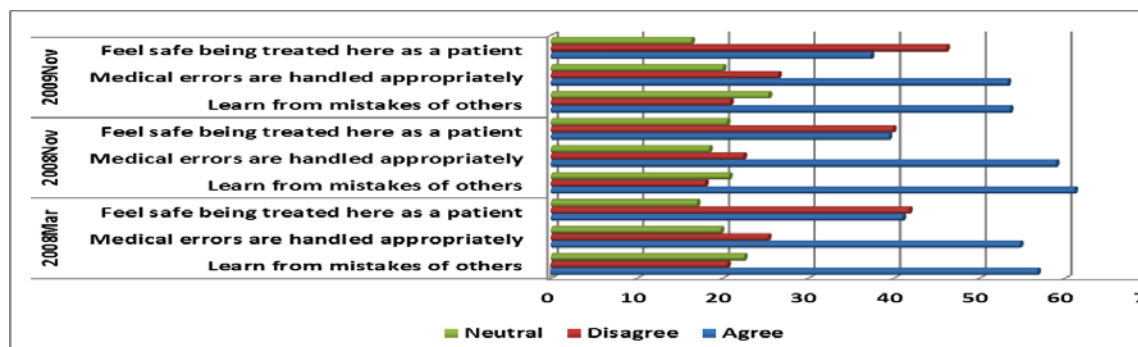
Figure 5.24: Safety culture in clinical area

The responses of the items used to measure leadership are presented in Figure 5.25. Approximately 50% of the respondents at each point in time agreed that leadership was driving them to produce a safety-centred institution, with only 40% agreeing that senior leadership in their hospital listen to them and care about their concerns. However, less than 50% of the participants at each time in point agreed that medical officer(s) and nurse leaders in their areas listen to them and care about their concerns.
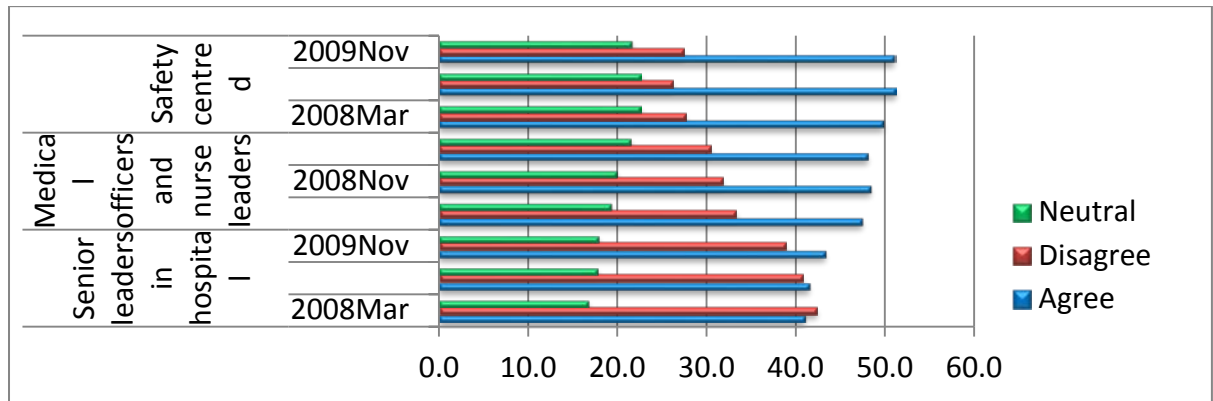
Figure 5.25: Leadership and safety climate

The distribution of the responses on the items used to measure safety concerns is shown in Figure 5.26. Nearly three-quarters of the participants at each time point agreed that they had followed the proper channels to direct questions about patient safety, with approximately two thirds agreeing that they are encouraged by colleagues to report any safety concerns they might have. About 40% of the participants at each point in time agreed that leadership does not knowingly compromise safety concerns for the sake of productivity and that their suggestions about safety would be acted upon if they were expressed to management.
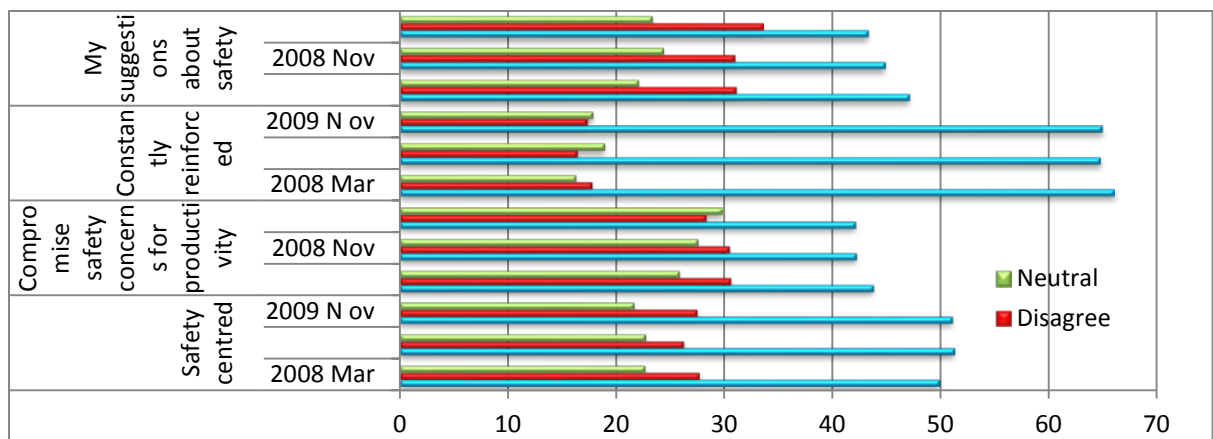
Figure: 5.26 Safety concerns

The distribution of the responses on the items used to measure briefing activities is shown in Figure 5.27. Nearly 70% of the participants at each time point agreed that briefing personnel before the start of a shift is an important part of safety and only 40% agreed that they receive appropriate feedback about their performance. However, less than 50% agreed that "briefings are common here".

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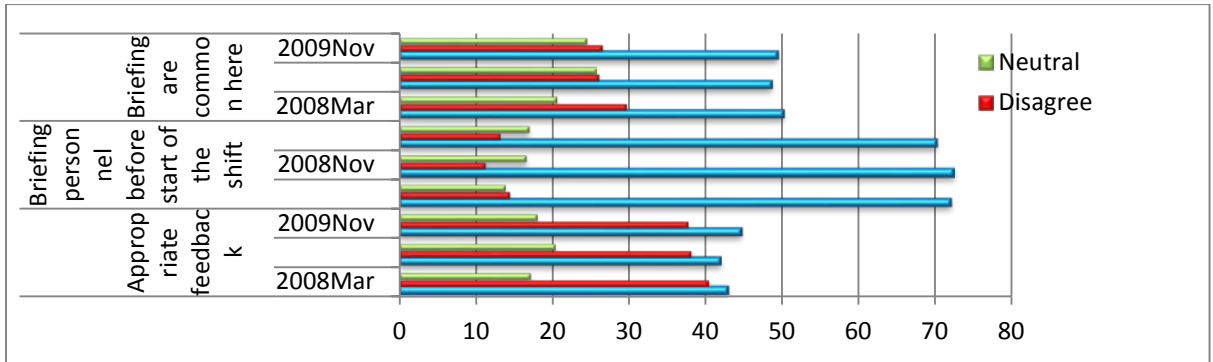
Figure 5.27: Briefing sessions

The distribution of the responses to items used to measure patient safety is displayed in Figure 5.28. Seventy per cent of the participants at each time point agreed that the personnel in their clinical area take the responsibility for patient safety, with nearly two-thirds agreeing that patient safety is constantly reinforced as a priority in their clinical area. However, only about 45% of the participants agreed that "this institution is doing more for patient safety now than it did one year ago."
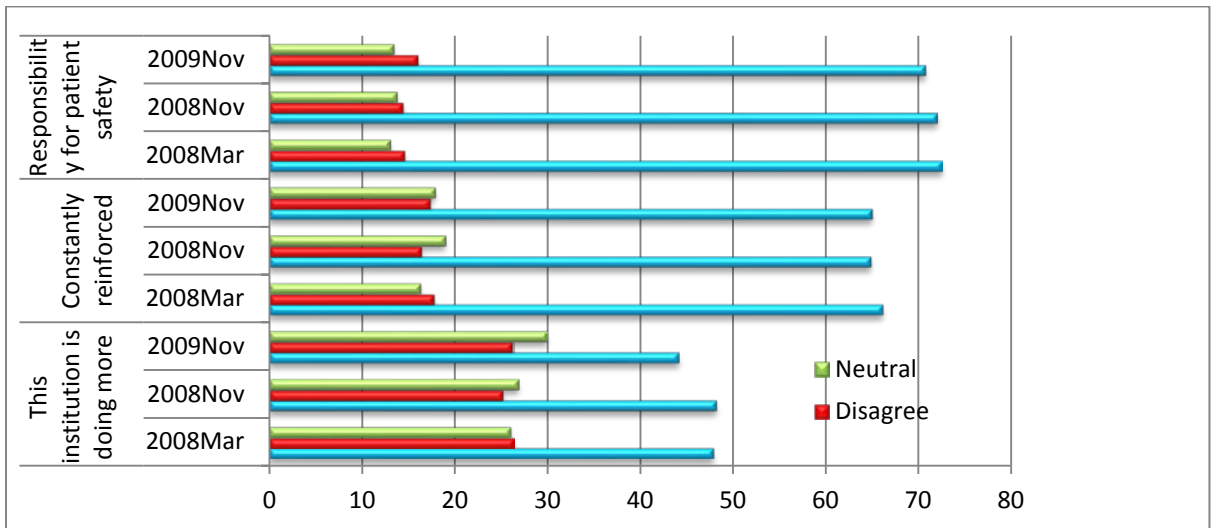
Figure 5.28: Patient safety

The distribution of the responses measure clinical leadership is shown in Figure 5.29. At each of the three time points less than 50% of the participants agreed that the leadership was available for each of the professional- and management groups set out in Figure 5.29.
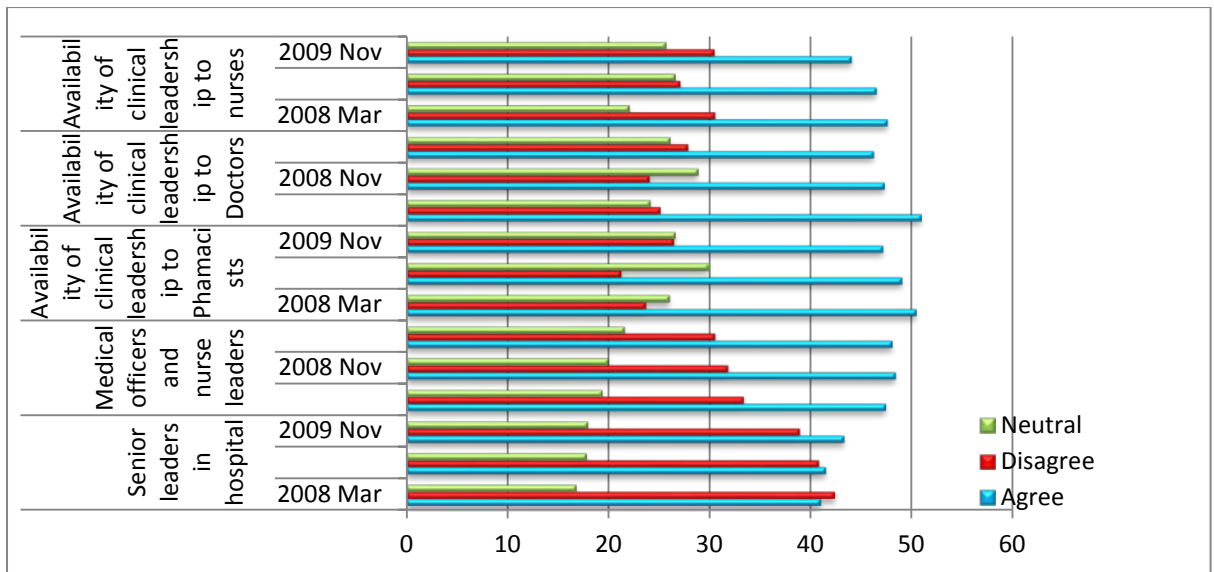
Figure 5.29 Clinical leadership

The distribution of the responses regarding rules and guidelines and system failures is shown in Figure 5.30. More than 40% of the participants disagreed that personnel frequently disregarded rules or guidelines that had been established for their clinical area. However, more than 50% of the participants agreed that "I believe that most adverse events occur as a result of multiple system failures and are not attributable to one individual's actions."
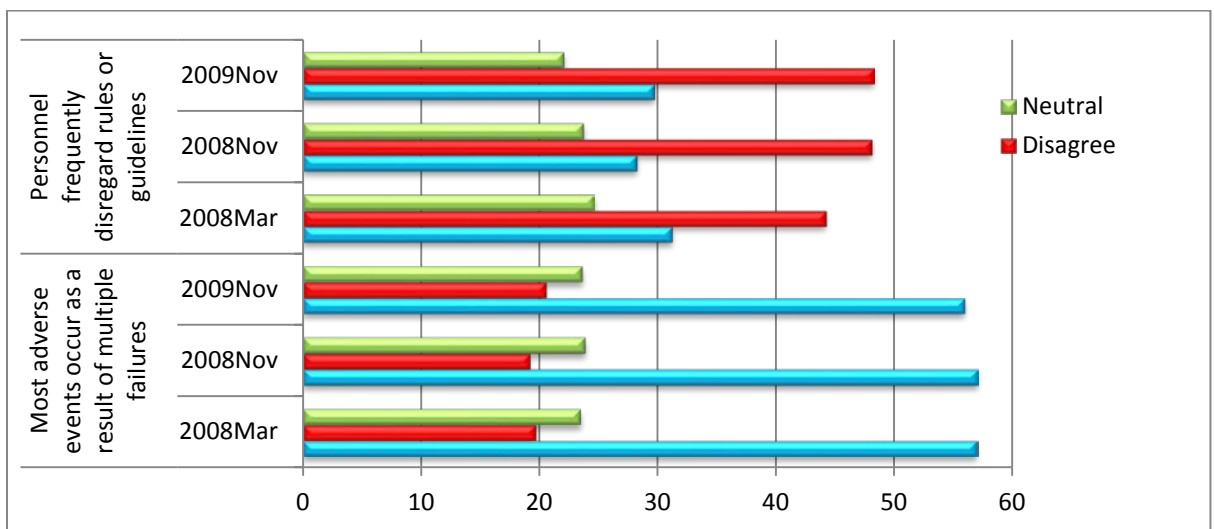
Figure 5.30 Rules or guidelines on multiple system failures

The mean scores of the designated domains are compared in Table 5.8. There was an improvement in the average positive scores from March 2008 to November 2008. However, the average positive scores had decreased by November 2009 for all the dimensions except for leadership, where the average had increased although this increase was not statistically significant. There was a statistically significant (p=0.0299) difference in the average positive scores for the culture of clinical area dimensions. The differences of all the other dimensions were not statistically significant (all p-values>0.05).

Table 5.8: The distribution of the average scores for the created dimensions

Domain	Statistic	2008 Mar	2008 Nov	2009 Nov	P-value
Leadership		**n=1590**	**n=1004**	**n=797**	
	Mean	45.95	46.95	47.55	0.6272
	Median	33.33	33.33	33.33	
	IQR	100-0	100-0	100-0	
	Range	100-0	100-0	100-0	
Culture of clinical area		**n=1543**	**n=978**	**n=788**	
	Mean	51.05	52.97	48.39	0.0299
	Median	66.67	66.67	50.00	
	IQR	66.67-33.33	66.76-33.33	100-33.33	
	Range	100-0	100-0	100-0	
Information provided		**n=1584**	**n=988**	**n=801**	
	Mean	54.95	54.18	54.68	0.8657
	Median	66.67	66.67	66.67	
	IQR	100-33.33	83.33-33.33	100-33.33	
	Range	100-0	100-0	100-0	
Patient safety		**n=1552**	**n=976**	**n=779**	
	Mean	62.11	61.71	59.91	0.3709
	Median	66.67	66.67	66.67	
	IQR	100-33.33	100-33.33	100-33.33	
	Range	100-0	100-0	100-0	
Clinical leadership		**n=1557**	**n=972**	**n=777**	
	Mean	49.78	47.94	45.73	0.0781
	Median	33.33	33.33	33.33	
	IQR	100-0	100-0	100-0	
	Range	100-0	100-0	100-0	
Concerns		**n=1538**	**n=979**	**n=783**	
	Mean	69.07	69.08	67.46	0.4788
	Median	75	75	75	
	IQR	100-50	100-0	100-50	
	Range	150-0	150-0	150-0	

A decision to explore whether there were any differences in the performances between the intervention and control groups with respect to the designated domains for the safety climate survey, as illustrated in Tables 5.9 and 5.10, was taken and resulted in the observations set out below.

In the intervention group (Table 5.9), the differences between the means, measured during the three time points in the survey for all the six domains were statistically insignificant, except for the culture of a clinical area domain (p=0.0158). This finding

was consistent with the finding of the average scores for the created dimensions for all facilities in Table 5.8 above.

Table 5.9: Patient safety climate - The distribution of the mean scores per domain [Intervention]

Domain	Statistic	2008 Mar	2008 Nov	2009 Nov	P-value
Leadership		n=861	n=459	n=325	
	Mean	47.08	50.84	51.38	0.1301
	Median	33.33	33.33	33.33	
Culture of clinical area					
	Mean	53.53	58.16	52.65	0.0158
	Median	66.67	66.67	66.67	
Information provided					
	Mean	56.60	56.23	57.80	0.8121
	Median	66.67	66.67	66.67	
Patient safety					
	Mean	66.27	67.87	63.04	0.1634
	Median	66.67	66.67	66.67	
Clinical leadership					
	Mean	48.41	50.42	44.20	0.1142
	Median	33.33	66.67	33.33	
Concerns					
	Mean	70.01	70.53	69.44	0.8984
	Median	75.00	75.00	75.00	

In the control group, however, the differences between the means of the domains measured at the three point intervals were also found to be statistically insignificant, except for the clinical leadership domain. The means for the clinical leadership domain declined significantly over the three point intervals (p=0.0382)

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Table 5.10: Patient safety climate: The distribution of the mean scores per domain [Control Group]

Domain	Statistic	2008 Mar	2008 Nov	2009 Nov	P-value
Leadership		n=722	n=539	n=472	
	Mean	44.74	43.60	44.92	0.8425
	Median	33.33	33.33	33.33	
Culture of clinical area					
	Mean	48.24	48.39	45.47	0.3400
	Median	33.33	66.67	33.33	
Information provided					
	Mean	53.09	52.34	52.53	0.9255
	Median	66.67	66.67	66.67	
Patient safety					
	Mean	57.45	56.40	57.70	0.8346
	Median	66.67	66.67	66.67	
Clinical leadership					
	Mean	51.31	45.65	46.78	0.0382
	Median	33.33	33.33	33.33	
Concerns					
	Mean	68.19	67.78	66.11	0.5437
	Median	75.00	75.00	75.00	

5.4.2 The effects of AMCu on patient safety culture?

The distribution of the responses to the items that measured the overall perception of healthcare workers on patient safety culture is set out in Figure 5.31. A higher percentage of health workers disagreed that "it is by chance that more serious mistakes do not happen around here" for all the three surveys. However, the majority of the participants agreed that their procedures and systems were good at preventing errors from happening at all the three time points (60.6%, 61.9% and 56.4% for March 2008, November 2008 and November 2009 respectively). Most participants disagreed that they had patient safety problems in their unit at all during all the surveys except in November 2008 where 43% agreed that they had problems. More than half of the participants agreed that patient safety was never sacrificed for the sake of getting more work done at all the three time points.
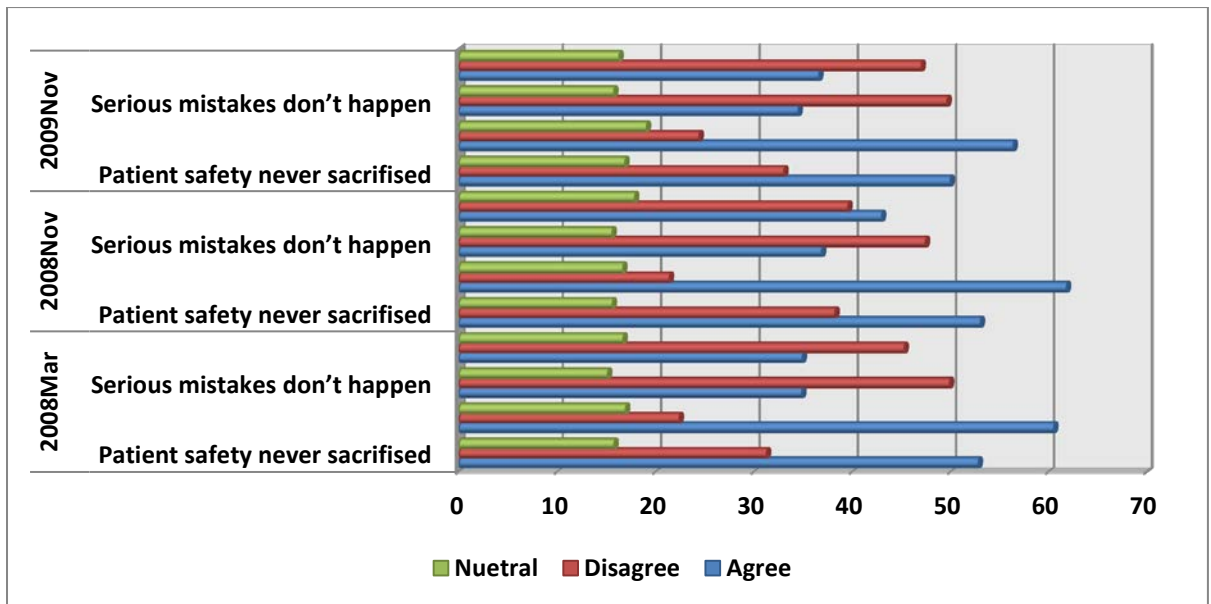
Figure 5.31: Overall perception of patient safety culture

The items used to measure improving patient safety are presented in Figure 5.32. More than 80% of the participants agreed that they were actively doing things to improve patient safety during all the surveys, except for the November 2009 survey where 79% agreed. At least 50% of the participants agreed to the statement "mistakes have led to positive changes here" for all the three time points. Nearly 60% of the participants agreed to the statement "After we make changes to improve patient safety we evaluate their effectiveness."
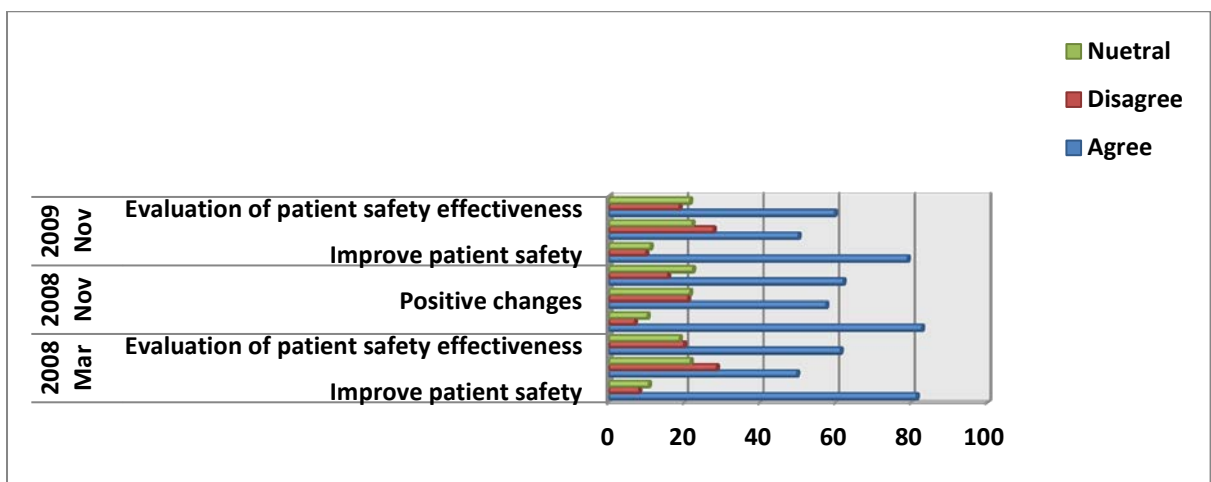
Figure 5.32: Improving patient safety

The items measuring team work are presented in Figure 5.33. More than 60% of the participants agreed that "people support one another in this unit" and more than 70% agreed that "we work together as a team to get work done" at all the three time points. At least 50% of the participants agreed that they treated each other with respect in the unit and helped one another when the unit was busy at all the three time points.

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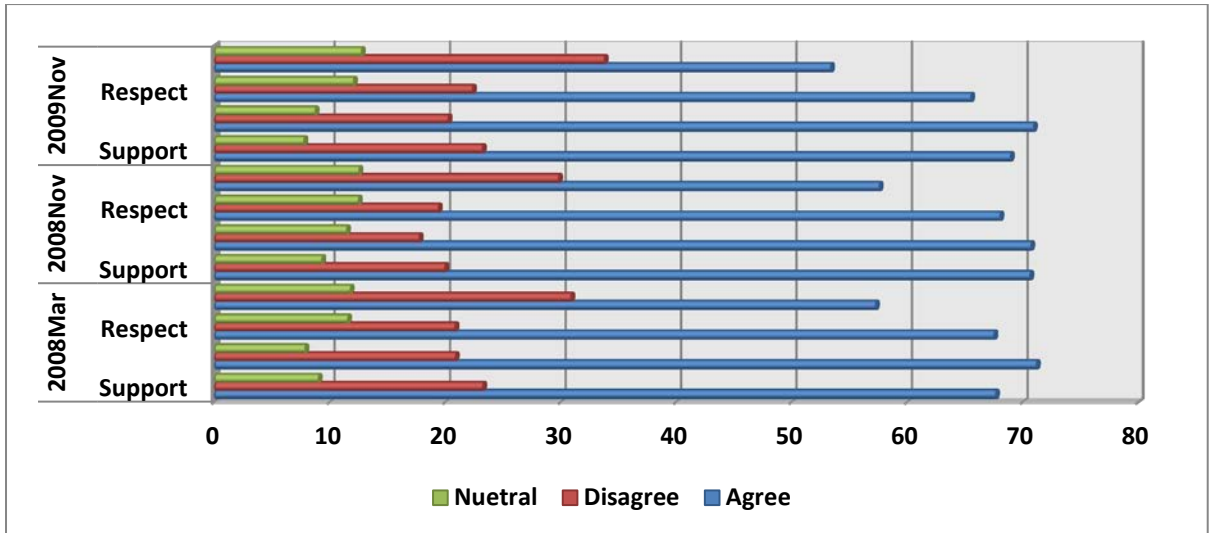
Figure 5.33: Team work

The items used to measure communication are presented in Figure 5.34. Nearly 45% of the participants agreed that they were afraid to ask questions when something did not seem right. Only 35% of the participants agreed that they felt free to question decisions or actions taken by those with more authority.
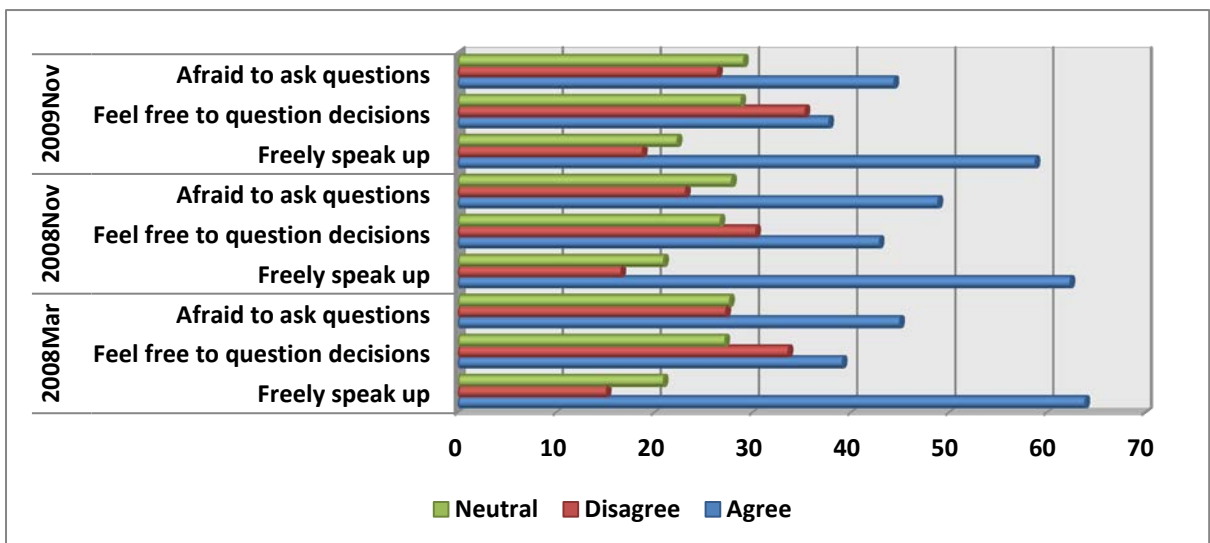
Figure 5.34: Communication

Figure 5.35 shows the distribution of the responses to items measuring communication about errors. At least 60% of the participants agreed that they were informed about the errors that happened in their unit and that the health care personnel in the unit discussed ways to prevent errors from happening at all the three time points. Only 40% of the participants agreed that they received feedback about changes put into place based on event reports for all the three time points. This lack of feedback was a cause for concern as it could be an indication that professionals at the coalface may not be learning as much as they should be learning about incidents in the manner that was intended for reporting systems.

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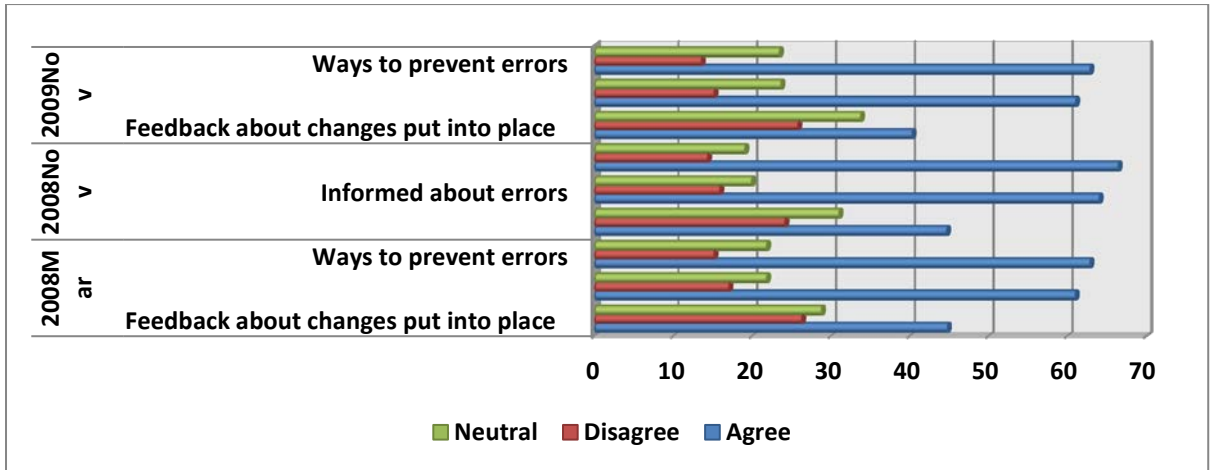
Figure 5.35: Communication of errors

The distribution of the responses of the participants towards staff and work is shown in Figure 5.36. More than half of the participants disagreed that the work was in crisis mode with more than three-quarters disagreeing that they had enough staff to handle the workload. Nearly 60% of the participants disagreed that they worked long hours. More than half of the participants agreed that they used more agency/temporary staff than was best for patient care.
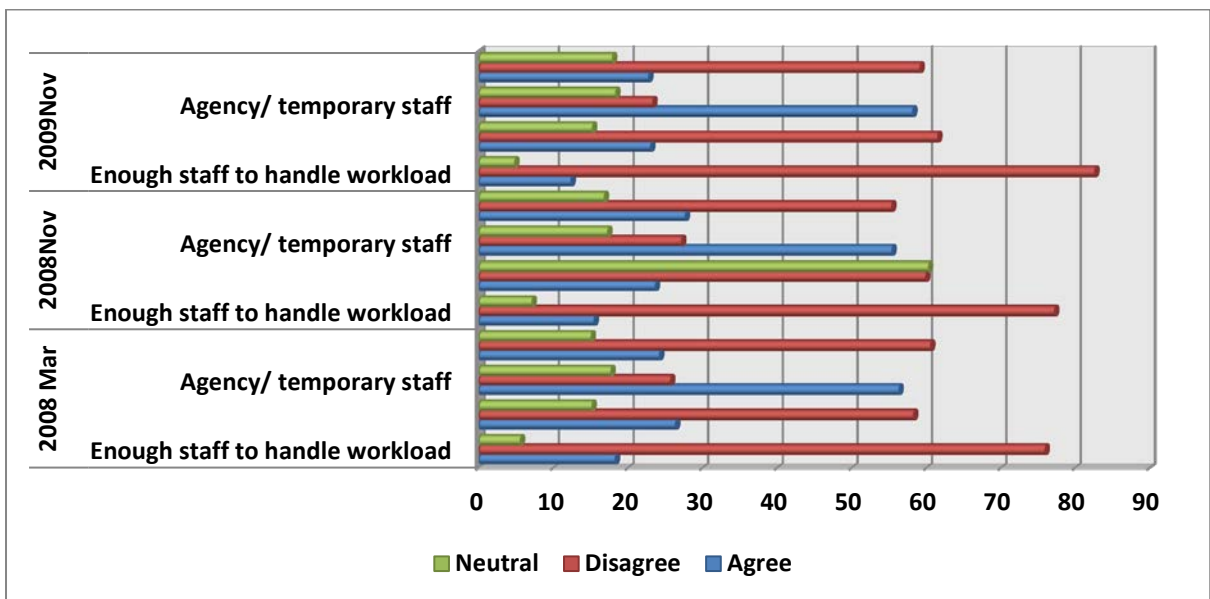
Figure 5.36: Staff and work

The distribution of the responses of the participants to management issues is shown in Figure 5.37. Nearly 45% of the participants disagreed that hospital management seemed interested in patient safety only after an adverse event had happened, with more than half agreeing that hospital management provided a work climate that promoted patient safety as well as agreeing that actions of hospital management shows that patient safety was a top priority.

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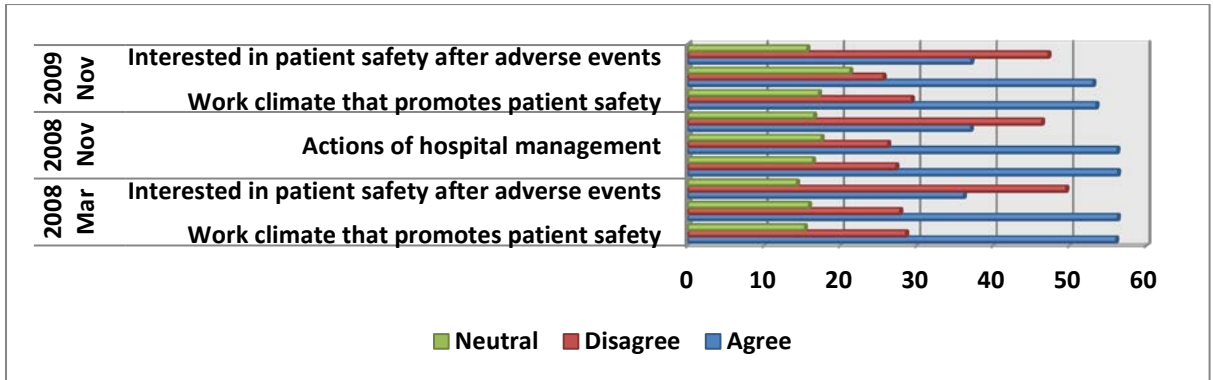
Figure 5.37: Management

The distribution of the responses to the items used to measure safety is presented in Figure 5.38. Nearly half of the participants agreed that it was often unpleasant to work with staff from other units, with approximately 40% agreeing that hospital units did not coordinate well with each other at all three time points.

Nearly 60% of the participants agreed that hospital units worked well together to provide the best care for patients. Just over 50% of the participants agreed that there was good cooperation among hospital units that needed to work together. These agreements were happening at all three time points.
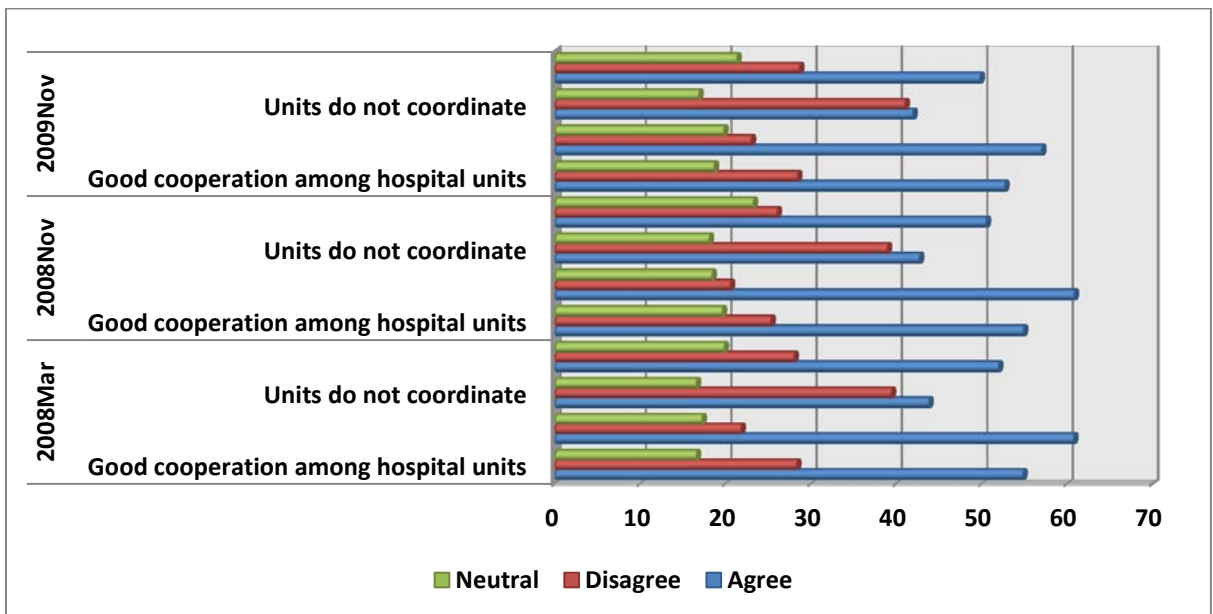
Figure 5.38: Safety grade

The responses to the items used for measuring handovers are shown in Figure 5.39. Nearly 50% of the participants agreed that important patient care information was often lost during shift changes and that shift changes were problematic for patients in this hospital. Less than 40% of the participants agreed that things "fall between the cracks" when patients were being transferred from one unit to another.

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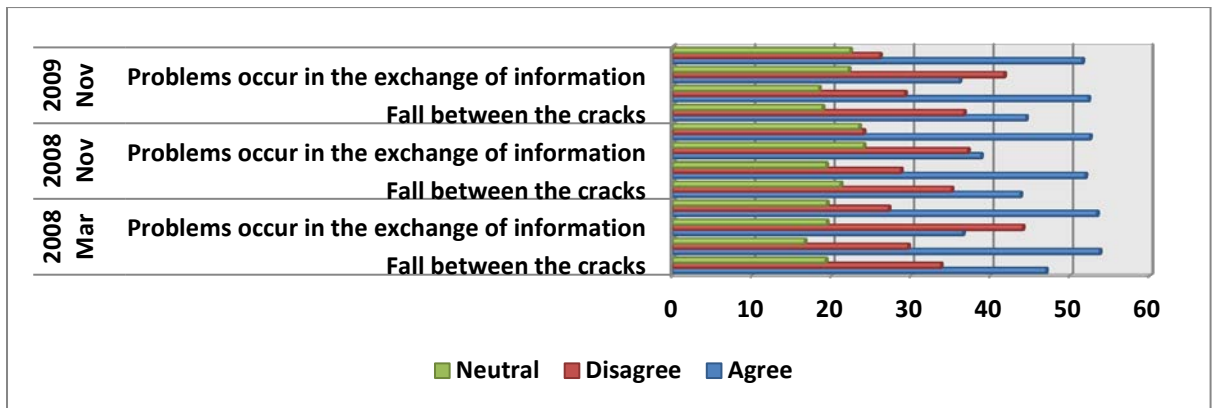
Figure 5.39: Handovers

Information about non-punitive measures is presented in Figure 5.40. Nearly 50% of the participants disagreed that staff felt that their mistakes were held against them and disagreed that staff worried that mistakes they made were kept in their personnel file.

Less than 50% of the participants disagreed that when an event was reported that it felt like the person was being written up, not the problem. These results were similar at all three time points.
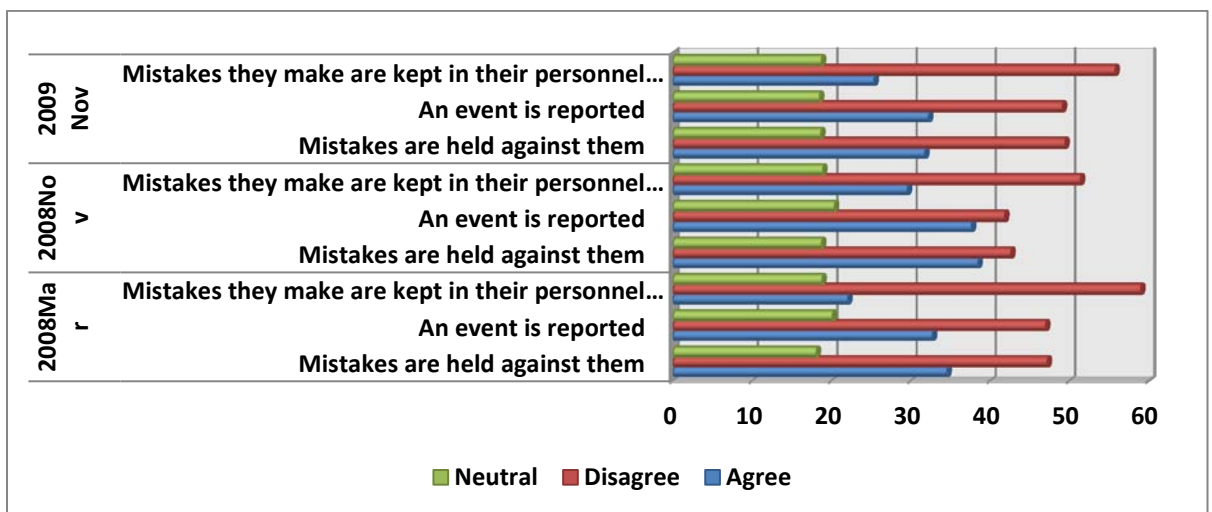
Figure 5.40: Non-punitive practices

Only 4 out of 12 dimensions showed statistically significant ($p < 0.05$) variations over time. The average perceptions of these dimensions increased from March 2008 to November 2008 and they all decreased in November 2009, except for the safety culture, which increased consistently. For all of the four dimensions, the average per cent positive perceptions were similar for all the three time periods, except for the dimension: safety culture at unit level ($p=0.0332$), overall perception ($p=0.0438$), continuous improvement ($p=0.0332$) and non-punitive ($p=0.0007$) where the differences are statistically significant (Table 5.11).

Table 5.11: Comparison of the average positive perception across the three time periods

DOMAIN	March 2008 (n=1634)	November 2008 (n=1026)	November 2009 (n=816)	P-Value
Frequency of event reporting				
Mean	48.55	47.21	45.22	0.1924
Median	33.33	33.33	33.33	
IQR	100-0	100-0	100-0	
Range	100-0	100-0	100-0	
Overall Perceptions of Safety				
Mean	43.54	45.83	42.49	0.0438
Median	50.00	50.00	50.00	
IQR	75-25	75-25	75-25	
Range	100-0	100-0	100-0	
Safety Culture				
mean	57.60	58.07	59.41	0.0332
Median	50.00	50.00	75.00	
IQR	75-25	100-25	100-25	
Range	100-0	100-0	100-0	
Continuous improvement				
mean	60.77	64.20	60.99	0.0332
Median	66.67	66.67	66.67	
IQR	100-33.3	100-33.3	100-33.3	
Range	100-0	100-0	100-0	
Non-punitive				
mean	28.01	33.11	28.68	0.0007
Median	0.00	33.33	0.00	
IQR	33.3-0	66.6-0	66.6-0	
Range	100-0	100-0	100-0	
Communication openness				
mean	46.80	48.31	45.51	0.2537
Median	0.00	33.33	33.33	
IQR	66.6-0	66.6-0	66.6-0	
Rang	100-0	100-0	100-0	
Communication about errors				
mean	53.26	54.71	52.98	0.5719
Median	66.67	66.67	66.67	
IQR	100-0	100-0	100-0	
Range	100-0	100-0	100-0	
Management				
mean	46.29	45.22	45.47	0.7521
Median	33.30	33.33	33.33	
IQR	66.67-0	66.67-0	66.6-0	
Range	100-0	100-0	100-0	
Safety grading				

mean	49.50	47.51	47.92	0.3068
Median	50.00	50.00	50.00	
IQR	75-25	75-25	75-25	
Range	100-0	100-0	100-0	
Staffing				
mean	29.74	28.97	28.13	0.077
Median	25	25	25	
IQR	50-0	50-0	50-0	
Range	100-0	100-0	100-0	
Hospital handovers				
mean	44.03	41.93	43.63	0.3454
Median	50.00	50.00	50.00	
IQR	75-0	75-0	75-0	
Range	100-0	100-0	100-0	

When the mean scores of the items that constitute the measured domains were disaggregated into the intervention and control groups, the following was observed. The mean scores for the intervention group that are illustrated in Table 5.12, indicate that 4/12 items indicate differences between the three time points that are statistically significant ($p < 0.05$). These items are similar to those indicated in the aggregated scores, except for the hospital handovers, which was indicated instead of the safety culture. The rest of the items were found to have differences in their mean scores that were not statistically significant over the three time points.

Table 5.12: Group 1- Patient safety culture- [Intervention group]

Domain	March 2008 (n=875	November 2008(n=463)	November 2009 (n=333)	P-Value
Frequency of event reporting				
Mean	50.48	46.22	47.95	0.2105
Median	33.33	33.33	33.33	
Overall Perceptions of Safety				
Mean	44.00	49.95	44.67	0.0028
Median	50.00	50.00	50.00	
Safety Culture				
mean	49.06	46.49	48.72	0.5849
Median	50.00	50.00	50.00	
Continuous improvement				
mean	61.98	69.47	61.86	0.0003
Median	66.67	66.67	66.67	
Teamwork				0.2631
mean	63.71	67.06	65.17	
median	75.00	75.0	75.00	
Non-punitive				
mean	27.96	35.78	32.23	0.0005

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Median	0.00	33.33	33.33	
Communication openness				
mean	48.27	49.32	47.45	0.7659
Median	33.33	33.33	33.33	
Communication about errors				
mean	56.42	58.00	49.60	0.6024
Median	66.67	66.67	33.33	
Management				
mean	48.84	46.87	48.35	0.6580
Median	66.67	33.33	66.67	
Safety grading				
Mean	49.06	46.49	48.72	0.5849
Median	50.00	50.00	50.00	
Staffing				
mean	30.34	27.86	29.73	0.2382
Median	25.00	25.00	25.00	
Hospital handovers				
mean	43.11	39.04	46.40	0.0168
Median	50.00	25.00	50.00	

The differences in the mean scores for all three point periods in all the measured domains in the control group were found to be statistically insignificant (p>0.05).

Table 5.13: Group 2 - Patient safety culture [Control group]

Domain	March 2008 (n=756	November 2008(n=553)	November 2009 (n=483)	P-Value
Frequency of event reporting				
Mean	46.38	48.16	43.34	0.1903
Median	33.33	33.33	33.33	
Overall Perceptions of Safety				
Mean	43.00	42.54	40.99	0.4952
Median	50.00	50.00	50.00	
Safety Culture				
Mean	50.17	48.33	47.34	0.3633
Median	50.00	50.00	50.00	
Continuous improvement				
Mean	59.44	60.04	60.39	0.8891
Median	66.67	66.67	66.67	
Teamwork				
Mean	62.47	61.12	61.49	0.7885
Median	75.00	75.00	75.00	
Non-punitive				
Mean	28.09	30.98	26.22	0.0723
Median	33.33	33.00	0.00	

Communication openness				
Mean	45.11	47.32	44.17	0.3490
Median	33.33	33.33	33.33	
Communication about errors				
Mean	46.60	52.26	51.48	0.4596
Median	66.67	66.67	66.67	
Management				
Mean	43.43	44.00	43.48	0.9602
Median	33.33	33.33	33.33	
Staffing				
Mean	29.10	29.93	27.02	0.1468
Median	25.00	25.00	25.00	
Safety grading				
Mean	50.17	48.33	47.36	0.4189
Median	50.00	50.00	50.00	
Hospital handovers				
mean	45.24	44.21	41.72	0.2588
Median	50.00	50.00	25.00	

5.4.3 Effects of AMCu on patient satisfaction?

5.4.3.1 Patient Satisfaction Assessment

Table 5.14 displays the profile of admissions to hospital, and its frequency, at the time of the study. The majority (31% in 2009 and 55% in 2010) of the participants that were included in the study were in hospital for illnesses related to the discipline of medicine. Approximately 20% of the participants were admitted for maternity reasons.

Table 5.14: The clinical area of admission to hospital

	2009 (n=1 065)		2010 (n=1 158)	
Admission area	**Frequency**	**Percent (%)**	**Frequency**	**Percent (%)**
Maternity	208	19.53	244	21.07
Medical	331	31.08	631	54.49
Surgical	146	13.71	225	19.43
Other	380	35.68	58	5.01

Figure 5.41 shows the patient evaluations of the waiting time and essential rooms used during their hospital visit. More than 90% of the participants evaluated the essential rooms as good in both years. However, the values for 2010 were higher than those for 2009. This increase in the scores indicates that there an improvement in the evaluations had occurred.

150
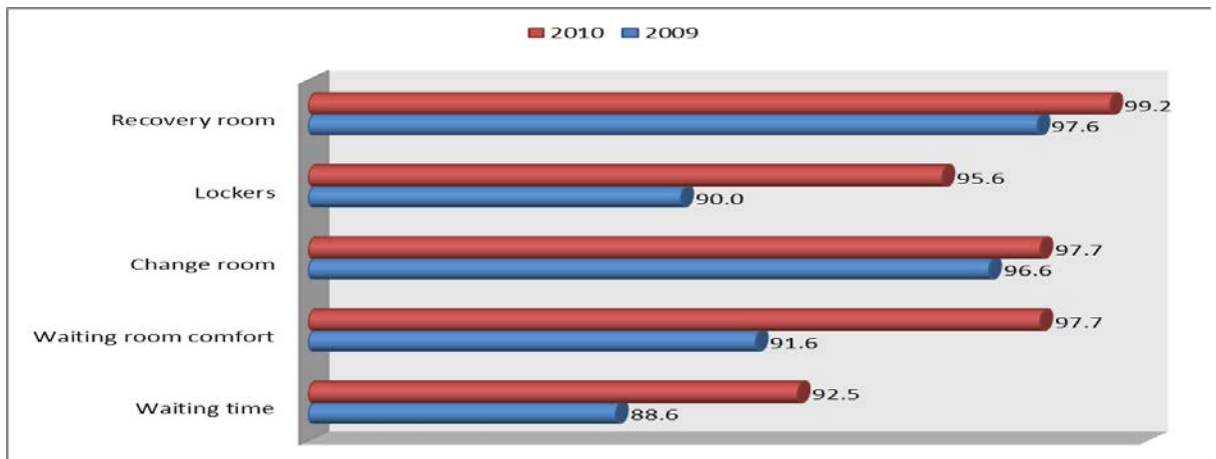
Figure 5.41: Patient's evaluation of waiting times and utility of essential rooms 2009 and 2010

Figure 5.42: Shows the perceptions of patients on staff attitude, information received and length of time between health seeking steps and hospital admission. For all the items displayed in this Figure 2010 values were higher than those for 2009, except for the amount and clarity of information received. For this item there was a decrease in the percentages of positive perception.
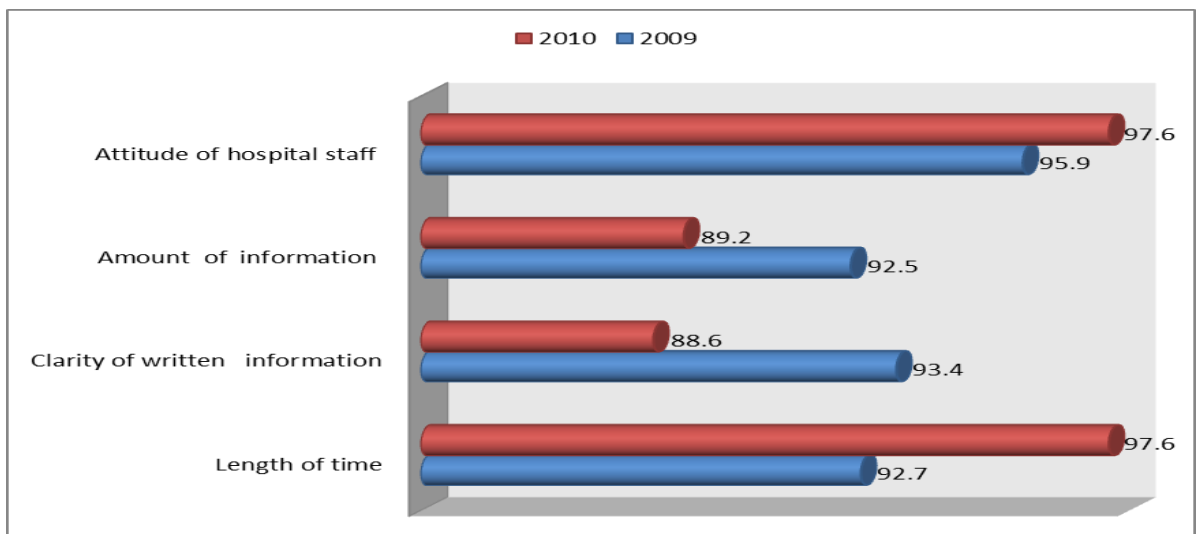
Figure 5.42: Patient's perception of staff attitudes, information received and delays in health attendance

Patients' perceptions of the admission process at the hospital are presented in Figure 5.43. More than 90% of the patients had a positive perception of the admission process for both years. The positive perceptions percentages decreased in year 2010 compared to 2009 for consideration of personal needs and wants (94.5% vs. 90.7%) as well as hospital routine and procedures (95% vs. 90%)

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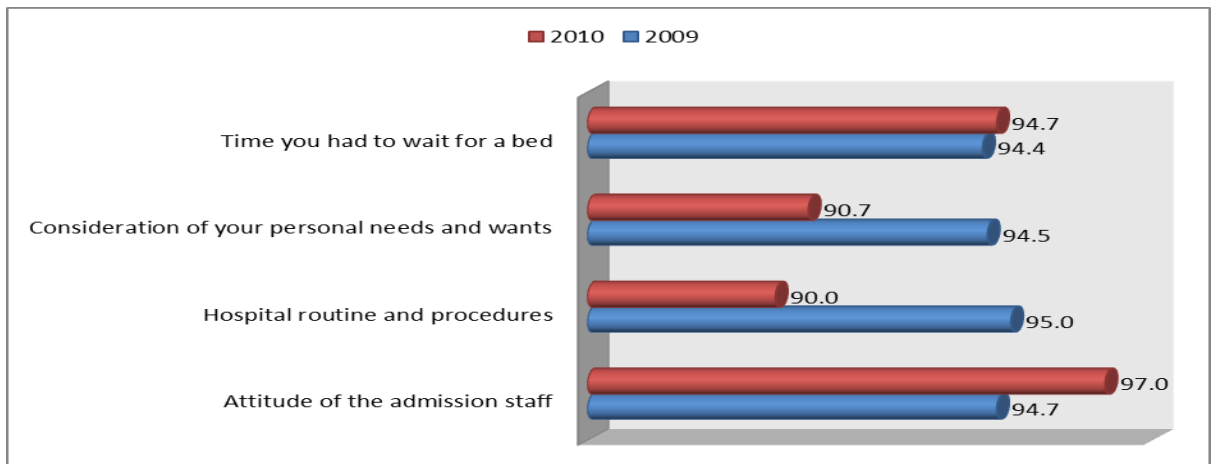
Figure 5.43: The patient's perception of the hospital admission process

Patients' perceptions of the time they spent in hospital are shown in Figure 5.44. There was an increase in the percentage of positive perceptions for all the items reflected, except for "way the nurses explained your treatment you", where there was a decrease in the percentage perception
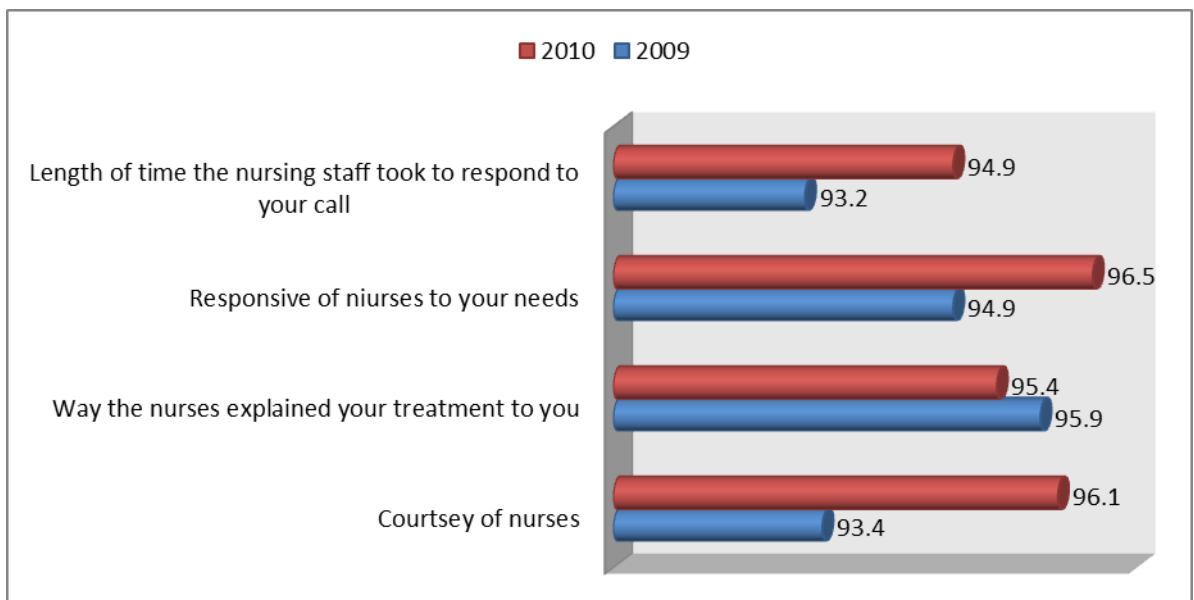
Figure 5.44: Patient's perceptions of nurse's' attitudes during their time in hospital

Patients' perceptions of the doctors during their time in hospital are displayed in Figure 5.45. The proportion of patients with positive perceptions about doctors was at least 99% for both years for all the items assessed.

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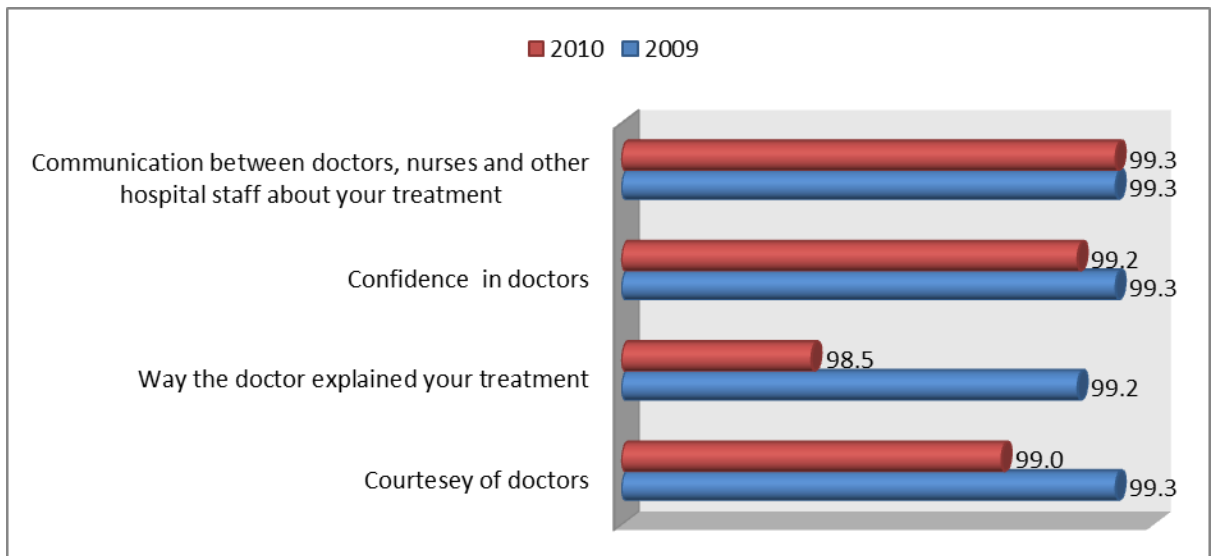
Figure 5.45: The patient's perceptions of doctor's attitudes during their time in hospital

The patient's perceptions of the hospital staff in general are depicted in Figure 5.46. At least 95% of the patients had a positive perception about hospital staff in general for both years.

Figure 5.46: The patient's perceptions of patients of hospital staff in general

The patient's perceptions regarding the attitude of hospital staff are presented in Figure 5.47. All (100%) the patients who participated in the study agreed that possible side effects of medicines were explained well to them for both years. The proportions of patients with positive perceptions on staff attitude were at least 90% for both years. The percentages of patients with positive perceptions decreased in 2010 compared with 2009.

153
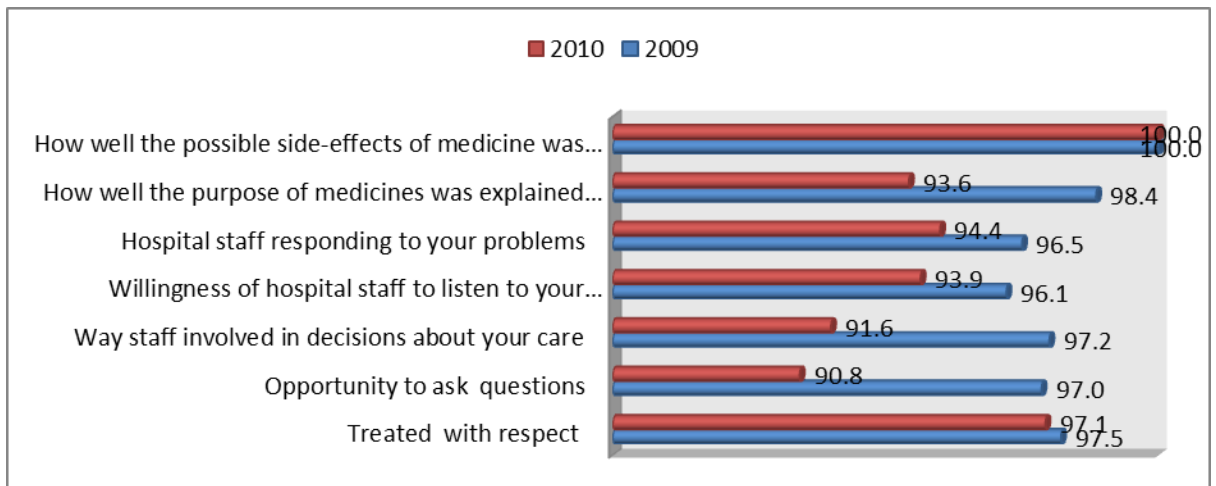
Figure 5.47: The patient's perceptions of hospital staff attitudes

The perceptions regarding the quality of services offered are presented in Figure 5.48. All the proportions of positive perceptions are above 91% for both years except for the quality of food for the year 2010, which had a value of 87.3%.
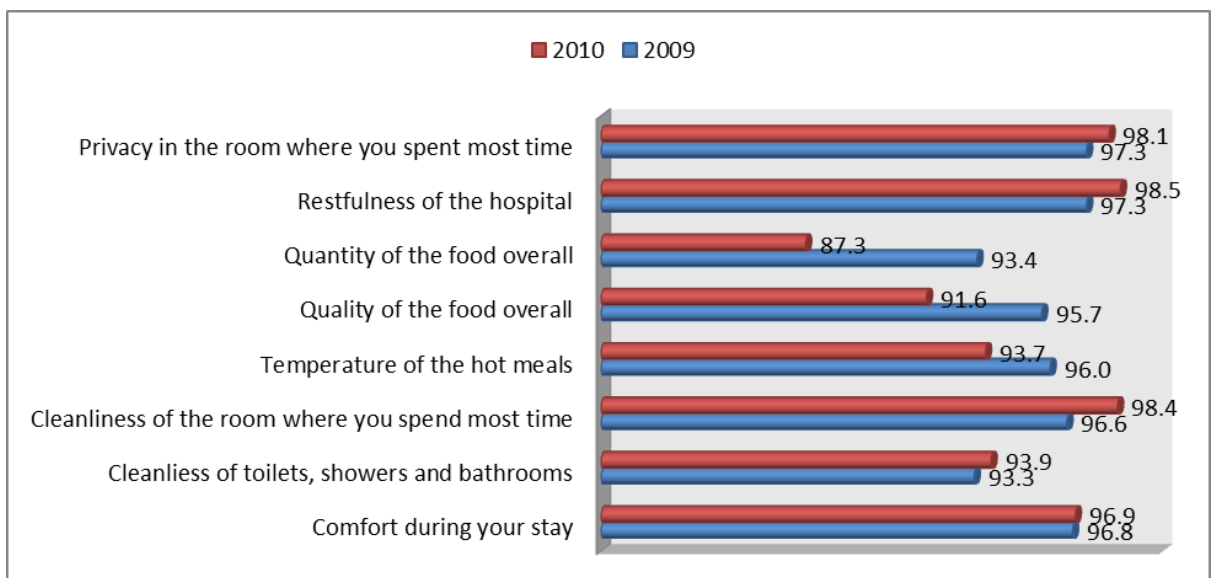
Figure 5.48: The patient's perceptions of the quality of services offered

The perceptions of patients on the activities surrounding their discharge from hospital are shown in Figure 5.49. In general, at least 91% of patients had a positive perception regarding the quality of services for both years except for "the services and care arranged for you by the hospital when you got home" where only three-quarters had a positive perception.

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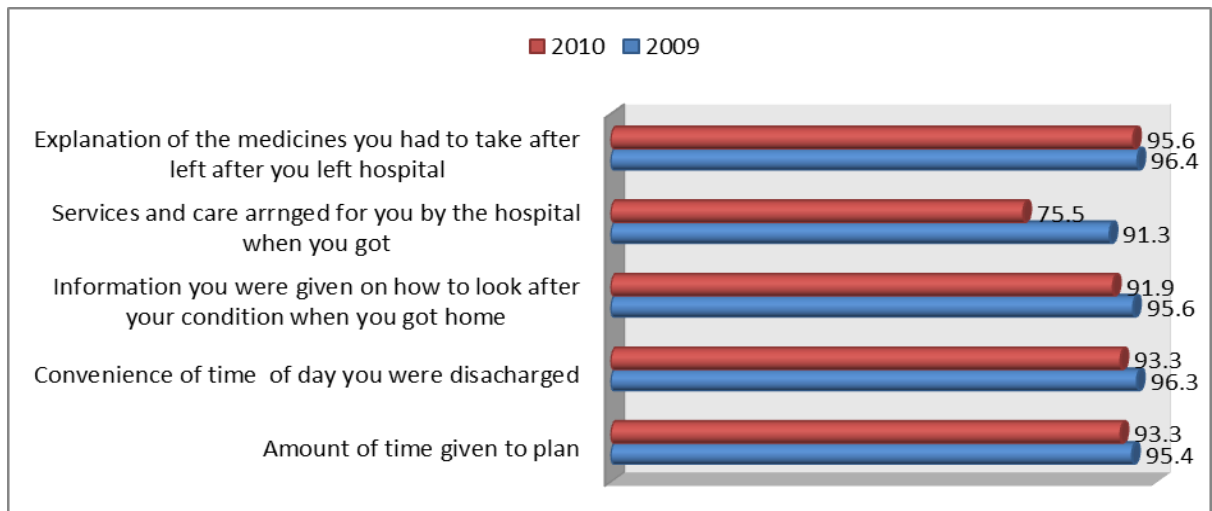
Figure 5.49: The patient's perceptions of the activities surrounding their discharge from hospital

A comparison of the created scores on hospital environment and discharge processes is presented in Table 5.15. Different dimensions were created on the basis of the themes of the questions (See Appendix D). All the reliability coefficients are greater than 0.6. The average of the created dimensions for 2009 and 2010 are compared in Table 5.20. There is no significant difference in average dimensions that measure general information (p=0.9598) and respect (p=0.2561) between 2009 and 2010. However, 50% of the dimensional scores were 100% for both years. The average score of the dimension regarded as measuring the environment (p=0.0259) and discharge (<0.0001) for the year 2010 was significantly lower than for 2009.

Table 5.15: A comparison of the formulated scores on hospital environment and discharge processes

Dimension		Years of the survey		p-value
		2009	**2010**	**p-value**
General information		**(n=1026)**	**(n=1116)**	
	Mean	96.83	96.8	0.9598
	Median	100	100	
	IQR	100-100	100-100	
	Range	100-0	100-0	
Environment		**(n=785)**	**(n=1135)**	
	Mean	96.1	94.8	0.0259
	Median	100	100	
	IQR	100-100	100-100	
	Range	100-0	100-0	
Respect		**(n=960)**	**(n=917)**	
	Mean	98.6	98.22	0.2561
	Median	100	100	
	IQR	100-100	100-100	
	Range	100-42.86	100-28.57	
Discharge		**(n=668)**	**(n=957)**	
	Mean	95.54	90.53	<0.0001
	Median	100	100	
	IQR	100-100	100-80	
	Range	100-0	100-0	

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A comparison of the formulated scores on hospital room factors and staff attitude is presented in Table 5.21. There was a significant (p=0.0001) improvement in the average percentage score pertaining to rooms between 2009 and 2010. The average percentage on staff attitude significantly (p=0.0173) decreased from 94.89 in 2009 to 93.03 in 2010. All the items presented in Table 5.16 had 50% of their scores at 100% in both years.

Table 5.16: Comparison of formulated scores on rooms and staff attitude dimensions

		Years of the survey		
Dimension		**2009**	**2010**	**p-value**
Rooms		**(n=581)**	**(n=336)**	
	Mean	93.08	97.14	0.0001
	Median	100	100	
	IQR	100-100	100-100	
	Range	100-0	100-20	
Information received		**(n=183)**	**(n=324)**	
	Mean	93.58	93.9	0.8366
	Median	100	100	
	IQR	100-100	100-100	
	Range	100-0	100-25	
Staff attitude		**(n=989)**	**(n=1137)**	
	Mean	94.89	93.03	0.0173
	Median	100	100	
	IQR	100-100	100-100	
	Range	100-0	100-0	
Nurses courtesy		**(n=1044)**	**(n=1148)**	
	Mean	94.35	95.80	0.0522
	Median	100	100	
	IQR	100-100	100-100	
	Range	100-0	100-0	
Doctors courtesy		**(n=1009)**	**(n=1105)**	
	Mean	99.28	99.10	0.5539
	Median	100	100	
	IQR	100-100	100-100	
	Range	100-0	100-0	

5.4.4 The effectiveness of AMCu in improving health care quality as measured by COHSASA evaluation scores?

5.4.4.1 COHSASA results [19]

Table 5.17 shows the service elements, their abbreviations as well as the items used to measure each of the four performance areas based on COHSASA standards. There is a comparison of the average scores for the sites in the intervention group on each performance area between the baseline (2007) and the evaluation (2010) period reflected on the same table. Although the average scores for 2010 are higher than those for 2007, these increases were not statistically significant (all p-value>0.05) for all the performance areas except for: nuclear medicine service (p=0.0295); radiology and diagnostic imaging service (p=0.0164); pharmaceutical service (p=0.0116);

medical physics services (p=0.0125); and maintenance service (p=0.0159). These are only 5/35 service elements

Table 5.17: Comparison of 2007 and 2010 Performance Area Indicators in the Intervention group

Performance area	Service Element	Abbreviation	2007	2010	p-value
Management					
	Management & leadership	ML	91.2	93.7	0.2717
	Human resource management	HR	91.6	95.0	0.1195
	Administrative support	AS	92.0	94.8	0.4292
	Access to care	AC	94.3	97.5	0.0917
	Patient and family rights	PFR	89.7	96.4	0.0682
	Management of information	MI	80.8	91.9	0.0890
	Risk management	RM	79.1	84.6	0.1977
	Quality management & improvement	QMI	80.9	88.4	0.0609
	Prevention & control	PR	79.9	90.3	0.0594
Clinical & clinical support					
	Medical care	MC	76.5	85.8	0.0731
	Surgical care	SC	87.5	93.3	0.2837
	Critical care	CC	87.1	92.8	0.4243
	Obstetric care	OMC	87.7	93.9	0.3345
	Pediatric care	PC	82.1	89.9	0.0776
	Operating theatre and anaesthetic service	OTAS	81.0	92.1	0.1609
	Nuclear medicine service	NMS	78.8	91.1	0.0295
	Laboratories service	LS	91.9	98.9	0.4832
	Radiology and diagnostic imaging service	RDIS	84.9	93.7	0.0164
	Pharmaceutical service	PS	86.0	92.5	0.0116
	Outpatient care	OC	68.1	89.9	0.0957
	Sterilizing and disinfecting unit	SDU	76.2	90.6	0.1403
	Resuscitation system	RS	77.2	80.8	0.3946
	Medical physics services	MPS	81.0	91.8	0.0125
	Radiation oncology	RO	87.2	90.2	0.3945
	Medical oncology	MO	74.9	85.6	0.1011
Domestic and Technical					
	Food services	FS	79.9	90.0	0.0685
	Linen management	LM	81.0	87.8	0.3173
	Housekeeping services	HS	73.5	76.2	0.7718
	Maintenance service	MS	80.5	90.2	0.0159
	Medical equipment management	MEM	87.7	92.1	0.2422
Professional Allied Medical Services					
(PAMS)	Physiotherapy service	PS	88.7	93.4	0.1599
	Occupational therapy service	OTS	89.1	90.3	0.8815
	Dietetic service	DS	82.3	94.5	0.2449
	Speech therapy Service	STS	76.6	99.5	0.1955
	Social work service	SS	98.4	92.8	0.5324

Table 5.18 compares the average scores for the sites in the control group on each performance area between the baseline (2007) and the evaluation (2010) period. There was no statistical significant (all p-value>0.05) improvement in all the performance areas, except for medical physics services (p=0.0291).

Table 5.18: Comparison of 2007 and 2010 Performance Area Indicators in the Control group

Performance area	Service Element	Abbreviation	2007	2010	p-value
Management					
	Management & leadership	ML	87.3	88.0	0.8734
	Human resource management	HR	85.2	89.8	0.4754
	Administrative support	AS	88.9	86.7	0.6346
	Access to care	AC	90.4	91.1	0.5203
	Patient and family rights	PFR	83.1	86.3	0.5972
	Management of information	MI	84.4	91.2	0.1919
	Risk management	RM	72.5	78.9	0.3681
	Quality management & improvement	QMI	70.3	79.9	0.1878
	Prevention & control	PR	77.6	84.4	0.2797
Clinical & clinical support					
	Medical care	MC	73.9	71.7	0.6715
	Surgical care	SC	80.3	85.9	0.5608
	Critical care	CC	79.3	83.2	0.8231
	Obstetric/maternity care	OMC	84.4	80.9	0.4346
	Paediatric care	PC	77.3	81.0	0.4461
	Operating theatre and anaesthetic service	OTAS	74.4	82.3	0.2215
	Nuclear medicine service	NMS	83.0	88.1	0.3143
	Laboratories service	LS	84.1	90.0	0.1457
	Radiology and diagnostic imaging service	RDIS	83.3	80.4	0.6957
	Pharmaceutical service	PS	77.6	83.2	0.6918
	Outpatient care	OC	76.8	73.3	0.4382
	Sterilizing and disinfecting unit	SDU	82.6	83.0	0.9222
	Resuscitation system	RS	81.2	88.3	0.2135
	Medical physics services	MPS	69.4	87.3	0.0291
	Radiation oncology	RO	79.4	81.2	0.7687
	Medical oncology	MO	86.5	88.9	0.3490
Domestic and Technical					
	Food services	FS	66.2	47.5	0.0649
	Linen management	LM	78.0	82.5	0.5236
	Housekeeping services	HS	84.8	86.9	0.6931
	Maintenance service	MS	80.2	89.5	0.1528
	Medical equipment management	MEM	91.3	94.6	0.4966
Professional Allied Medical					
(PAM)	Physiotherapy service	PS	94.0	88.5	0.4750
	Occupational therapy service	OTS	89.5	94.3	0.3195

Table 5.19 compares the average composite scores for the sites in the intervention group on each performance area between the baseline (2007) and the evaluation

(2010) period. There was a statistically significant (all p-value<0.05) improvement in all the performance areas except for PAM (p=0.1314).

Table 5.19: Comparison of 2007 and 2010 average composite scores for sites in the intervention group for the performance areas

Performance area	Abbreviation	2007 Average score	2010 Average score	P-value
Management	Mgt	86.7	92.5	0.0001
Clinical & clinical support	CCS	81.5	89.8	<0.0001
Domestic and technical	DT	80.8	88.8	0.0007
PAM	PAM	88.9	92.6	0.1314

Table 5.20 compares the average composite scores for the sites in the control group in each performance area between the baseline (2007) and the evaluation (2010) period. There was no statistically significant (all p-value>0.05) improvement in all the performance areas except for 'management' (p=0.0285).

Table 5.20: Comparison of 2007 and 2010 average composite scores for sites in the control group for the performance areas

Performance area	Abbreviation	2007 Average score	2010 Average score	P-value
Management	Mgt	82.0	86.5	0.0285
Clinical & clinical support	CCS	79.0	79.4	0.8847
Domestic and technical	DT	79.0	84.0	0.0856
PAM	PAM	85.8	91.0	0.0608

Table 5.21 compares the composite average scores for all the sites on each performance area between the baseline (2007) and the evaluation (2010) period. There was a statistically significant (all p-value<0.05) improvement in all the performance areas as measured by the performance indicators. The greatest improvement was in 'management'.

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Table 5.21: Comparison of 2007 and 2010 average composite scores for the Performance areas

Performance area	Abbreviation	2007 Average score	2010 Average score	P-value
Management	Mgt	84.38	89.51	<0.0001
Clinical & clinical support	CCS	80.25	84.79	0.0065
Domestic and technical	DT	79.90	86.40	0.005
PAM	PAM	87.26	91.75	0.0159

Figure 5.50 compares the service elements measuring the performance area 'management'. All the performance indicator scores for each of the service elements improved between 2007 and 2010. These improvements were not statistically significant except for 'management of information' (p=0.028), 'quality management and improvement' (p= 0.043) and 'prevention and control of infection' (p=0.0367). The performance indicator scores for 'access and care' as well as 'administrative support' were above average in the performance indicators in both years.

	ML	HR	AS	AC	PFR	MI	RM	QMI	PR
P-value	0.5431	0.2424	0.9323	0.2102	0.1633	0.028	0.1498	0.043	0.0367
2007	89.3	88.4	90.5	92.5	86.6	82.7	75.8	75.3	78.7
2010	90.9	92.4	90.8	95.3	91.6	91.5	81.7	84.1	87.3
Average 2007	84.4	84.4	84.4	84.4	84.4	84.4	84.4	84.4	84.4
Average2010	89.5	89.5	89.5	89.5	89.5	89.5	89.5	89.5	89.5
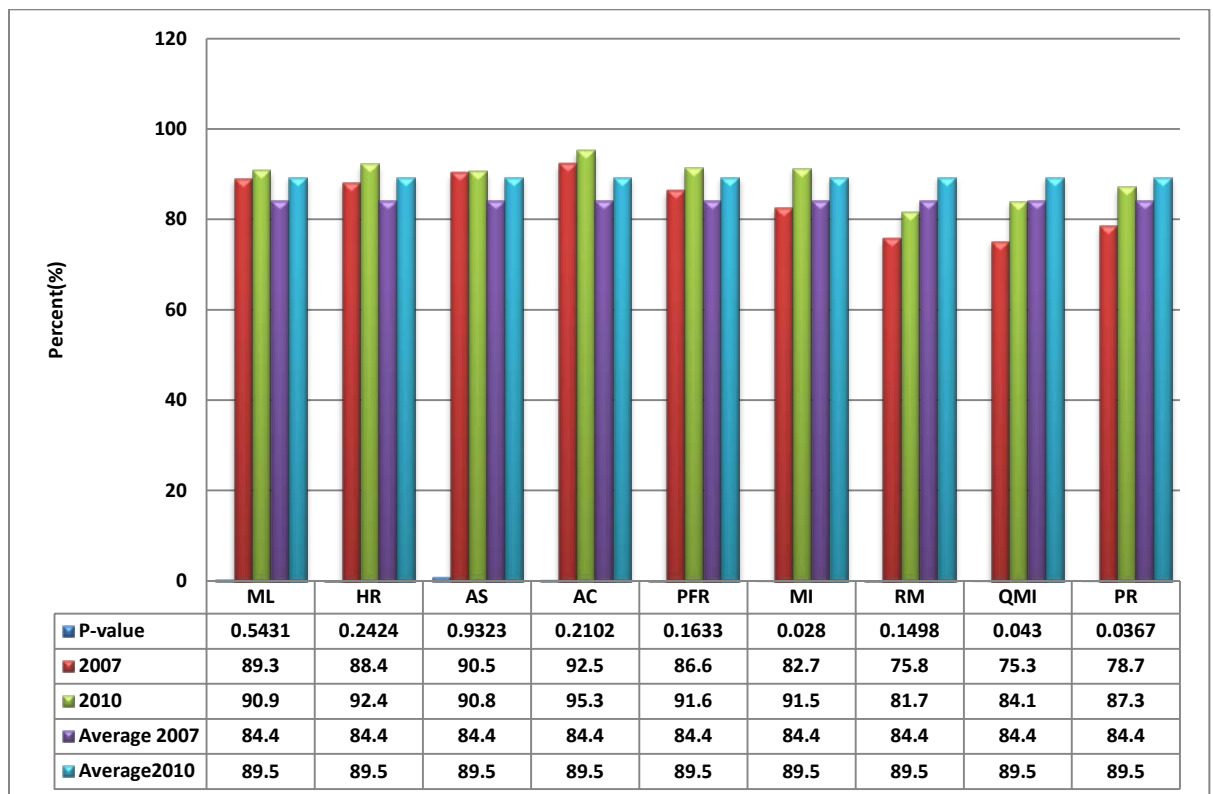
Figure 5.50: Comparison of performance scores of the service elements measuring performance area management

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Figure 5.51 compares the performance scores of the service elements measuring performance area 'clinical and clinical support'. All the performance indicator scores of all the service elements measuring the performance area 'clinical and clinical support' increased from 2007 to 2010, except for resuscitation systems, which decreased from 69.9% to 61.9%. There were statistically significant improvements in the performance indicators for 'operating theatre and anaesthetic service' (p=0.0142), 'radiology and diagnostic imaging service' (p=0.0212) and 'pharmaceutical service' (p=0.0085). Most of the service elements were performing above average in both years.

	MC	SC	CC	OMC	PC	OTAS	LS	RDIS	PS	OC	SDU	RS
■ P-value	0.1802	0.3152	0.4511	0.5467	0.0986	0.0142	0.1494	0.0212	0.0085	0.2273	0.0637	0.2687
■ 2007	84.8	83.7	84.4	83.3	79.1	77.0	86.6	84.0	85.1	77.0	81.7	69.9
■ 2010	90.6	89.4	89.6	85.2	87.0	87.4	99.3	91.0	91.3	86.9	87.6	61.9
■ Average 2007	80.3	80.3	80.3	80.3	80.3	80.3	80.3	80.3	80.3	80.3	80.3	80.3
■ Average2010	84.8	84.8	84.8	84.8	84.8	84.8	84.8	84.8	84.8	84.8	84.8	84.8
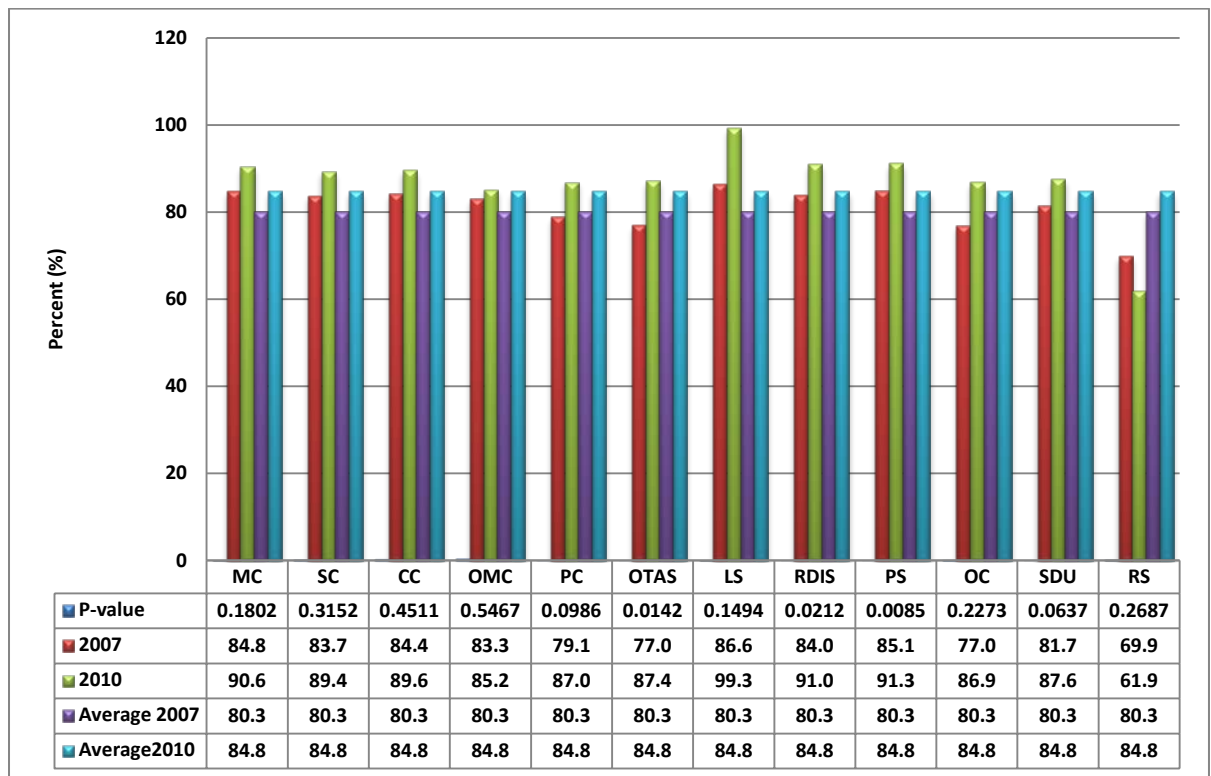
Figure 5.51: A comparison the performance scores of the service elements measuring performance area clinical and clinical support

A comparison of performance indicators of the service elements measuring performance area 'domestic and technical' is shown in Figure 5.52. Although there were improvements in the performance scores of the 'domestic and technical' service elements from 2007 to 2010, the improvements were not statistically significant, except for linen management which improved from 72,2% to 86,5% with a p-value of 0.0051.

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	Food services	Linen Management	House keeping Services	Maintenance service	Medical Equipment Management
■ P-value	0.1285	0.0051	0.1494	0.8729	0.0755
■ 2007	84.2	72.2	79.7	83.6	79.3
■ 2010	89.2	86.5	85.6	84.3	86.4
■ Average 2007	79.9	79.9	79.9	79.9	79.9
■ Average2010	86.4	86.4	86.4	86.4	86.4
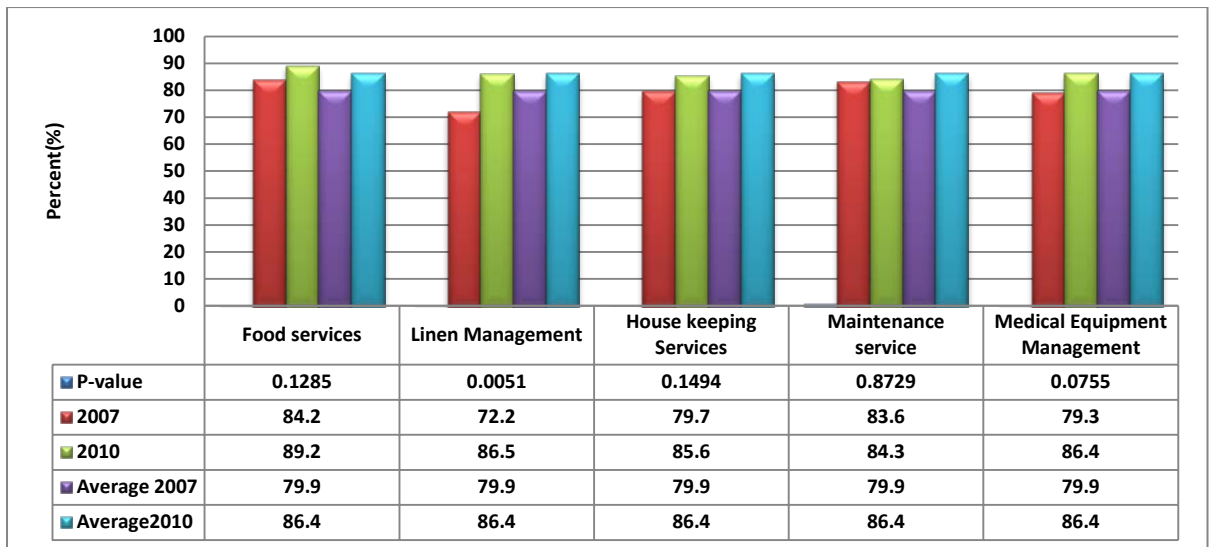
Figure 5.52: Comparison of performance indicators of the service elements measuring performance area domestic and technical

A comparison of the performance indicators for the service elements measuring the performance area 'professional allied medical services' (PAMS) is presented in Figure 5.53. Although all the scores of the performance indicators have improved, these are not statistically significant (all p-values >0.05). 'Dietetic services' and 'social work service' performed above average in both years.

	Physiotherapy service	Occupational Therapy service	Dietetic service	Speech Therapy Service	Social work Service
■ P-value	0.3368	0.0576	0.5747	0.3144	0.7796
■ 2007	86.3	83.9	90.2	85.3	92.5
■ 2010	89.4	91.3	92.6	93.4	93.7
■ Average 2007	87.3	87.3	87.3	87.3	87.3
■ Average2010	91.8	91.8	91.8	91.8	91.8
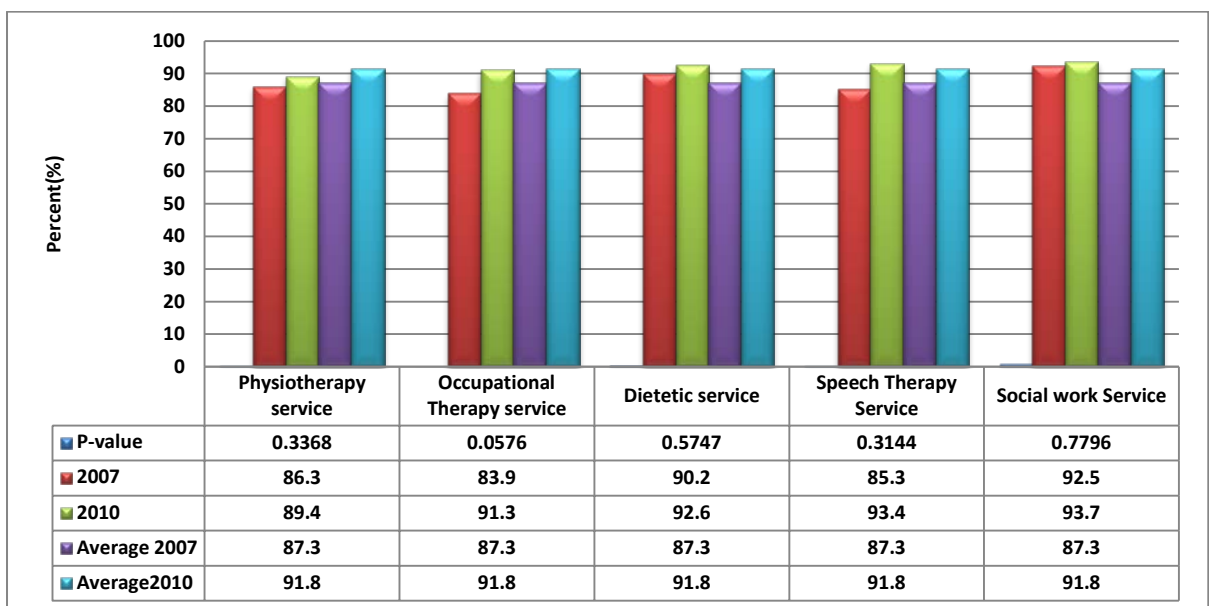
Figure 5.53: A comparison of the performance indicators for the service elements measuring performance area PAMS

The COHSASA evaluation scores indicated some improvement between 2007 and 2010. The more significant improvements were found at the intervention sites. This observation is further discussed in Chapter 6.

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CHAPTER 6: Discussion, Conclusions and Study Limitations

6.1 Introduction

This chapter provides for a detailed discussion of the results, the conclusions and the study limitations. The recommendations of the study are presented in Chapter 8. In order to present the arguments and discussion in a manner that is easy to follow, we have adopted the format of structuring these as answers to the key research questions. It is important to note the presence of the secondary interventions, as reflected in the time line (Figure 4.1) that started before, during and after the actual study period. The value of reflecting on these secondary interventions is to provide a context for the interpretation of the study results.

6.2 Discussion of results

Despite the study limitations that are referred to later on in this chapter, there is some indication that the interventions that were implemented in the study were effective. This has already been demonstrated through the results that were presented in Chapter 5; this effectiveness is the gist of the arguments that are presented in this section. The key research questions that are answered by the key findings of the study are:

6.2.1 Can AIMS [68] be successfully implemented and maintained at an operational level in a developing country setting?

6.2.2 Does AIMS provide insights about the risks associated with reported incidents and adverse events that inform health system managers about sustainable policy and clinical interventions?

6.2.3 Does AMCu affect patient safety outcomes?

    a. Does the implementation of AMCu improve safety climate?

    b. Does the implementation of AMCu improve patient safety culture?

    c. Does the implementation of AMCu improve patient satisfaction?

    d. Does the implementation of AMCu improve the overall quality of health care services as measured by COHSASA [33,34] evaluation scores?

6.2.4 Given the study results set out in Chapter 5, is there a model for hospital patient safety risk reduction that could be developed based on the Free State experience?

6.3 Can AIMS be successfully implemented and maintained at an operational level in a developing country setting?

The answer to this question is a "Yes". The detailed discussions and answer to this question are however addressed in section 6.3.1 to 6.3.5.

6.3.1 The first nine months

In the first nine months there was a significant increase ($p < 0.05$) in the number of reported incidents and adverse events at the intervention sites as compared to the control sites. There were 706 incidents reported at the intervention sites compared to the 3 that were reported at the control sites. This difference remained statistically significant even after the removal of the randomisation bias (see 6.9.1).

The number of reported incidents at the intervention sites using the advanced incident management system (AIMS) was significantly higher than those reported at the control sites, which used the paper-based system.

The differences in the reported incidents between the intervention and control sites in the first nine months are consistently high even when their unit of measurement was converted to 100 000 PDEs. The monthly reporting rates per 100 000 PDEs at the control sites ranged from 0 incidents per 100 000 PDEs to 2 incidents per 100 000 PDEs during the first nine months. However, the reporting rates per 100 000 PDEs at the intervention sites remained high, even after the conversion. This reporting rate ranged from 95 incidents per 100 000 PDEs in January 2008 to 172 incidents per 100 000 PDEs in July 2008.

This increase in the reporting of incidents is possibly due to the introduction of a more user-friendly reporting system, as well as the introduction of a non-punitive, developmental approach to incident reporting. The secondary interventions that were implemented in the Free State hospitals in preparation for the implementation of the computerised incident reporting system are also believed to be responsible for the increased reporting of incidents in that first nine months. This increased reporting was however, only observed in the intervention sites because the control sites only had the non-user friendly paper-based system and not AIMS. This increased reporting of incidents and adverse events therefore clearly demonstrates the superiority of AIMS compared to the paper-based system with respect to encouraging the reporting of incidents.

The increase in the average number of reported incidents due to the implementation of a computerised incident reporting system is also confirmed by Nakajima et al [190]. who conducted a similar study in Japan. This increased reporting of incidents was ascribed by these authors to the ease and convenience of reporting as well as the removal of the psychological resistance to reporting. This increase in the number of reported incidents was regarded as an important step in the implementation of a sustainable patient safety programme in a hospital setting.

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Several studies [186,196] have indicated that the reporting of incidents does not come naturally to all and that certain professional groups, especially physicians, find the reporting even more difficult than others. Fear of litigation, that reports may be used for punitive purposes and a deep-seated culture of autonomy, collegiality and self-regulation have been identified as some of the key barriers to incident reporting by professionals, especially medical professionals [237,238]

This increase in reported incidents is line with the expectations prior to the implementation of the study. There were expectations that the reported incidents would initially increase as a result of the more favourable reporting environment and the implementation of the computerised reporting system.

Hutchinson et al [239] also report a steady increase in the number of reported incidents in UK hospitals following the introduction of an electronic reporting system, and they were able to report that there was a positive correlation between these reporting rates and the development of a positive safety culture.

6.3.2: Beyond the first nine months

The second part of this key research question interrogates whether this implementation of AIMS in a developing country setting can be sustained or not. In response to this, we argue that with the evidence that has already been presented in Chapter 5, this incident reporting system was successfully implemented during the study period, and was maintained beyond that point.

The AIMS incident reporting system, which was developed by the Australian Patient Safety Foundation, has been successfully implemented in Australia. There are also various studies that have demonstrated the usefulness of AIMS in improving patient safety in different settings within the health care environment [163,194,240]. The question as to whether AIMS can be successfully implemented as part of routine operations in a developing country environment such as South Africa is therefore an important and relevant one.

There is very little recorded evidence of the implementation of an incident reporting system in a developing country, such as South Africa. The main deterrent for the implementation of any medical error detection system, whether it is medical record reviews, direct observation or incident recording system, is probably their high cost. Milch et al [241], however, argue that the incident reporting system may actually be the best system to implement in a resource-constrained developing country setting, given the high costs attached to direct observation and medical record review methodologies for medical error detection.

The AIMS reporting system that is an essential part of AMCu was maintained in the Free State Province beyond the first nine months and for the entire 3-year period under study. This system was implemented in January 2008 at the beginning of the project after a training and development phase from September 2007, and has been in operation as part of the routine to date. In other words, AIMS was sustained beyond the three 9-month cycles that are part of the study.

In addition to the 709 incidents reported in the first 9 months of the study, an additional 2 889 incidents were reported during the rest of the last three 9-month periods in portions of 996, 976 and 917 respectively. The magnitude of the reported incidents in the last three 9-month periods also appears to indicate a levelling out.

Apart from the first 9 months, where the average number of reported incidents from all study sites was about 78, these remained constant between 102 and 110 for the rest of the three 9-month periods. This observation also seems to support the steadying of the reported incidents that was set out above. This steadying of the monthly average of reported incidents is another clear indication that AIMS was successfully implemented and operationalised in the Free State Department of Health on a sustainable basis during the period under study.

The number of reported incidents in both the intervention and control sites, measured in four 9-month intervals, indicates month-to month-consistency except for the first 9 months (Table 5.2.)

The proportion of the incidents reported for the last three 9-month periods is also constant between 25.5 and 27.7%, as opposed to the lower 19.7% of the first 9 months. This finding and the above two findings that indicate an initial increase in the total and average monthly reported incidents in the first 9 months, followed by a levelling out in the last three 9-month periods; confirm that the main differences between the intervention and control sites with respect to the reported incidents is confined to mainly the first 9 months. In the last three 9-month periods, the differences in the reported incidents become less pronounced.

The reported incidents per 100 000 PDEs per month as illustrated in Fig.5.3 also demonstrates seasonality with troughs in December and peaks around November each year. It should be noted that the larger regional and tertiary teaching hospitals were the main contributors to the reporting of incidents and adverse events. Strong anecdotal evidence indicates that the peaks in November across the study period are somewhat related to the examinations for both under- and postgraduate studies that occur at this time of the year in these hospitals. It is suggested that during these examinations, the clinical leadership and majority of the clinical personnel focus more on the academic programmes at the expense of service provision. This is characterised by theatre lists being restricted to only emergencies, patients being kept longer in the wards because they have been selected as examination cases and decreased clinical personnel availability. This relationship will, however, need to be further explored and researched in order to confirm these alleged negative impacts.

The trough that has been noted in December each year of the study also happens at the time of the year when most of the clinical personnel take leave for their annual holiday after examinations. Patients that do not need urgent and intensive medical attention are often discharged to be with their families at this time of the year. This accounts for the low clinical activities and the low number of reported incidents and adverse events at this time of the year. Anecdotal evidence again indicates that there

is a relationship between this period of reduced patient activity in hospitals with this trough.

The total reported incidents per 100 000 PDE per month beyond the first nine months remains consistently high with a range between 45 and 82 at both intervention and control sites. This is an indication of the sustainability of the incident reporting system in a developing country setting.

To date, the Free State Department of Health still maintains incident reporting through the computerised system that was implemented in January 2008. This indicates that implementation of the advanced incident management system in 24 Free State public hospitals is a success, since there is a sustained increase in the number of incidents reported compared to the days of the paper-based system.

6.3.3 Personnel perceptions of AIMS

In an additional effort to determine whether AIMS had been successfully implemented in the study groups or not, we conducted a survey that reported on the perceptions of the users on the usefulness and effectiveness of AIMS as an incident reporting system. The results of the survey were presented in Chapter 5, and indicate the following:

- Seventy-seven percent of all respondents were familiar with AIMS;
- Seventy percent of respondents would recommend AIMS to other hospitals and other provinces;
- There was a 62% overall approval rating for AIMS; and
- Concerns exist about the availability of support for AIMS reporting and poor feedback, as indicated by scores of 54% and 48% respectively.

When AIMS was compared to the paper-based reporting system, the following was reported:

- Fifty-two percent of respondents believed that AIMS gives better value for money; as opposed to 13% who did not
- Seventy-one percent of respondents believed that AIMS was more user friendly; compared to 15% who did not
- Eighty-six percent of respondents believed that AIMS was more effective in reporting incidents and adverse events, compared to 14% who did not.

These findings indicate an overall positive set of attitudes and beliefs regarding the usefulness and effectiveness of AIMS as an incident- and adverse-event reporting system. There were, however, serious concerns that were raised with respect to the managerial support for AIMS reporting and the feedback that was provided to the reporters. These two factors were identified by Firth-Cozens [242] as very important in ensuring the development of a learning organisation through teamwork. In addition, Benn et al [243] have described managerial feedback as essential for learning, awareness and for team motivation towards the improvement of patient safety and quality health care. It is, therefore, very important that the Free State Department of

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Health corrects these shortfalls speedily in order to improve patient safety. In Chapter 8, specific recommendations are made to the Free State department of Health, in order to address these shortfalls that have been identified.

6.3.4 Comparison between AIMS and the paper-based system

The quantitative comparison between the reported incidents at the control sites and at the intervention sites was presented with the results in Chapter 5. The superiority of the electronic reporting system over a paper-based system in terms of increased reporting rates is also reported by Tuttle et al [189], who conducted a study similar to this one, but at a single institution over time. It is, however, important to examine some of the qualitative advantages that AIMS has over the paper-based system in order to provide a comprehensive analysis of the two reporting systems.

A brief comparison between the paper-based system and AIMS, which is essentially the data capturing tool for the AMCu intervention, reveals certain key differences as captured in Table 6.1, below.

Firstly, the paper-based system was designed with the overall aim of determining whether the reported incident was due to negligence or not. This determination would then be followed by the appropriate disciplinary action. The advanced incident management system, on the other hand, seeks to understand the underlying human and system-related contributory factors to the incident.

Secondly, it is also evident that the incident information required for the paper-based system is focused on identifying all the parties involved for possible discipline, whereas AIMS is more focused on the clinical details and associated factors in order to determine the contribution of both human and system-related factors to the reported incident.

Thirdly, investigations in the paper-based system era were mandatory, irrespective of the severity of the incident and the approach was to determine misconduct and file the appropriate charges. AIMS, on the other hand, places more emphasis on root cause analysis and enables the investigation of the more severe as well as the more frequent minor incidents in order to be cost effective.

Fourthly, the communication according to the paper-based system was directed to internal stakeholders such as the managers, committees, and the CEO. The communication appears to have been based on compliance with reporting procedures rather than addressing the negative impacts of incidents. AIMS on the other hand advocates for communication with all key stakeholders, including the patients and their families.

Finally the overall accountability and fate of each incident in the paper-based system lies with the hospital CEO. This person decides whether an incident finally gets reported and communicated to all or not. The computerised call-centre-based system gives this opportunity to any person and ensures that all incidents can be anonymously reported.

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According to the WHO [9], the core principles for incident reporting systems are:

- Reporting systems must enhance patient safety through learning from health system failures.
- Reporting must be safe. Individuals who report incidents must not be harmed in any manner or form.
- Reporting is only useful if it leads to a constructive response guided by an intention to learn from the mistake.
- There has to be meaningful analysis of the data collected and dissemination of the lessons learned.

It seems that the reporting system that comes closer to the WHO's core principles is AIMS. The capabilities of the two systems are compared in Table 6.1.

Table 6.1: A comparison of the capabilities of AIMS and the paper-based reporting system

	Paper Based Reporting System	Advanced Incident Management System
Incident Information	Names and employment number of involved personnel	Clinical details; associated and contributory factors, service area and investigation outcome
Investigation Purpose	Mandatory, misconduct and disciplinary	Root cause analysis; Identify more severe incidents on time and correction of system status.
Management Process	CEO final accountability	HOD and MEC accountable
Communication	Internally focused	Covers all stakeholders including family
Overall aim	Determine negligence	Understand underlying cause and implement system changes and required policies

6.3.5 Conclusion

In conclusion, the arguments that have been presented above clearly demonstrate that AIMS **was** successfully implemented in the Free State, as demonstrated by the fact that incident reporting was higher at the intervention sites as compared to the control sites in the first nine months. There was also a clear demonstration of the continued and sustained reporting of incidents beyond the first nine months up to 36 months. This reporting through an incident reporting system was demonstrated to be superior to the paper-based system and this was confirmed by the perceptions of personnel. The study has demonstrated a very strong association although it cannot be confirmed as causal between the implementation of AIMS and the increased reporting of incidents at the intervention sites during the first 9 months of the study.

Apart from perceptions, opinions and attitudes of personnel regarding the usefulness of AIMS, there is additional information to be considered in assessing the added value of the implementation of AIMS in the Free State province.

Firstly, the province invested a total of R10,2 m in the five years between 2007 and 2011 on the implementation of AIMS; this translates to about R2,04m per annum. This expenditure includes training, feedback, motivational workshops and licence fees. During the process 267 master trainers were trained and 45 individuals were licensed. The improvements that are measured in terms of patient safety and overall quality of health as well as lives saved as a result of these efforts have to be compared to the annual R2m overall costs or investment made on AIMS and it is the author's considered view that these benefits outweigh the costs by far.

Secondly, considering the fact that, according to a local report [244], Gauteng Province, South Africa, is likely to run into serious budgetary trouble following the increasing number and amounts of the medico-legal claims against it based on clinical adverse events. This budget crisis follows reports that in the first three months of 2012, the province had already settled three medico-legal claims amounting to R27.5m due to adverse events. The South African Minister of Health Dr A. Motsoaledi was, in fact, quoted [245] as indicating that another province Kwa-Zulu Natal had outstanding medico-legal claims amounting to R600m in 2011. These unnecessary and unaffordable costs clearly indicate that some drastic action needs to be taken to stop further leaks of health resources and re-channel these to other key priorities.

Finally, the larger but difficult-to-measure benefits to the health system and the economy in general is the amount of money saved as a result of reduced average length of stay, reduced re-admissions, reduced disability, rehabilitation and lives saved. These items mentioned are perhaps the biggest incentive for investing in a reporting system with the intention of improving patient safety and overall quality of health care services.

6.4. Does AIMS provide insights about the risks associated with reported incidents and adverse events that inform health system managers about sustainable policy and clinical interventions?

The short answer to this question is a "Yes". The detailed discussions, arguments and conclusions are presented in sections below between 6.4.1 to 6.4.6

The usefulness of an incident reporting system lies in the wealth of information that it collects about the circumstances surrounding the incidents. This ability to provide useful information however needs to be supported by the capacity to analyse and investigate the incidents in order to determine their root causes. It is only when the root causes have been identified that the appropriate interventions can be put in place to reduce or prevent similar incidents from occurring.

This approach is strictly applicable in an ideal world where there is sufficient time and other resources to apply the approach in a systematic and rigorous manner. In the real

world, we sometimes need to provide quick interventions even before each incident has been subjected to a thorough root cause analysis. We often lack the resources to subject each incident to a root analysis process and, therefore, often prioritise the most severe and extreme incidents in terms of harm and risk assessment.

At a practical level it becomes crucial, therefore, that – as incidents are reported – the key stakeholders are able to get some sense of the risk elements that are associated with these reported incidents and are able to provide quick but logical approaches to formulate the necessary interventions. It is being argued here that the manner in which AIMS collects, processes and feeds back to the institutions enables the health system managers to develop and implement appropriate interventions at a policy level or a clinical level.

The results that are presented in Chapter 5 indicate that there are specific characteristics of the reported incidents that were identified in the study, which are useful in the development and implementation of effective and sustainable interventions. In Chapter 4, we discussed the adopted approach of classifying the reported incidents into the following broad categories:

1. Impact
2. Type
3. Domain
4. Cause
5. Intervention

In order to demonstrate the effectiveness of AMCu in providing interventional insights the following specific categories of incident characteristics were isolated for the study after extensive discussions with key managers in the Free State Department of Health:

- Characteristics of the type of reported incidents
- Characteristics of reported incidents based on the setting
- Characteristics of reported incidents and their associated factors
- Characteristics of reported system incidents
- Characteristics of reported incidents by type and severity
- Seasonal character of reported incidents
- Response of reported incidents to cost-containment

These identified characteristics provide us with useful information that if acted upon would reduce or minimise the risks of the user of health care services from being exposed to a clinical incident or adverse event. An example of this would be for instance the characteristic of reported incidents by setting. A careful user of health care services would if given a choice between being treated as an out or in-patient, choose the former. This choice would ensure that they have as little contact as possible with the wards or treatment areas in the hospital and thereby reducing their chances of being involved in an incident or adverse event.

These characteristics are discussed in detail in the following sections from 6.4.1 to 6.4.6

6.4.1 Characteristics of the type of reported incidents

The majority of reported incidents during the period under study were classified as adverse events (57%), followed by hazards (36%) and then by near-misses (3%). At the heart of any credible reporting system is its ability to provide information that will provide learning opportunities for others in order to prevent future incidents from occurring. The ability of AIMS to capture actual adverse events means that the organisation is able to get additional information about the nature and causes of these reported incidents, which can be shared by all. The learning that occurs from adverse events, however, comes at a cost, as harm has already occurred by then. The learning opportunities that emanate from hazards and near misses are not directly associated with harm. In reality this means that for the health services users, if an incident occurs in a Free State hospital there was a high (57%) probability that it would be an adverse event, where the patient suffers harm.

In the USA, Barach et al [193] are convinced after reviewing the near-miss reporting systems in aviation, nuclear and other industries that there is more value added to patient safety by focusing on near misses compared to adverse events. These authors recommend that health systems should adopt this approach owing to the improved safety performances seen in these industries.

The number of adverse events reported in the last three 9-month period progressively increased, whilst the hazards and near misses decreased. This pattern seems to indicate that AIMS does not appear to lose its ability to encourage the reporting of adverse event over time; instead the opposite appears to be true for hazards and near-misses. This observation may also be an indication that with time, when hazards and near misses are presented and the information is shared among personnel; near misses tend to occur less frequently.

6.4.2 Characteristics of reported incidents based on the setting

More than half (58%) of the reported incidents were clinical in nature as opposed to the non-clinical incidents. This important finding confirms that the reported incidents occurred in the course of rendering clinical care to patients, which is the core function of health systems. In other words, incidents and adverse events occurred as a result of the interaction between patients and the health care system. This link between incidents and health care provision, therefore already indicates that any attempt to improve patient safety that does not incorporate clinical solutions is bound to be unsuccessful and unsustainable. The high numbers of clinically related reported incidents also indicates that AIMS is effective in detecting incidents of unsafe care and provides us with valuable information that can be used to prevent these incidents from occurring.

The fact that 42% of reported incidents were non-clinical in origin is a very important finding that informs us that any interventions aimed at improving patient safety that ignore the non-clinical contributory factors is bound to fail. These non-clinical sources

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of unsafe care include organisational leadership, vision, culture, policies, budgets, and organisational structures.

6.4.3 Characteristics of reported incidents and their associated factors

The identified factors closely associated with the reported incidents are predominantly system errors (49%), followed by duty of care incidents (DOCI) (33%) and lastly human error (18%). This proportion of factors associated with reported incidents appears to be in line with the understanding that a great majority of adverse events are a result of system defects rather than human error. An analysis of 2000 incidents reported through AIMS in Australia [246] indicates that between 70% and 80% of system errors involved humans. The overall contribution of humans to the causality of incidents was, however, small and system and process shortfalls were the primary cause of up to 85% of these incidents. This observation is also supported by Cohen [192], who asserts that the analysis of serious incidents reveals that the majority of causes are multiple system failures and that these involve many individuals.

This understanding of the role of humans in the causality of incidents encourages the correction of health systems in order to ensure that further adverse events are prevented. Reinertsen [95] argues that while the individual professional is the final pathway by which medical error occurs, errors are inbuilt into our systems and are waiting to be made by the next professional.

The pattern that is observed for the proportion of the system-, duty of care- and human factors associated with reported incidents in the four 9-month periods indicates that there is a steady decline in the system- and duty of care incidents and an increase in the human factors in reported incidents. This finding may be an indication that as more incidents were reported and found to be systems- or duty-of-care related, effective interventions were implemented to address these.

6.4.3.1 Characteristics of reported system incidents

A further examination of the system errors associated with the reported incidents indicates that the most predominant elements are personnel, management, equipment and facility challenges. This analytical breakdown indicates where management and leadership of the organisation have to focus in order to reduce these system-related adverse events and incidents. This observation immediately indicates the considerable effort needed to motivate and train personnel in order that the necessary skills and competence are developed for dealing with incidents and adverse events.

These reported incidents provide a clear link between the system shortfall and the surrounding circumstances that finally lead to the occurrence of the incidents. This link therefore provides clues about how the correction of these system defects will lead to the prevention of future adverse events.

The observed trends in the factors associated with reported incidents reveal that personnel and management issues increased over the final three 9-month periods,

whereas there were decreases in challenges that were related to equipment, facilities and transportation. This finding could be an indication that the transportation- and facility-based challenges were being addressed and that there was improvement in these areas; those reported incidents that were due to personnel and leadership at institutional level remained a challenge.

6.4.4 Characteristics of reported incidents by type and severity

The key findings regarding the reported incidents that are classified according to the Severity Assessment Coding are:

- The proportions of reported incidents classified as SAC are: SAC 3 (56%); SAC 4 (18.8%); SAC 2 (15.6%); SAC 1 (9.4%);
- More than 50% of the reported incidents in the four 9-month periods are SAC 3
- SAC 3 and SAC 4 reported incidents decreased over the four 9-month periods;
- The majority of reported SAC 1 and SAC 2 incidents are adverse events; duty of care incidents and maternity and paediatric in terms of clinical origin; and
- The majority of reported SAC 1 and SAC 2 incidents that are due to system shortfalls are caused by organisational-, management- and transport-related problems. how best to present this

According to these findings, most of the reported incidents are not necessarily the most severe and extreme incidents but are the minor to moderate incidents. This therefore indicates that even those incidents that are not life-threatening are reported and these incidents actually constitute the majority. It is an indication that personnel are comfortable reporting all incidents and are not just reporting those incidents that are impossible to hide because of their severity. This reporting pattern signals a major paradigm shift from the pre-research era, where only those incidents where a patient was disabled, dead or there was a major lawsuit, complaint or a negative newspaper article were reported.

The majority of reported incidents throughout the four 9-month periods were the moderate SAC 3 incidents, while the more severe to extreme incidents were in the minority. This finding is supported by other studies that have investigated the nature and number of reported incidents in different medical settings [247,248].

The decrease in the number of reported moderate to minor incidents over the four 9-month periods as illustrated in Fig 5.16 is contrary to our expectations. Our expectations were that as more and more personnel felt comfortable in the reporting of near misses and minor incidents, the reported SAC 3 and SAC 4 would increase. The explanation for this observed phenomenon is at this stage not clear and needs further investigation. A possible explanation for this finding is that this decrease in the number of reported SAC 3 and SAC 4 may be an indication that these are occurring less and less as a result of the successful implementation of AMCu interventions.

Another finding of note is a trend that indicates an increase in the number of reported SAC 1 and SAC 2 with time during the research period, as illustrated in Figures 5.16, 5.22 and 5.23. The source of discomfort emanates from the expectation that as

incidents are reported and interventions are put in place to address the most severe and extreme of these, they would occur less and therefore the reported severe and extreme incidents would decrease. The finding of an increasing number of reported severe and extreme incidents may suggest that these severe and extreme incidents are on the rise in terms of occurrence, despite the interventions that have been put in place to prevent and to reduce them.

A key part in the explanation of this apparently conflicting observed phenomenon lies in the fact that not all incidents that occur are reported. It is these unreported incidents, whose nature and composition is unknown that provides this skewed picture that is based on the reported incidents. This understanding is very important in the interpretation of the nature and number of reported incidents as captured by the reporting system compared to the number of actual incidents that have occurred. These increasing reported SAC 1 and SAC 2 incidents may be more a reflection of increased reporting due to a convenient system and an environment conducive to reporting rather than an actual increase in the occurrence of these incidents.

Vincent [249] warns that making sense of reported incidents requires expertise, a good understanding of the task, context and the contributory factors. Vincent [249] further suggests that for reporting systems to deliver results, there needs to be an additional investment in developing a capacity for incident analysis.

The most logical incidents to target for reduction in order to make the biggest impact on overall patient safety are the severe to extreme SAC 1 and SAC 2 incidents. This simply means that the number of patients that die or suffer permanent disability as a result of presenting themselves for medical treatment would be reduced. It is also clear from the findings that in reducing these incidents, one would also be reducing a great number of adverse events and duty of care incidents.

What is also very important in the South African context, where the maternal mortality and infant mortality rates are high, is that the majority of SAC 1 and SAC 2 incidents also happen to be maternity- and paediatrics related. Any effort, therefore, that is aimed at reducing SAC 1 and SAC 2 reported incidents will simultaneously reduce maternal, infant and under-5 mortality. This will not just improve patient safety and overall quality of health care services in the Free State, but will also improve the overall health outcomes of the province and the country and support the achievement of the MDGs.

It is these insights that enable managers in the health system to develop effective interventions that will improve health outcomes. In other words, by focusing on the root causes of SAC 1 and SAC 2 reported incidents the probability that effective interventions will be developed in order to improve patient safety, overall quality of health care services and health outcomes are high.

Finally, according to these findings, the majority of SAC 1 and SAC 2 incidents have a systemic element to them and that these are mainly organisational-, management- and transport-related challenges. Strong anecdotal evidence exists that when the Free

State Department of Health bought additional ambulances and dedicated some of these as obstetric ambulances and deployed these in line with the district referral system maternal mortality began to decline in the Free State. The appointment of key leaders and managers at key hospitals whose responsibility also includes patient safety improvement is also seen as one of the key interventions aimed at improving patient safety and overall quality of health care services. This is a clear illustration that the identified characteristics of reported incidents provides key insights into their root causes which then informs the effective interventions required to improve patient safety.

The classification of incidents reported through AIMS by type, associated factors and severity provided better insights as to their root causes and provided a basis for the development of informed interventions. Firstly, the ability of AIMS and its processes to classify the reported incidents by type and associated factors enables health system managers to do the in-depth analysis that is required for developing interventions that can improve the safety of patient and overall quality of health care services. Secondly, the superior numbers of reported incidents makes this analysis more robust than what could be achieved with the less than modest number of incidents reported through the paper-based system.

It has been successfully argued in the preceding section that the support that is provided by an incident reporting system such as AIMS to the process of classification of reported incidents and the identification of the factors associated with risk enables health system managers to develop effective and sustainable clinical and policy interventions. This is made possible by the insights that are gained through the processing of the data that is sourced through the incident reporting system.

6.4.5 Seasonal character of reported incidents

The pattern of reported incidents indicates that there were consistent peaks in the months of November and troughs in the months of December throughout the study period. The November peaks are thought to be related to the examinations period for both the under- and postgraduate programmes. During the examinations there is greater emphasis and more time spent attending to the academic demands as opposed to clinical service provision. This invariably results in fewer patients being discharged, decreased theatre procedures and therefore increased length of stay for patients.

The decrease or trough that is experienced in December is also thought to be related to the seasonal holiday reduction of activities in hospitals. During this period many patients are discharged; there are fewer theatre cases and less staff is available for clinical care. The overall clinical service delivery at this period is reduced to the barest minimum.

In the USA, several authors [250,251] have described an increase in patient mortality and clinical inefficiency in the July and August months, due to the intake of new inexperienced medical and surgical professionals at this time of the year. In South

Africa, this intake of new professionals occurs between November and January. It will therefore be important to further research this relationship to determine if the intake of inexperienced professionals is one of the factors responsible for the seasonal variation.

The importance of the identification of this seasonal risk is aimed more at alerting the leadership and management of these affected hospitals about this observation so that they can develop and implement the necessary corrective measures.

6.4.6 Response of reported incidents to cost-containment

Nieva et al [252] have identified cost containment as one of those factors that can negatively influence the culture of patient safety and, therefore, the patterns and numbers of reported incidents. Several authors [246,253] clearly warn that while it is important to support efforts aimed at reducing wastage in order to add value, any effort aimed at cost cutting needs to be balanced against the possible negative impacts on patient safety to ensure good health outcomes.

There is a distinct pattern of reported incidents and adverse events between October 2008 and March 2009, which is attributable to the cost-containment measures that were introduced in the Free State during that period as illustrated in Table 5.7. and Fig 5.8. During this period we see a deeper decline of reported incidents in the December 2008 period, following an increase in the number of incidents after February 2009. The decline between November 2008 and March 2009 may be a reflection of the service restrictions that were imposed during this period. The fact that there is an over-representation of the smaller district hospitals in the sample could have resulted in the magnification of the effect of the service restrictions during this period.

The introduction of cost containment in September 2008 may have contributed in a tangible way to severe (SAC 1 & 2) incidents that were reported after its introduction when compared to the period before and after (Figure 5a.22). When cost containment was introduced, management needed to be ready for an increase in the demand for more complex and sophisticated services. If management is not well prepared for complicated cases in the future more severe and extreme incidents will occur.
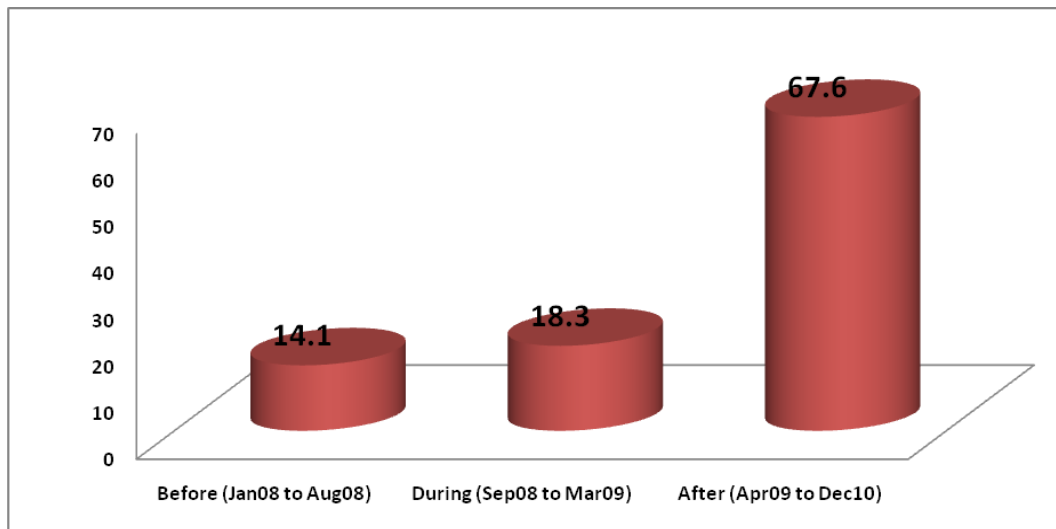
Figure 6.1: The distribution of SAC 1 & 2 across the cost-containment period

While these patterns are based on what is visualised in the figures and have not been subjected to statistical analysis for the determination of their significance because that was beyond the scope of the study, they seem to suggest that there is an increased number of reported incidents following this period of cost containment and service restrictions. This distinct pattern that seems to suggest that the highest increase in the reported incidents that happened in February 2009 could be attributed to the return of those patients who had previously been sent home back to hospitals, as a result of complications and increased severity of their conditions.

The importance of identifying cost containment as a key risk factor to patient safety is to bring to the awareness of the leadership and management at both corporate- and hospital level that cost-containment decisions need to be taken with great circumspection in the health sector, given their potential negative impact on patient safety and health outcomes.

6.4.7 Conclusion

In the preceding sections from 6.4.1 to 6.4.6 it has been demonstrated and comprehensively argued that the rich information provided by the incident reporting system provides important clues about the root causes of reported incidents. When these clues are carefully analysed they provide a solid basis for developing effective and sustainable policy and clinical interventions in order to improve patient safety.

6.5 Effects of AMCu on patient safety climate

Many authors use the terms "safety culture" and "safety climate" interchangeably. Sexton et al [254] maintain that the administration of a questionnaire that measures the perceptions of individuals and groups on patient safety is most likely to be measuring the safety climate rather than the safety culture. Sexton et al [254] argue that the evaluation of the patient safety culture should in addition include the assessment of behaviour, competencies and values.

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According to the NHS in the UK [255], safety culture is a "product of individual and group values, attitudes, perceptions and patterns of behaviour that determines a team or group's commitment to safety management". The safety climate is the measurable components of a safety culture and provides a snapshot of the culture at a particular point in time.

The evaluation of safety climate for this study was achieved through the administration of a safety climate survey that was developed by the Institute of Healthcare Improvement [66] at all the study hospitals. Embedded within the AMCu interventions are certain general and specific interventions that are aimed at improving patient safety climate and culture. This survey was therefore used as an evaluation tool to determine whether the implementation of the AMCu interventions would result in the improvement of the safety climate.

The survey was administered at the study hospitals at three time points within the study period, namely March 2008, November 2008, and November 2009. In order to determine whether the safety climate improved over time, we determined if there were measurable differences between the three time periods, and also whether these differences were statistically significant or not. It was also decided to compare the control and the intervention groups, in order to determine if there were any significant differences between these groups.

The demographic data indicated that more than 75% of the respondents have between 3 and more than 21-years' experience in their area of operation. This already indicates that these respondents were very experienced and knowledgeable about their area of operation and therefore also the best people to comment about the various practices in their area of operation.

In determining the safety culture in the clinical areas, it was found that more than half of the respondents at each of the three time points agreed that the culture of their clinical area made it easy to learn from the mistakes of others and that medical errors were handled appropriately in that clinical area. However, nearly 40% of the participants disagreed that they would feel safe being treated there as patients. This finding appears to indicate that while clinicians were aware of the value of learning from mistakes in the course of providing care, the level of safety practices had not convinced them to become willing patients in their facilities.

This finding needs, however, to be interpreted with caution in the South African context where there is a highly competitive private sector that is mainly serving the elite, who are privately funded. It is in this sector that health professionals are likely to access health care services, owing to the perceptions that the quality of health care services there are superior to those provided by the public sector, where this survey was administered.

It is a generally acceptable precondition that unless a cultural change initiative is driven from the highest level in an organisation it is unlikely to succeed and patient safety climate is no exception. Provonost et al [256] assert that there can be no

sustainable safety culture in an organisation without leadership support, motivation and establishment of a learning environment based on robust analysis of incidents.

Approximately 50% of the respondents at each point in time agreed that leadership was driving them to be a safety-centred institution with only 40% agreeing that senior leadership in their hospital listened to them and cared about their concerns. However, less than 50% of the participants at each point in time agreed that medical officer(s) and nurse leaders in their areas listened to them and cared about their concerns.

This is a disturbing finding that seems to suggest that while there is some leadership support for patient safety interventions, there is a clear perception that the views and concerns of the personnel at the "coalface" are being ignored. This environment is not conducive to the improvement of a patient safety culture and needs to be addressed as a matter of urgency.

Nearly three-quarters of the participants at each time point agreed that they followed the proper channels to direct questions regarding patient safety, with approximately two-thirds agreeing that they were encouraged by colleagues to report any safety concerns they may have. About 40% of the participants at each point in time agreed that leadership does not knowingly compromise safety concerns for productivity and that their suggestions about safety would be acted upon if they were expressed to management. This finding seems to suggest that there was good compliance with reporting procedures and good teamwork and support.

Arora et al [257] acknowledged that poor communication and briefing by clinical personnel during shift changes can lead to serious incidents and adverse events. Nearly 70% of the participants at each time point agreed that briefing personnel before the start of a shift was an important part of safety and only 40% agreed that they received appropriate feedback about their performance. However, less than 50% agreed that "briefings are common here".

This finding indicates that while clinicians acknowledge the importance of briefings during shift handovers, it is not happening to the extent that it should and that there is poor feed-back. This is yet another red flag that needs to be addressed with the clinical personnel across the hospitals in order entrench this practice and improve patient safety. This finding is consistent with the lack of feedback that was reported on personnel perceptions about AIMS earlier. Benn et al [243] acknowledge that effective feedback from reporting systems is one of the essential ingredients that are required in order to learn from failures and recommends that better feedback systems need to be developed.

Seventy percent of the participants at each time point agreed that the personnel in their clinical area take the responsibility for patient safety, with nearly two-thirds agreeing that patient safety is constantly reinforced as a priority in their clinical area. However, only about 45% of the participants agreed that "this institution is doing more for patient safety now, than it did one year ago". These perceptions of patient safety indicate that while the respondents acknowledge that there has been implementation

of interventions aimed at improving patient safety, they are not convinced about their sustained effectiveness. This perception is consistent with what was found in a different survey about personnel perceptions about AIMS that was discussed earlier.

At each of the three time points less than 50% of the participants agreed that the leadership was available to nurses, doctors and pharmacists. This finding indicates that a substantial number of service providers are 'thrown into the deep end' in the course of dealing with complex clinical problems, with no leadership availability and support. The reasons for this need to be investigated urgently and corrective interventions implemented. There is anecdotal evidence that indicates that shortage of key personnel, the lack of training in clinical leadership and governance, clinicians who fraudulently engage in private work while being remunerated by the public sector could be some of the issues that may be responsible for this negative finding.

More than 40% of the participants disagreed that personnel frequently disregarded rules or guidelines that had been established for their clinical area. However, more than 50% of the participants agreed that "I believe that most adverse events occur as a result of multiple system failures and are not attributable to one individual's actions". This finding underscores the basic tenet of the systems approach to medical error that asserts that the majority of the errors are not a product of irresponsible and reckless behaviour by clinicians but are a result of a series of events that are linked to system failures. This view is supported by the classical NHS publication [10] on the matter, which states that "The evidence of a large number of accident inquiries indicates that bad events are more often a result of error-prone situations and error-prone activities rather that error-prone people".

There was an improvement in the average positive scores from March 2008 to November 2008. However the average positive scores had decreased by November 2009 for all the dimensions, except for leadership, but even this average increase was found not to be statistically significant. There was a statistically significant (p=0.0299) difference in the average positive scores for the culture of clinical area dimension and the differences of all the other dimensions were not statistically significant (all p-values>0.05).

The disaggregation of the mean scores for safety climate in the designated domains indicates that for the intervention group the findings were exactly the same as those for the composite scores, where the only statistically significant differences were in the culture of the clinical area (p=0.0158) and the rest were insignificant over the three time points.

In the control group, the mean scores for safety climate were also found to follow the same pattern as the composite scores, except for the clinical leadership domain, which displayed statistically significant differences (p=0.0382) and the rest were insignificant over the three time points.

6.5.1 Conclusion

The question as to whether the implementation of AMCu interventions in the study hospitals had led to an improvement of the climate of safety there cannot be conclusively and comprehensively answered based on the findings of the surveys across the three time points. The reasons for this is that while some findings clearly indicate that the leadership has implemented patient safety interventions, that people on the ground understand, acknowledge and support these, there are still some major shortfalls in safe health care practices. These shortfalls in safety climate are fundamental in nature and need urgent attention. The failure to address the identified shortcomings will reverse whatever gains that the Free State Department of Health has made with respect to patient safety. A number of specific recommendations are, however, presented in Chapter 8 to address these shortfalls.

6.6 Effects of AMCu on patient safety culture

The hospital patient safety culture survey questionnaire, developed by the Agency for Healthcare Research and Quality [65] was administered at all the study hospitals and for the purpose of this research was used to evaluate whether the AMCu interventions resulted in improved patient safety culture. It has already been explained that whilst the questionnaire itself is not an intervention, embedded within the AMCu interventions were also patient safety culture improvement interventions. This survey therefore was aimed at measuring the patient safety culture in the study hospitals across three time points.

The demographics of the respondents indicated that more than 80% of the respondents had worked in that particular unit and also the particular hospital for more than a year. More than 90% of the respondents work 40 hours per week or more in their unit. This clearly indicates that the respondents were the most appropriate group to participate in the survey.

A higher percentage of health workers disagreed that "it is by chance that more serious mistakes do not happen around here" for all the three surveys. However, the majority of the participants agreed that their procedures and systems are good at preventing errors from happening at all the three time points. Most participants disagreed that they had patient safety problems in their unit at all during all the surveys except in November 2008 where 43% agreed that they had problems and this happened during the period of cost containment. More than half of the participants agreed that patient safety is never sacrificed to get more work done at all the three time points. All of these are positive responses and indicate a sense of an organisation that is dealing adequately with patient safety challenges, by placing all the necessary barriers to prevent the occurrence of incidents and adverse events. This augurs well for the development of a positive patient safety culture and is supported by Reason's theory of causation of organisational accidents [218].

More than 80% of the participants in all the surveys agreed that they were actively doing things to improve patient safety except for the November 2009 survey where

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79% agreed. At least 50% of the participants agreed to the statement "mistakes have led to positive changes here" for all the three time points. Nearly 60% of the participants agreed to the statement "After we make changes to improve patient safety we evaluate their effectiveness". These positive responses demonstrate an intention by the organisation to improve its patient safety practices.

More than 60% of the participants agreed "people support one another in this unit" and more than 70% agreed that "we work together as a team to get work done" at all the three time points. At least 50% of the participants agreed that they treated each other with respect in the unit and helped each other when the unit was busy at all the three time points. This group of positive responses clearly indicates that teamwork is an important requirement in implementing programmes aimed at   improving the quality of health care services. This finding is supported by Provonost et al [258], who identified teamwork as a key element to building a safety culture in a group of hospital ICUs.

Nearly 45% of the participants agreed that they were afraid to ask questions when something did not seem right. Only 35% of the participants agreed that they felt free to question decisions or actions of those with more authority. This observation unfortunately, a common occurrence in many hierarchical organisations, especially those that are led by highly qualified specialists in their fields or those that wield autocratic power and will lash out at a whim. This erratic behaviour, unfortunately, suppresses local opinion or input that may make the difference between the occurrence or non-occurrence of an adverse event.

In term of communication of errors, at least 60% of the participants agreed that they were informed about the errors that happened in their unit and discussed ways to prevent errors from happening at all the three time points. Only 40% of the participants agreed that they got feedback about changes put into place based on event reports for all the three time points. While there is good communication about error, the lack of feedback is a serious concern as it demotivates the reporters and also fails to spread the message on lessons learned.

More than half of the participants disagreed that the work was in crisis mode, with more than three-quarters disagreeing that they had enough staff to handle the workload. Nearly 60% of the participants disagreed that they work long hours. More than half of the participants agreed that they use more agency/temporary staff than is best for patient care. This finding in particular means that patients are exposed to inadequately trained or motivated personnel. The overuse of agency personnel is often an indication of personnel shortage due to recruitment and retention failures. Recruitment and retention need to be addressed in order that patient safety culture can be improved.

Nearly 45% of the participants disagreed that hospital management seemed interested in patient safety only after an adverse event had happened, with more than half agreeing that hospital management provided a work climate that promoted patient safety as well as agreeing that actions of hospital management showed that patient

safety was a top priority. This is a clear indication of good leadership and support for patient safety interventions and bodes well for the development of a positive patient safety culture.

Nearly half of the participants agreed that it was often unpleasant to work with staff from other units, with approximately 40% agreeing that hospital units do not coordinate well with each other at all the three time points. Nearly 60% of the participants agreed that hospital units worked well together to provide the best care for patients. Just over 50% of the participants agreed that there was good cooperation among hospital units that needed to work together. These agreements happened at all the three time points. This is an indication that while there is good teamwork within units, there appears to be a reluctance to work and cooperate with other units. This is another issue that needs to be addressed in order to improve the culture of patient safety.

In response to a group of questions enquiring about shift handovers, nearly 50% of the participants agreed that important patient care information was often lost during shift changes and that shift changes were problematic for patients in the study hospital. Less than 40% of the participants agreed that things "fall between the cracks" when transferring patients from one unit to another. This particular finding seems to suggest that there are not too many challenges with handovers in the Free State Department of Health. This finding is in direct contrast with an earlier finding that evaluated the impact of handovers on the patient safety climate.

In terms of the creation of a non-punitive response to medical error, nearly 50% of the participants disagreed that staff felt their mistakes were held against them and disagreeing that staff worry that mistakes they make were kept in their personnel files. Less than 50% of the participants disagreed that when an event was reported it felt like the person was being written up, not the problem. These results were similar at all the three time points and seem to indicate that there is still significant anxiety around the reporting of adverse events. This anxiety needs to be comprehensively addressed in order to improve the patient safety culture.

Only 4/12 dimensions showed statistically significant (p<0.05) variations over time. The average perceptions of these dimensions increased from March 2008 to November 2008 and they all decreased in November 2009, except for safety culture which increased consistently. For all the four dimensions, the average percent of positive perceptions were similar for all the three time periods, except for the dimension: safety culture at unit level (p=0.0332), overall perception (p=0.0438), continuous improvement (p=0.0332) and non-punitive (p=0.0007), where the differences are statistically significant.

When the measured scores were disaggregated into the intervention and control groups, the intervention group displayed close similarities with the aggregated mean scores. The intervention group also showed that 4/12 domains demonstrated statistically significant differences in the three time points, except that the affected domains included hospital handovers instead of the safety culture domain. The

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measured scores for all the domains in the control group demonstrated no statistical significance in their differences over the three time points.

These findings collectively indicate that while there were a few domains that indicated differences that were statistically significant, these were in the minority (4/12) and that these were mainly contributed by the intervention group as compared to the control group. This also means that the differences between the different time points and the differences between the intervention and control groups are marginal and not overwhelming.

6.6.1 Conclusion

The question as to whether the AMCu interventions that contain safety culture improvement elements resulted in the improvement of the patient safety culture or not can be answered in the following manner. In terms of the findings set out above, the majority of the findings are positive for the successful implementation of patient safety culture. There are, however, areas the need urgent attention in order that patient safety culture can be improved.

Ferlie et al [259] warn that even the most brilliant interventions aimed at improving the organisation's performance will not succeed if they ignore the multi-level approach to organisational change. There must be a recognition that change starts with individuals, groups and teams before it permeates the entire organisation and this takes time. While organisational culture change is expected to occur over time, the 3 years of the study is sufficient time to make a determination of whether a patient safety culture intervention has made a difference or not.

Grol et al [260] introduce another dimension to this argument by exposing the big gap that exists between research and practice. Grol et al [260] indicate that while there are more than 10 000 clinical trials per annum that confirm the usefulness of health care innovations, very few of them find their way into routine use by professionals. These authors are advocates of the multi-level approach with interventions for change being tailor-made to suit the circumstances and beliefs of the particular target group.

Carroll et al [261] indicate that in the health sector where there is an entrenched culture of individualism and autonomy within the ranks of the health professionals and it is therefore difficult to introduce changes that include teamwork, reporting of error and learning as these are seen to be in direct conflict with the accepted beliefs.

The observed difficulties in changing an organisational culture is endorsed by Scott et al [262] who indicate that while there are many models that have been proposed to explain the characteristics of culture change in health care organisations, one of the key difficulties is the lack of consensus on the definition of culture change in health care. There is, however, agreement that factors that impede cultural change in health care organisations include: poor leadership, lack of ownership, external constraints and sub-culture diversity.

Finally, while these results indicate an improvement in the patient safety culture because of the implementation of AMCu, it is crucial for the Free State Department of Health to address the key challenges that have been identified in order to ensure that these patient safety culture gains are sustained.

6.7 Effects of AMCu on patient satisfaction

According to the following authors [263,264] patient satisfaction is regarded as an important measure of patient outcomes, a determinant of successful implementation of structure, process and outcomes, as well a good determinant of future consumer behaviour. Other studies [265,266] have indicated that patient satisfaction has been found to be high in settings that provide more personal health care, characterised by good communication, patient involvement, good relations between professionals, adequate staff and good managerial support.

In order to determine whether the implementation of the AMCu interventions would result in improved patient satisfaction, a survey questionnaire was administered at all study hospitals at two time points. This evaluation was therefore aimed at determining whether there was patient satisfaction at each time point and also at determining if the differences in patient satisfaction between the two time points were significant or not.

The demographics of the respondents indicate that the majority (31% in 2009 and 55% in 2010) of the participants had a medical condition as opposed to surgical or others. Approximately 20% of the participants were admitted for maternity reasons.

More than 88% of the participants evaluated the facilities and waiting times as good in both years. However, the values for 2010 were higher than those for 2009.

In the evaluation of staff attitude, information received and length of time between health-seeking steps and hospital admission, it was found that the values for all the measured dimensions were greater than 88% and the 2010 values were higher than those for 2009, except for amount and clarity of information received where there was a decrease in the percentages of positive perception. The decrease in the perceptions about the amount and clarity of information received by patients on admission is cause for concern that needs to be addressed.

More than 90% of the patients had a positive perception of the admission process for both years under study. The positive perception percentages decreased in year 2010 compared to 2009 for consideration of personal needs and wants (94.5% vs. 90.7%) as well as hospital routine and procedures (95% vs. 90%). These findings indicate an overall good performance, but the significance of these decreases in measured values needs to be tested before one should be concerned about them.

In determining the patient perception of their experience during admission, all the elements evaluated were higher than 93% and there was an increase in the percentage of positive perception between 2009 and 2010, except for "way the nurses

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explained your treatment to you", where there was a slight decrease in the percentage perception. This decrease from 95.9% to 95.4% is not material.

The proportion of patients with positive perceptions regarding doctors was at least 99% for both years for all the items assessed. At least 95% of the patients had a positive perception about hospital staff in general for both years. This is an important finding, as most of the complaints regarding the quality of services or reported incidents involve personnel.

All the patients who participated in the study agreed that possible side effects of medicines were explained well to them for both years. The percentages of patients with positive perceptions of staff attitude were at least 90% for both years. The percentages of patients with positive perceptions decreased in 2010 compared to 2009. This decrease in perception of staff attitudes needs to be investigated and acted upon before it becomes a major problem.

All the proportions of positive perceptions were above 91% for both years except for the quality of food for the year 2010, which had a value of 87.3%. The poor perceptions of the quantity and quality of food were a cause for concern. This negative finding needed to be investigated to determine if the service providers are a factor in this, as in our larger hospitals this service was outsourced to private companies. This finding may, on the other hand, be an indication of poor management of these outsourced services.

In general, at least 91% of patients had a positive perception of the quality of services for both years except for "the services and care arranged for you by the hospital when you got home" where only three-quarters had a positive perception. This finding needs to be followed up, as it may be an indication that there are challenges with the downward referral of patients after discharge. This finding may also indicate the lack of a seamless transfer of patients from higher to lower levels, including all key stakeholders in primary health care.

In terms of whether the differences in the measured perceptions are statistically significant or not, there is no significant difference in average dimensions measuring general information (p=0.9598) and respect (p=0.2561) between 2009 and 2010. However, 50% of the dimensional scores were 100% for both years. The average score for the dimension regarded as measuring the hotel services (p=0.0259) and discharge (<0.0001) for the year 2010 were significantly lower than those of year 2009.

There was a significant (p=0.0001) improvement in the average percentage score for the facilities between 2009 and 2010. The average percentage on staff attitude significantly (p=0.0173) decreased from 94.89% in 2009 to 93.03% in 2010. All the items presented in Table 5.28 had 50% of their scores at 100% in both years.

In terms of the perception scores, it is clear that for the majority of the elements tested that these are very high (>83%). There is also a generalised increase in the perception scores between 2009 and 2010 for the majority of the elements tested. The

decrease in the perception scores for staff attitudes, hotel services and discharge procedures was found to be statistically significant. The increase in the perception scores for hospital facilities and courtesy of nursing staff was found to be statistically significant. The findings set out above, therefore, indicate that there is evidence that the implementation of the AMCu interventions has resulted in the improvement of patient satisfaction.

6.7.1 Conclusion:

The data presented in this section in order to determine whether the implementation of AMCu resulted in improved patient satisfaction between the two time points, clearly indicates that this was indeed the case. The high scores (>90%) that were recorded for the various measured dimensions provides evidence for this. The small and often insignificant differences between the measured dimensions in the two time points further confirms the high and consistent ratings on these dimensions. It can therefore be concluded without fear of contradiction that the implementation of AMCu resulted in the improvement of patient satisfaction during the period under study.

6.8 Effects of AMCu in improving health care quality as measured by COHSASA evaluation scores

The COHSASA facility improvement programme was in place in Free State hospitals long before this study was contemplated. The programme itself cannot and should not be viewed as part of the AMCu interventions because it was implemented before AMCu. This means therefore that any changes that are measured over and above this programme should be attributed to AMCu. The study is using the COHSASA evaluation tools to determine whether there was an overall improvement of the quality of the services provided by the study hospitals during the AMCu interventions or not.

The study made use of the baseline evaluation of all the hospitals that was done at the end of 2007 and compared these to a subsequent evaluation that was done in 2010 in the same sample of hospitals. The results of the COHSASA evaluations for the 2 periods are clearly indicated in the results section in Chapter 5. Given the fact that AMCu interventions were implemented only in January 2008, this part of the results therefore constitutes a "before" and "after" evaluation of the AMCu interventions, using COHSASA scores as an evaluation tool. The following discussions will therefore focus on the comparison of the COHSASA evaluation scores between the two time periods of 2007 and 2010.

There is a statistically significant ($p<0.05$) improvement in the average performance scores of all the study hospitals across all the key performance areas between 2007 and 2010. The survey and scores of 2007 should be considered routine pre AMCu scores, whereas those of 2010 should be considered scores that reflect the influence of AMCu. The performance areas that were measured for in all the facilities were:

- Management
- Clinical and clinical support services
- Domestic and technical [Food services, linen, maintenance etc]

- Professional Allied Medical Services [Physio, Speech, Occupational therapy etc.]

It should be noted that whilst there is significant improvement across the different performance areas, the most significant was for management, followed by clinical and support services, domestic and technical and, finally, the professional allied services. According to this finding, the quality of the core services and their support are the most significant in the period of study.

In general there was an increase in the number of service elements that complied with COHSASA standards from 2007 to 2010 in all the study hospitals except for five hospitals. This means that 19 of 24 study hospitals demonstrated an increase in the number of the compliant service elements tested against the 36 standard service elements designed by COHSASA. Only these five showed no increase in the number of compliant service elements. This finding indicated an overall improvement in the compliance with COHASASA norms and standards over the period.

All the performance indicator scores for each of the service elements improved between 2007 and 2010, although the improvements were not statistically significant except for management of information (p=0.028), quality management and improvement (p= 0.043) and prevention and control of infection (p=0.0367). Details of this improvement are further expanded below:

- All the performance indicator scores of all the service elements measuring the performance area clinical and clinical support increased from 2007 to 2010 except for resuscitation systems, which decreased from 69.9% to 61.9%.

- There were statistical significant improvements in the operating theatre and anaesthetic service (p=0.0142), radiology and diagnostic imaging service (p=0.0212) and pharmaceutical service (p=0.0085) performance indicators.

- Although there were improvements in the performance scores of the domestic and technical service elements from 2007 to 2010, the improvements were not statistically significant, except for linen management which improved from 72.2% to 86.5% with a p-value of 0.0051.

- Although all the scores of the performance indicators of the PAMS improved, these are not statistically significant (all p-values >0.05).

The overall facility scores for all study hospitals show a significant (all p-values <0.05) improvement in terms of COHSASA standards between the baseline in 2007 and the evaluation values measured in 2010, except for one hospital where there was a significant decrease from 89.1% to 83.3%. This indicates that a substantial number of study hospitals had improved their quality of health services as measured by the COHSASA overall facility scores.

Only 11 of 24 study hospitals demonstrated a statistically significant improvement or deterioration in their overall average COHSASA compliance scores. Out of these, only one hospital demonstrated a significant deterioration of its average compliance score

over the period. Thirteen of 24 study hospitals demonstrated statistically insignificant differences between the 2007 and 2010 average COHSASA compliance scores. Nine of these were improvements and 4 were deteriorations.

6.8.1 Conclusion

The findings overwhelmingly demonstrate that the overall quality of health care service provided by the study hospitals as measured by the COHSASA scores improved significantly between the 2007 baseline evaluation and the 2010 evaluation. This period is also inclusive of the period when AMCu interventions were implemented in the study hospitals. It is therefore reasonable to surmise that any quality improvement interventions that were a direct outcome of AMCu have made some contribution towards these quality improvement measures that are reflected in the COHSASA scores.

6.9 Study Limitations:

6.9.1 Hospital size and randomisation

The interpretation of a number of findings in this study is largely determined by the profile of the hospitals in the intervention and control or delayed intervention study groups (Table 6.1), despite the randomisation that was undertaken during the preparatory and design stages of the study. The randomisation process produced a reasonable balance of the total number of beds in each group with the same number of hospitals in each group. However, three out of five level 2 hospitals were randomly allocated to intervention sites and only two were allocated to the control sites.

The randomisation process, however, resulted in over-representation of the larger regional and tertiary hospitals in the intervention sites. These hospitals tend to be relatively well resourced in terms of personnel, equipment, infrastructure and systems and more than half (2 114/3 598) of the incidents were reported from these large hospitals (Table 6.1) during the study period. This may seems to be a contradiction in terms, where better-off hospitals are reporting more incidents, but it also needs to be understood that the higher-level hospitals are also faced with a more complex case load compared to the smaller hospitals and are also the hospitals to which the smaller hospitals refer all their complex cases.

The control sites are mainly smaller district hospitals, which tend to be relatively less resourced in terms of personnel, equipment, infrastructure and systems. These hospitals also tend to be located in the remote, smaller towns of the province and approximately one quarter (940/3 598) of the incidents were reported from these sites during the study period.

Table 6.2 Profile of the hospitals in the control and intervention groups 36 months

		Control group			Intervention group		
	Hospital	**Total Beds**	**No of Incidents**		**Hospital**	**Total Beds**	**No of incidents**
Level 1							
	Thebe	71	21		Botshabelo	135	23
	Mantsopa	26	17		Itemoheng	55	25
	E Ross	110	50		Dr JS Moroka	180	22
	Katleho	78	59		Parys	50	13
	National	177	124		Stoffel Coetzee	23	18
	Embekweni	25	15		Phutuloha	31	52
	Mafube	29	43		Thusanong	86	78
	Mohau	28	16		JD Newberry	42	30
	Phekolong	85	13		Winburg	55	37
Sub Tot		**629**	**358**			**657**	**298**
Level 2							
	Boitumelo	312	139		Dihlabeng	140	146
	Manapo	270	17		Pelonomi	620	**1090**
	FSPC	760	426		*Universitas-**Level 3**	627	**1124**
Sub Tot		**1 342**	**582**			**1 387**	**2 360**
Total		**1971**	**940**			**2044**	**2658**

*During analysis, Universitas (Level 3) was included in level 2 hospitals

The finding that there is increased reporting of incidents in the intervention sites compared to the control sites in the first nine months and that the reported incidents increased in the delayed intervention sites beyond this period and that this pattern was sustained (see Table 5.2) indicates that the interventions that were implemented were effective.

In order to determine whether the number of reported incidents is related to the size of the hospital or the level of care, we examined the available data. Table 6.3 presents a comparison of the average number of incidents reported from level 1 (district) hospital and level 2 (regional and central) hospitals per month and per hospital.

A minimum of 4 incidents and a maximum of 43 incidents per month were reported from level 1 hospitals compared to level 2 hospitals where a minimum of 34 incidents and a maximum of 113 incidents were reported per month. In general the number of incidents reported from level 1 hospitals (18 on average) was less than one quarter of the number of incidents reported from level 2 hospitals (nearly 82 on average) per month.

In total there were 18 level 1 and 6 level 2 (including Universitas) hospitals in the study (Table 6.3). The average number of incidents reported per hospital in the level 1 group (36) was much lower than the average number of incidents reported per hospital in the level 2 (409) group of hospitals. There is a statistically significant difference (p=0.0069) in the median number of incidents reported per hospital in the level 1 group compared to the median number of incidents reported per hospital in the level 2 group, with the median number reported in the level 2 group being higher.

These clear differences suggest that the hospital size is not that important with regard to reported incidents; the most important distinguishing factor is the level of care. This finding that there is no association between the number of reported incidents and the size of the hospital is consistent with that of Hutchinson et al [239] and Thornlow et al [267] in similar studies. Farley et al [268] support this argument and even further declare that the change in incident reporting rates is not influenced by hospital characteristics such as bed size and ownership.

It is therefore clear that the higher the level of care, the higher the number of reported incidents. The fact that randomisation did not take into account the levels of care may explain any differences in the number of incidents reported between the control and intervention sites, which can be seen when the intervention is introduced to all the sites.

Table 6.3 Comparison of the number of incidents reported in level 1 and level 2 hospitals

	Statistic	Level 1 hospitals	Level 2 hospitals	P-value
Monthly				
	Number of months	**36**	**36**	
	Mean	18.22	81.72	<0.0001*
	Median	16.5	86.5	
	IQR	23.5-14	98.5-65.0	
	Min	4	34	
	Max	43	113	
Overall				
	Number of hospitals	**18**	**6**	
	Mean	36.44	490.3	
	Median	24	139	0.0069[+]
	IQR	50-17	1090-139	
	Min	13	17	
	Max	124	1124	

*t-test for means   [+]P-value - Wilcoxon rank sum test for medians

In order to exclude the effect of this randomisation bias, only the incidents reported from the smaller-sized level 1 hospitals were considered. Table 6.4 below indicates a significant difference (p<0.002) in the median number of reported incidents from the intervention and the control sites during the first nine months. Beyond the first nine months of the study, the median number of incidents reported decreases in the intervention sites compared to the control sites and the difference was not statistically significant (p=0.8934) during the last nine months of the study. These results support the argument that even after eliminating the randomisation bias related to the level of care, there is still a significant difference between the intervention and the control sites in the first nine months in terms of the number of incidents reported. This difference can only be attributed to the study interventions that were implemented at the intervention sites.

This observation also supports the argument that the differences in the number of reported incidents between the intervention and control sites are most significant in the first nine months. The introduction of the interventions to the control sites beyond the first nine months progressively reduces the significance of the differences in the number of reported incidents among the different groups of hospitals.

Table 6.4 Comparison of the median number of incidents reported: Control and intervention sites

Period	Comparison of Monthly averages and Medians Between control and intervention for Level 1 hospitals		
	Control (Paper based) Only for 1st 9 months	Intervention (AMCu)	p-value
January 2008 to Sep2008			
Average ±sd	0.1±0.3	12.±5,6	
Median	0.0	14.0	0.0002
Range	1.0-0.0	22-4	
Oct 2008 to Jun 2009			
Average ±sd	17.2±9.1	5.4±4.5	
Median	16.0	5.0	0.0012
Range	40-10	14-1	
July 2009 to March 2010			
Average ±sd	12.9±4.7	7.3±7.8	
Median	14.0	3.6	0.0169
Range	19-6	12-2	
April 2010 to Dec2010			
Average ±sd	9.6±6.2	7.6±1.9	
Median	8.0	8.0	0.8934
Range	22-2	10-4	

Note: P-value is comparing the median numbers reported for control and intervention

It can therefore be concluded that whilst there is a clear randomisation bias, and an over-representation of the higher level hospitals in the intervention group, the differences between the control and intervention sites in the first nine months are statistically significant and therefore demonstrate the effectiveness of the study interventions.

The fact that these significant differences between the intervention and control sites persist, even after the elimination of the randomisation bias, indicates that these differences can only be attributed to the interventions that were implemented in the first nine months.

6.9.2 Nature of the study

There are certain inherent limitations to a study of this nature, where an attempt is made to quantify incidents that have been reported through an incident reporting system. These limitations emanate from the following five key areas:

- General under-reporting of incidents
- The disparity between reported and actual incidents
- Incident classification
- Research environment

6.9.2.1 General Under-reporting

There is general consensus that there is under-reporting of incidents irrespective of the methodology used to measure this phenomenon. The extent of this under-reporting is to some extent dependent on the methodology used, the prevalent safety climate and culture in the specific organisation and the intensity of the barriers that prevent reporting of incidents. Mahajan [269] indicates a number of factors including fear, poor safety culture and ignorance about what should be reported, how this information should be collected and reported and the extent of protection from punitive action as some of the main barriers to the reporting of incidents.

Sheikh et al [270] also argue that the purpose for the collection of data on incidents also influences the extent of their reporting. If the data is to be used for litigation purposes, then the reporting rates will be very low; collection of data for confidential enquiries and for measurement of adverse events that excluded near-misses has, according to these authors, not been very useful.

While there was support for and access to the reporting system at all the study sites, it is likely that not all the incidents that occurred at these facilities were reported. This study is therefore exclusively dependent on only the reported incidents. This under-reporting of incidents has been cited in several studies as a key weakness of incident reporting systems [196,271,272]. This, however, does not take away the value added by these systems through the information and context they provide in understanding the nature and causes of incidents. McLoughlin et al [273] and Tamuz et al [88] believe that the development of a usable set of internationally recognised patient safety indicators will improve the classification and reduce the under-reporting of incidents.

There was a concerted effort to train the personnel from the different hospitals in terms of how they can interact with the reporting system and ensure that incidents are appropriately reported. It is, however, possible that this training was not understood and accepted by the different institutions in a similar way. These different levels of understanding may account for the different levels of motivation by the personnel in the different institutions to report incidents. Some studies have also identified that there is a reporting bias, which demonstrates that nurses are more likely to report these incidents when compared to medical doctors [274,275,276].

The limitation that under-reporting of incidents imposes on the research project is that any quantitative exercise that examines the numbers, patterns and frequency of occurrence of reported incidents will be subjected to some form of understatement. This important factor needs to be taken into account for the interpretation of the results of reported incidents.

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6.9.2.2 Disparity between reported and actual incidents

This factor is closely related to the one indicated in the discussion above, and is stated separately to emphasise the limitations that are imposed by this factor on the study. The incidents that occurred, but were not reported are the main cause of the differences between the actual and reported incidents. This means that in our reports, we can only include the reported versus the actual incidents. In other words we can report on reported incident rates instead of the actual incident rates. It is also important to note that because the reporting system focuses on the reported incidents, the non-incident cases that are a part of the denominator are not reported on, and this makes the calculation of incident rates subject to this error. If the incident rates are calculated from the medical records, the calculation of incident rates would be much more accurate.

6.9.2.3 Incident Classification

The difficulty of classifying incidents in general, irrespective of the methodology of reporting, is very severe and this also imposed some limitations to the study. Firstly, there is still no uniform international accepted manner of classifying incidents despite the great efforts aimed at achieving this through the auspices of the WHO [277,278] and the Joint Committee for the Accreditation of Health Organisations [90]. Some of the early publications [71,76], focused on whether the incidents were preventable or not and what their most likely cause was.

Reason [153] placed emphasis on whether the incidents occurred as a result of latent failures at corporate and or organisational level or that those that occurred were active failure due to errors or violations at a personal level. This kind of analysis led to the development of more sophisticated classification systems [90, 279,280] that began to look at whether the incident was as a result of patient-, provider-, task, team-, environmental- or institutional factors or a combination of these.

Other authors [195,281] tried to classify incidents in a primary care setting with a clear emphasis on whether these were due to diagnostic, treatment or preventative errors and also whether these have a clinical-, communication-, administration- or blunt end origins. An approach that classifies incidents on the basis of patient safety indicators has also been proposed by Romano et al [19]. Shaw et al [282] classified incidents according to whether they were regarded as slips, trips, falls or medication-, resource- or treatment related. All these multiple classification systems have posed serious limitations to the studies that incurred them, as it became very difficult to decide which classification methodology to follow.

Secondly, during the research it became very clear that the classification of incidents is a very subjective process. Different professionals classified the same incident differently depending on their experience, area of expertise and beliefs. Consensus was, however, reached after detailed presentations were made and intense discussions that occurred for each case under consideration.

Finally, the incidents that were classified as duty of care incidents that by definition required a detailed root cause analysis and investigation could not be classified further because of resource, time and other constraints. A recommendation for their analysis outside the study is proposed in the chapter 8.

6.9.2.4 Possible negative effects of research environment

In interventional studies such as this one where the investigators are unable to fully control the environment in which the experiment or research is occurring are subjected to specific biases that influence the interpretation of the research results. These biases include co-interventions and contaminations.

Co-interventions are interventions that are not part of the study but are inadvertently applied to the research sites and result in the inaccuracy in measuring the impact of the intended intervention, owing to the fact the measured result cannot be wholly attributed to the study intervention. "Contamination" refers to the unintended implementation of the interventions at the control site as well as in the intervention sites, which interferes with the measurement and interpretation of the impact of the intervention.

In order to improve the culture of patient safety, there were generalised interventions that were directed at clusters of hospitals at a district and provincial levels. These were generic interventions aimed at motivating personnel across the entire organisation to improve the patient safety culture. These include key policy decisions taken at the highest level in the organisation and were aimed at engendering a reporting and just culture. These interventions by their very nature could also not be exclusively focused and directed at the intervention sites in the first nine months, but were addressed in all hospitals in the province beyond the 24 study hospitals.

In the context of this research, these activities are viewed as unavoidable and an inherent element of health systems research in a dynamic service delivery environment and are therefore treated as enabling activities that ensure the successful implementation of the main intervention. These activities are therefore not regarded as the primary interventions but as secondary interventions whose impact is measured through the various safety culture and climate surveys. Apart from these secondary interventions, there are no other co-interventions that were identified in the study and therefore the results that are reported can be safely attributed to the above identified interventions.

It needs to be noted, however, that during the implementation of these interventions, for practical reasons, the information shared with the intervention hospitals invariably became shared with the control hospitals. This was anticipated at the planning stages of the research and a decision was taken at that stage not to attempt to implement these secondary interventions to intervention hospitals exclusively, but to all 24 hospitals.

6.9.3 Ethical Issues

It has already been stated that the period when there was a separation between the intervention and control sites was in the first 9 months. The question of whether 9 out of the 36 months of the study period was not too short a period to test the study interventions; has already been posed. The answer to this key question lies in the ethical issues that developed as the study unfolded, when there was a preliminary indication that there were large differences in the reported incidents between the control and the intervention sites. The researcher took a conscious decision to extend the intervention to hospitals in the control group beyond the first nine months for ethical reasons and the switch was anticipated in the planning phase of the study like any other clinical trial.

Cannistra [232] and Bassler et al [233] state that one of the indications for the early termination of clinical trial on ethical grounds is evidence of an either significant benefit or harm to the intervention group. The significant benefit in this instance therefore means that researchers have an obligation to maintain ethically allowed norms and standards; that is, not to deprive the control sites of the beneficial effects of the intervention for a longer period.

The clear difference in the number of incidents reported between the two groups of hospitals that was observed at 6 months (during interim analysis) with a much higher number being reported from hospitals in the intervention group that compelled the author to consider an early extension of the intervention to the control group. At 9 months the interim analysis showed that the median number of incidents reported in the hospitals from the control group and those reported in the hospitals from the intervention group was statistically significantly different (p= 0.0003), 0 vs. 71 respectively.

The difference in the average number of incidents reported at 9 months was also statistically significant (p<0.0001), 0.33 vs. 78.6 average number of incidents reported in the control sites compared to the average number reported in the intervention sites respectively.

The emergence of such an extreme result raised the question of whether it would be ethical to continue withholding AIMS intervention from the hospitals in the control group. These findings had exceeded the extreme level of significance recommended by Atkinson et al [283] for consideration of early termination of the trial. According to Friedman et al [284], these sustained extreme significant differences made it impossible to imagine that they could have happened by chance alone.

Therefore, considering the larger number of incidents reported in the hospitals from the intervention group the research team realised that there was a cause for concern. This huge difference give rise to the possibility of incidents not being reported from the hospital in the control sites considering what has been happening over the years when the paper-based system was the sole incident reporting mechanism. Taking into consideration the litigation associated with adverse events happening in the province –

sometimes without management knowledge – the researcher and the monitoring team took a conscious decision to extend the intervention to hospitals in the control group beyond the first nine months for ethical reasons and this switch had been anticipated in the planning phase of the study.

The overall implications of this study is that a group of quality and patient safety interventions centred around an incident report system can be successfully implemented and operationalized in a developing country setting, despite all the study limitations presented above. Despite the detailed study limitations described in the previous discussions, it is the authors considered view that none of these alter the validity of the results of the study presented materially. This has been clearly demonstrated and argued in the presentation of results and discussions in both Chapter 5 and 6. It has also been clearly demonstrated that the implementation of AMCu has had a positive effect on patient safety climate, culture and patient satisfaction. The quality as measured through the COHSASA evaluation scores also demonstrated a marked improvement as a result of the implementation of AMCu.

CHAPTER SEVEN: THE MODEL

7.1 Introduction:

One of the main aims of this study was the development of a hospital patient safety risk reduction model based on the experience of the Free State in South Africa. This model is meant for the use by other provinces or countries and also indicates what experiential lessons to avoid in developing sustainable patient safety programmes similar to the Free State. The research findings have clearly demonstrated that the set of interventions built around a computerised incident reporting system can be successfully implemented and maintained operationally in a developing country setting. These findings have also indicated that the reporting system can provide data, which upon analysis, will identify specific risk factors associated with the reported incidents. The findings have also indicated that these identified risk factors can enable health system managers to develop effective and sustainable policy and clinical interventions.

In this chapter we will develop the hospital risk reduction model using the various frameworks, activities and processes that were undertaken during the research project. This model is presented in this chapter as one of the critical success factors for the development of a sound hospital patient safety improvement programme in the Free State.

A model, according to Massoud et al [214] is a schematic representation or formula that is used to represent a complex process in a simplified manner so that some aspects of it can be studied and better understood. A model is often accompanied by certain assumptions and may not fully represent all the dynamics and dimensions of the complex process it seeks to depict. This understanding of a model needs to be bourne in mind in the examination of the Free State model.

7.2 Key elements of the model:

The risk reduction model for Free State hospitals has the following key elements:

- Planning framework
- Classification framework
- Risk assessment framework
- Analytical framework
- Investigation framework
- Intervention framework

7.2.1 Planning Framework:

The planning framework was proposed by Massoud et al [214] as a key element in assessing challenges in the health care environment and developing continuous quality interventions that are effective and sustainable. This framework is also referred to as an adaptation of the Shewhart 's Plan-Do-Study-Act cycle (PDSA) [215] by others in reference to the steps that are involved in the process.

Figure 7.1 illustrates this planning framework and all the key steps that are involved in the process: identification, analysis, development of the plan, and testing and implementation.
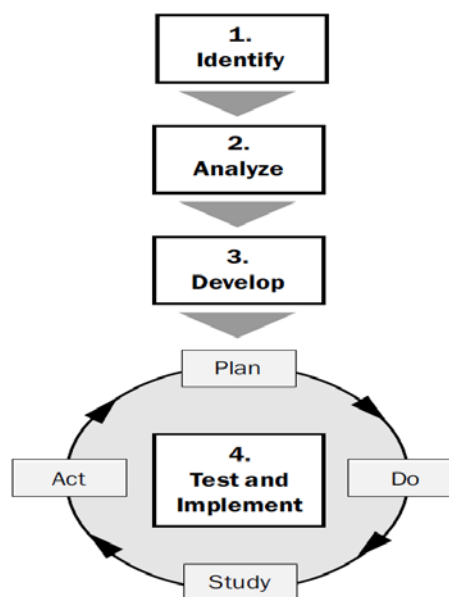
Figure 7.1: Quality improvement planning framework

7.2.1.1 Identification

The Free State Department of Health identified the need to have a patient safety improvement programme after experiencing an increasing number of incidents and adverse events that were reported in the media or through our own legal unit as lawsuits against the department. We believed that these incidents were a source of many complaints related to the poor health care quality provided by our institutions and that they were a major contributor to the unacceptably high infant, under-5 and maternal mortality rates. We identified the patient safety programme as a complex organisational intervention that affects the entire system and therefore that required teams for implementation.

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7.2.1.2 Analysis

We undertook a situational analysis in order to understand all the pertinent facts around patient safety challenges and what was being done to address these. This analysis examined the inputs, processes, outputs and outcomes and impacts of unsafe care. The results of this analysis indicated to us that there will need to major organisational changes in the manner in which patient safety was handled. These changes would affect the reporting systems, culture, leadership and governance as these relate to patient safety and overall health care quality.

7.2.1.3 Development of options

At this point we also developed a number of options that could possibly address the major patient safety challenges that we had already identified. The implementation of a new incident reporting system is one of the key changes that needed to be effected in order to improve patient safety. It was therefore important to examine the reporting system that was in place at the time in order to ensure that the identified shortcomings are addressed. The following key features emerged as basic requirements for a suitable system:

- Convenient reporting:
- Anonymous reporting:
- Developmental instead of punitive reporting:
- Efficient investigation and finalisation of reported incidents:
- Support and feedback to reporting units:
- Timely incident alerts:
- Strategic decision making and planning based on reported incidents:

The incident reporting and management structures were also targeted for change, because it was already clear that these were not effective and efficient at improving patient safety. In the period prior to the beginning of the research project in January 2008, incidents were handled as disciplinary cases and all the steps involved in the reporting, investigations and decisions were aimed at ensuring that the parties that were responsible for the incidents were successfully disciplined. This led to backlogs of disciplinary cases awaiting investigation and prosecution.

Apart from creating backlogs, the punitive approach was found to discourage professionals from reporting incidents and also made them reluctant to share these experiences. The "just culture" approach was at this point recommended. The just culture encourages the reporting of incidents by professionals but holds them accountable for their professional ethics and behaviour. This just culture was introduced through a series of strategic decisions and activities, which included the following:

- The release of an internal memo informing all the personnel in the department that they are encouraged to report incidents and that none of them would be penalised for the reporting of incidents;

- The reporting of incidents will be considered a strong mitigating factor even in instances where there was a human error;
- The release of this memo was supported by both the administrative and political heads of the department;
- A series of workshops on patient safety related topics were conducted throughout the province; and
- An overall amnesty was declared on all the outstanding disciplinary cases at that point in time

The structure for reporting and managing adverse events was also changed in order to improve patient safety. There was a decision to appoint patient safety champions at a unit level, ward level and hospital level. A decision was taken to establish hospital-, district- and provincial structures for the reporting and management of reported incidents. These structures were renamed and given the function of encouraging reporting and feedback on reported incidents as well as disseminating lessons learned. These structures also performed the role of monitoring and evaluation of the different recommended interventions aimed at improving patient safety.

The leadership and governance of patient safety is another area that was targeted for change in order to improve patient safety. The previous leadership and governance approach placed a lot of reliance on the CEOs of hospitals in order to manage the reported incidents effectively. The new approach ensured that the accountability chain ended with both the political and administrative heads of the department. This process also involved doing a stakeholder analysis and determining the response of the various stakeholders to the change initiatives and developing an approach for each of the identified stakeholders.

7.2.1.4 Testing and implementation

Once the areas that were targeted for change were identified, the next step was to test and implement the various interventions that were aimed at improving patient safety. This critical step involved testing whether the various interventions were effective while fine tuning the planned interventions through a cyclical plan, do, study, act. This process therefore involves implementing the interventions, reviewing them; making the necessary changes; and feeding back to the planning process.

7.2.2 Classification framework:

An incident reporting system requires certain basic information about the incident that is being reported. This set of data is about what happened. Where and when did it happen? Who was involved? What were the contributory factors? This basic information forms the basis of the many incident classification systems. There have been many attempts to develop a single universally accepted incident classification system with limited success, given the number of the actors and the vested interests they often have.

The WHO through its World Alliance for Patient Safety has been instrumental in the development of patient safety classification frameworks such as the International Classification for Patient Safety (ICPS). This classification framework was developed in different stages by Sherman et al [277] and by Thomson et al [278] through consensus-seeking approaches that were robust and comprehensive. Our model incorporates some of the risk-reduction elements that come from this classification framework.

Woods et al [285] also developed a detailed taxonomic classification of paediatric incidents. This classification system has in the researcher's view limited application outside the clinical discipline of paediatrics; its recommended preventative mechanisms are, however, universally applicable. Chang et al [90] consolidated a number of incident classification systems and proposed a system that had the following broad categories:

- Impact: Outcomes of medical error – extent of the 'harm';
- Type: Visible processes that failed;
- Domain: Setting and patient type;
- Cause: Factors or agents leading to incident; and
- Prevention and mitigation – measures taken to reduce effect of or prevent incident.

Each broad category has its own sub-categories, which results in a comprehensive classification system. In the Free State the information that was captured through AIMS was able to provide all the data that could be utilised in the classification described above. This basic classification was adopted because of its simplicity and practicability.

Figure 7.2 illustrates the classification framework that was utilised to classify reported incidents into broad categories and sub-categories. One of the key purposes for classifying reported incidents is to have sufficient information as soon as possible in order to answer the following questions: What human and system errors led to the incident? Is there something that can be done to alleviate or reduce the harm? What can be done to prevent these incidents from occurring in future? This classification framework was found to be adequate for providing these required answers.
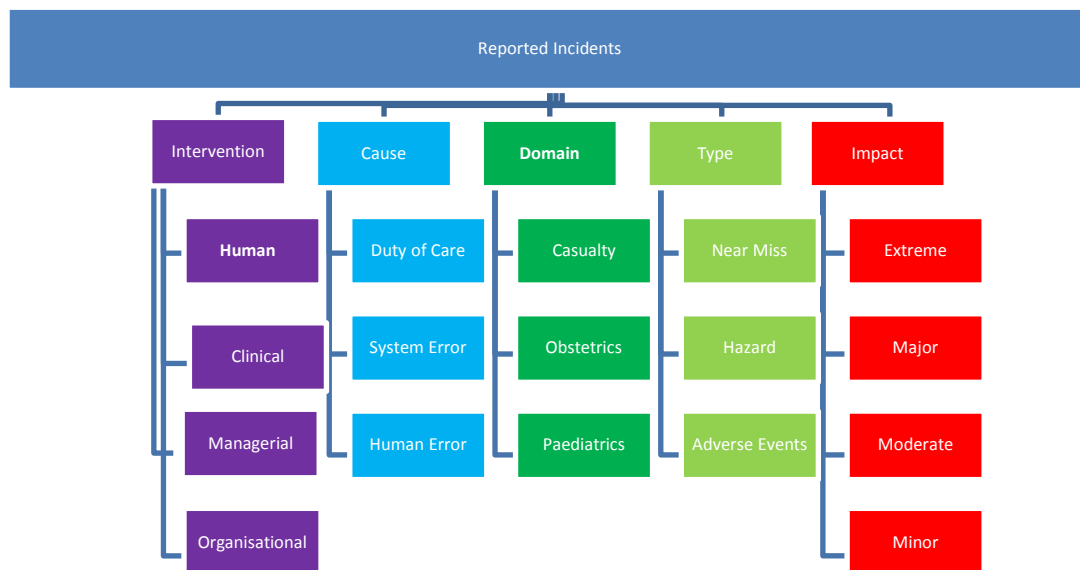
Fig 7.2: Classification of reported incidents by broad and sub-categories

7.2.3 Risk assessment framework

Risk identification is an important part of this model, because once an incident has occurred the individuals, management and the organisation need to actively respond to it. The magnitude and timing of the response to the reported incident is to a large extent dependent on how serious the harm to the individual patient. Risk assessment and analysis also give health system managers a good sense of what incidents are reported most, which ones are serious. Armed with this information the health system managers can develop ideas about what clinical and policy interventions to put in place in order to prevent future incidents.

Several tools are cited in the literatures that are useful in performing risk assessments in a health care environment. Zhan et al [286] believe that administrative data is a useful source of data for risk assessments and is particularly effective when used together with key patient safety indicators. Bonnabry et al [287] describe the Failure Mode Effective Analysis (FMEA) as a qualitative tool that is applicable to health care settings and isolates areas of possible failure in a process and estimates the impact of failure and then develops effective interventions. These authors also describe the Failure Mode Effective Critical Analysis (FMECA) and indicate that it takes this process a step further by quantifying the critical index on the basis of likelihood of occurrence.

What, however, appears to be the state of the art tool for risk analysis in health care settings is the Probabilistic Risk Assessment (PRA) described separately in detail by Marx et al. [288] and Wreathall et al. [289]. Both authors support the superiority of this tool over both the FMEA and the FMECA on the basis of its ability to analyse multiple incidents that lead to a single poor outcome and its applicability beyond a small unit in a health facility.

The Free State Department of Health instead adopted a tool that was developed and used by the New South Wales Health authorities in Australia, known as the Severity Assessment Code Matrix [230]. This tool was chosen over others because of its

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simplicity, practicality and affordability and because we could not afford the software and expertise that is required to implement the other systems in a developing country setting as ours.

The SAC comprises the three components set out below that should be seen as a set of steps in a process

Step 1: Consequence Table

This table has described reported incidents in terms of their impact or harm in the same way that we did in our classification as serious, major, moderate, minor and minimum. These reported incidents are also mapped against whether there is clinical or corporate harm. Clinical harm involves patients and corporate harm includes staff, services, the environment and finances. Numerous examples are then cited to give guidance to users, in terms of where the various reported incidents can be placed. The key components of consequence table are illustrated as Table 7.1

Step 2: Likelihood table

This table provides clear guidelines regarding the likelihood of the harm occurring. There are six categories of likelihood that are described such as frequent, likely, possible, rare and unlikely. All these categories are clearly defined in the table which also offers easy guiding steps. This table is illustrated as Table 7.2.

Step 3: SAC matrix

Table 7.3 represents a mapping of consequences against the likelihood of their occurrence. This cross-matching exercise results in a coding system that identifies the risk associated with each reported incident. The following codes are a product of this cross-matching risk assessment exercise:

1. Red represents Safety Assessment Code or SAC 1: Extreme risk
2. Orange represents Safety Assessment Code or SAC 2: High risk
3. Yellow represents Safety Assessment Code or SAC 3: Medium risk
4. Green represents Safety Assessment Code or SAC 4: Low risk

Step 4: Action required table

This is the last step in this risk assessment framework and dictates the type of response required for each reported incident. There is a specific suggestion in terms of what needs to be done per risk category. The appropriate response indicates the type of investigation required, and may even indicate the level and speed of managerial response. This is not an inflexible system and different provinces or countries can develop their own appropriate response. This table is illustrated below as Table 7.4.

Not all reported incidents are adverse events; there are near misses as well as hazards. The application of this risk assessment matrix is applicable to all these incidents, while for the adverse events the analysis will reflect the actual SAC rating. For hazards and near misses it will reflect the potential SAC rating. The development

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of the final patient safety intervention, whether it is alleviative or preventative in nature will to a large extent be determined by this type of differentiation.

STEP 1: Consequences table 7.1

		Serious	Major	Moderate	Minor	Minimum
CLINICAL CONSEQUENCE	Patient	Patients with **Death** unrelated to the natural course of the illness and differing from the immediate expected outcome of the patient management or: ■ **Suspected suicide**[1] ■ **Suspected homicide**[2] or any of the following: **The National Sentinel Events** ■ Procedures involving the wrong patient or body part ■ Suspected suicide in hospital ■ Retained instruments ■ Unintended material requiring surgical removal ■ Medication error involving the death of a patient ■ Intravascular gas embolism ■ Haemolytic blood transfusion ■ Maternal death associated with labour and delivery ■ Infant discharged to the wrong family	Patients suffering a **Major permanent loss of function (sensory, motor, physiologic or psychological)** unrelated to the natural course of the illness and differing from the expected outcome of patient management or any of the following: ■ Suffering significant disfigurement as a result of the incident ■ Patient at significant risk due to being absent against medical advice ■ Threatened or actual physical or verbal assault of patient requiring external or police intervention	Patients with **Permanent reduction in bodily functioning (sensory, motor, physiologic, or psychological)** unrelated to the natural course of the illness and differing from the expected outcome of patient management or any of the following: ■ Increased length of stay as a result of the incident ■ Surgical intervention required as a result of the incident	Patients requiring **Increased level of care including:** ■ Review and evaluation ■ Additional investigations ■ Referral to another clinician	Patients with **No injury or increased level of care or length of stay**
	Staff	Death of staff member related to work incident or suicide, or hospitalisation of **3** or more staff	Permanent injury to staff member, hospitalisation of **2** staff, or lost time or restricted duty or illness for **2** or more staff or pending or actual WorkCover prosecution, or threatened or actual physical or verbal assault of staff requiring external or police intervention	Medical expenses, lost time or restricted duties or injury / illness for **1** or more staff	First aid treatment only with no lost time or restricted duties	No injury or review required
	Visitors	Death of visitor or hospitalisation of 3 or more visitors	Hospitalisation of up to 2 visitors related to the incident / injury or pending or actual WorkCover prosecution	Medical expenses incurred or treatment of up to 2 visitors not requiring hospitalisation	Evaluation and treatment with no expenses	No treatment required or refused treatment
CORPORATE CONSEQUENCE	IV IC	Complete loss of service or output	Major loss of agency / service to users	Disruption to users due to agency problems	Reduced efficiency or disruption to agency working	Services: No loss of service
	Financial	**Loss of assets** replacement value due to damage, fire etc > $1M, **loss of cash/investments/assets due to fraud, overpayment or theft >$100K or WorkCover claims > $100K**	**Loss of assets** replacement value due to damage, fire etc $100K-$1M, **loss of cash/investments/assets due to fraud, overpayment or theft $10K-$100K or WorkCover claims $50K-$100K**	**Loss of assets** replacement value due to damage, fire etc $50K to $100K **or loss of cash/investments/assets due to fraud, overpayment or theft to $10K**	**Loss of assets** replacement value due to damage, fire etc to $50K	No financial loss
	Environment	Toxic release off-site with detrimental effect Fire requiring evacuation	Off-site release with no detrimental effects or fire that grows larger than an incipient stage	Off-site release contained with outside assistance or fire incipient stage or less	Off-site release contained without outside assistance	Nuisance releases

STEP 2: Likelihood table [Table 7.2]

Probability Categories	Definition
Frequent	Is expected to occur again either immediately or within a short period of time (likely to occur most weeks or months)
Likely	Will probably occur in most circumstances (several times a year)
Possible	Possibly will recur – might occur at some time (may happen every 1 to 2 years)
Unlikely	Possibly will recur – could occur at some time in 2 to 5 years
Rare	Unlikely to recur – may occur only in exceptional circumstances (may happen every 5 to 30 years)

STEP 3: SAC matrix [Table 7.3]

CONSEQUENCE					
	Serious	Major	Moderate	Minor	Minimum
Frequent	1	1	2	3	3
Likely	1	1	2	3	4
Possible	1	2	2	3	4
Unlikely	1	2	3	4	4
Rare	2	3	3	4	4

(LIKELIHOOD shown vertically on the left)

Every incident assessed against the Severity Assessment Code Matrix should be scored separately for both their actual and potential consequence or outcome

STEP 4 Action required table [Table 7.4]

Action Required	
1	**Extreme** risk – immediate action required – Reportable Incident Brief (RIB) for all SAC 1 incidents must be forwarded to the DoH within 24 hours. A Privileged Root Cause Analysis (RCA) investigation must be undertaken for all Clinical SAC 1 incidents with a report being submitted to the DoH.
2	**High** risk – need to notify senior management. Detailed investigation required. Ongoing monitoring of trended aggregated incident data may also identify and prioritise issues requiring a practice improvement project.
3	**Medium** risk – management responsibility must be specified – Aggregate data then undertake a practice improvement project. **Exception** – all financial losses must be reported to senior management.
4	**Low** risk – manage by routine procedures – Aggregate data then undertake a practice improvement project.
NB – An incident that rates a SAC 2, 3 or 4 should only be reported to the DoH if there is the potential for media interest or requires direct notification under existing DoH legislative reporting requirements or NSW DoH Policy Directive.	

7.2.4 Analytical framework

The analysis of reported incidents following risk assessment is based on the logic that in order to provide safe care one should prioritise the elimination of the extreme and high-risk incidents. The classification of incidents by the severity and type provides information that gives insights about their root causes. These insights provide a basis for investigation and analysis of these reported incidents. The development and implementation of effective and sustainable interventions to improve patient safety is highly dependent on the quality of the analysis provided.

7.2.5 Investigative framework

The causes of reported incidents are sometimes complex and not intuitively clear from the information provided. These complex incidents often require detailed investigations in order to determine the causes and some of the factors associated. The decision about the depth of investigation that is applicable to each reported incident is a very important and strategic one. Through discussions with key managers in the Free State Department of Health, it was agreed that given the resource constraints that we operated under and to ensure that the investigative processes are effectively and efficiently done, we will subject only the following reported incidents to investigations:

- Complex incidents where there are poor outcomes but the causes are not clear;
- Incidents where there was extreme or severe harm leading to permanent disability and / or death; and
- Minor incidents with a high reporting frequency

In terms of the risk assessment tool that was described above, in-depth investigations are reserved for the extreme and high-risk SAC 1 and SAC 2 reported incidents in Free State hospitals. Other incidents that we agreed needed in-depth investigations were the complex and difficult to classify reported incidents, which we referred to as duty of care incidents or DOCI. The reported incidents that were classified as medium to low risk are only subjected to in-depth investigations if they are repetitive. This type of incident is usually subjected to routine investigations. This prioritisation has ensured that we are able to focus our energies and resources on the most critical incidents.

This investigation framework is illustrated in Figure 7.3.
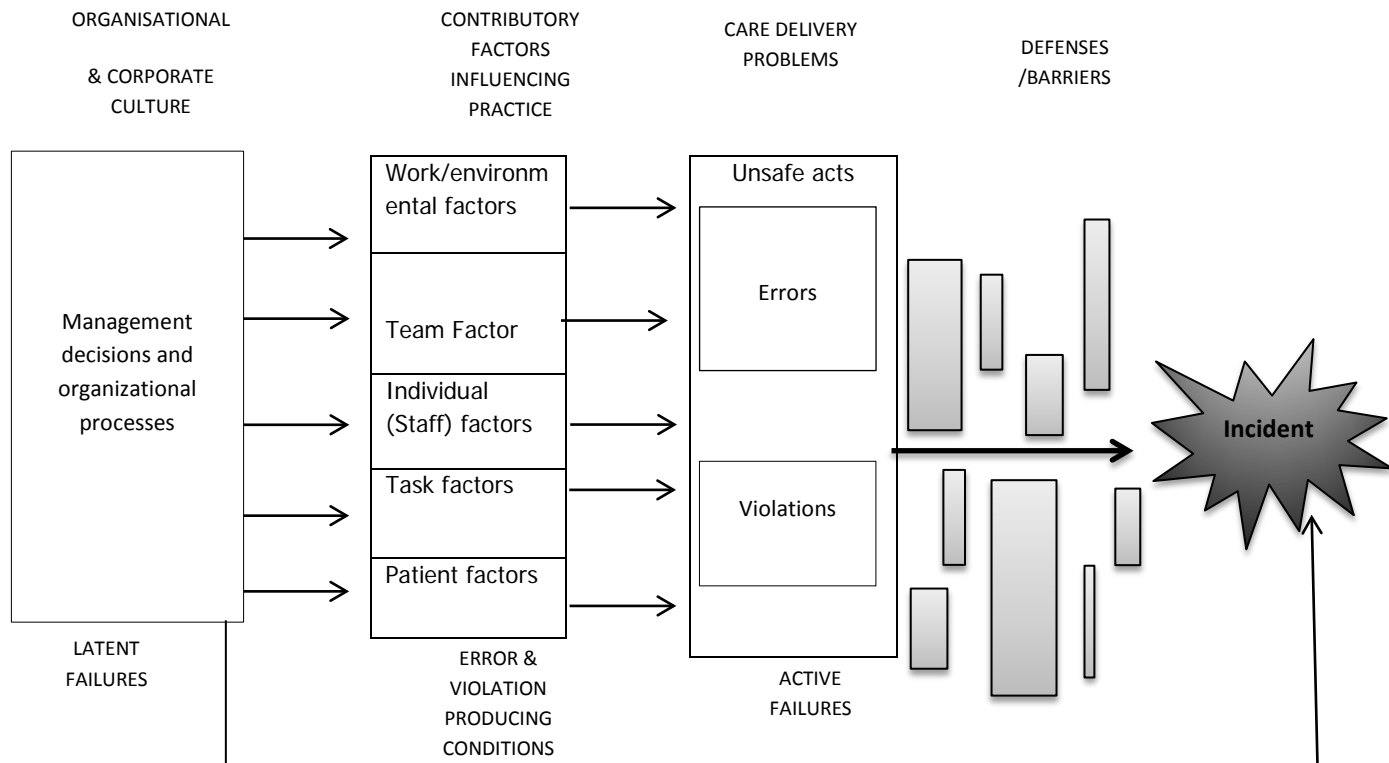
Figure 7.3 : Investigative framework adapted from Reason

The tool that the Free State Department of Health chose to use for in-depth investigations is the Root Cause Analysis (RCA) [234]. This approach to incident investigation is an adaptation of the accident approach used by other high-risk industries such as nuclear, petrochemical and aviation. The tool makes use of document- and audio-visual review, on-site inspections, equipment examination and in-depth interviews with personnel. The tool also provides a structured approach that ensures that no key investigation steps are skipped.

The RCA is usually undertaken by an external multidisciplinary team that includes specialists in the involved domain, nursing managers, clinical engineers, quality managers and executive managers. In the Free State Department of Health the training of these teams was prioritised and occurred before the reporting system went live at the intervention sites in January 2008. Each of the five districts had a pool of trained professionals out of which three teams could be assembled to investigate incidents as and when they were required to do so.

In the assembly of the teams for the investigation of an incident great care was exercised to ensure that one did not nominate the same individuals for the same team. This was done to ensure that teams remained as objective as possible and that the group affiliation was minimised. Members were also not allowed to be part of the team that would be investigating their own institution, in order to ensure that objectivity was maintained.

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The details of the approach adopted by the Free State Department of Health is based on the accident investigation and analysis process flow chart developed by Woloshynowych et al [290] for the National Health System in the UK. This approach that is illustrated in Fig 7.4 identifies the following key steps in incident investigation:

- Planning the investigation
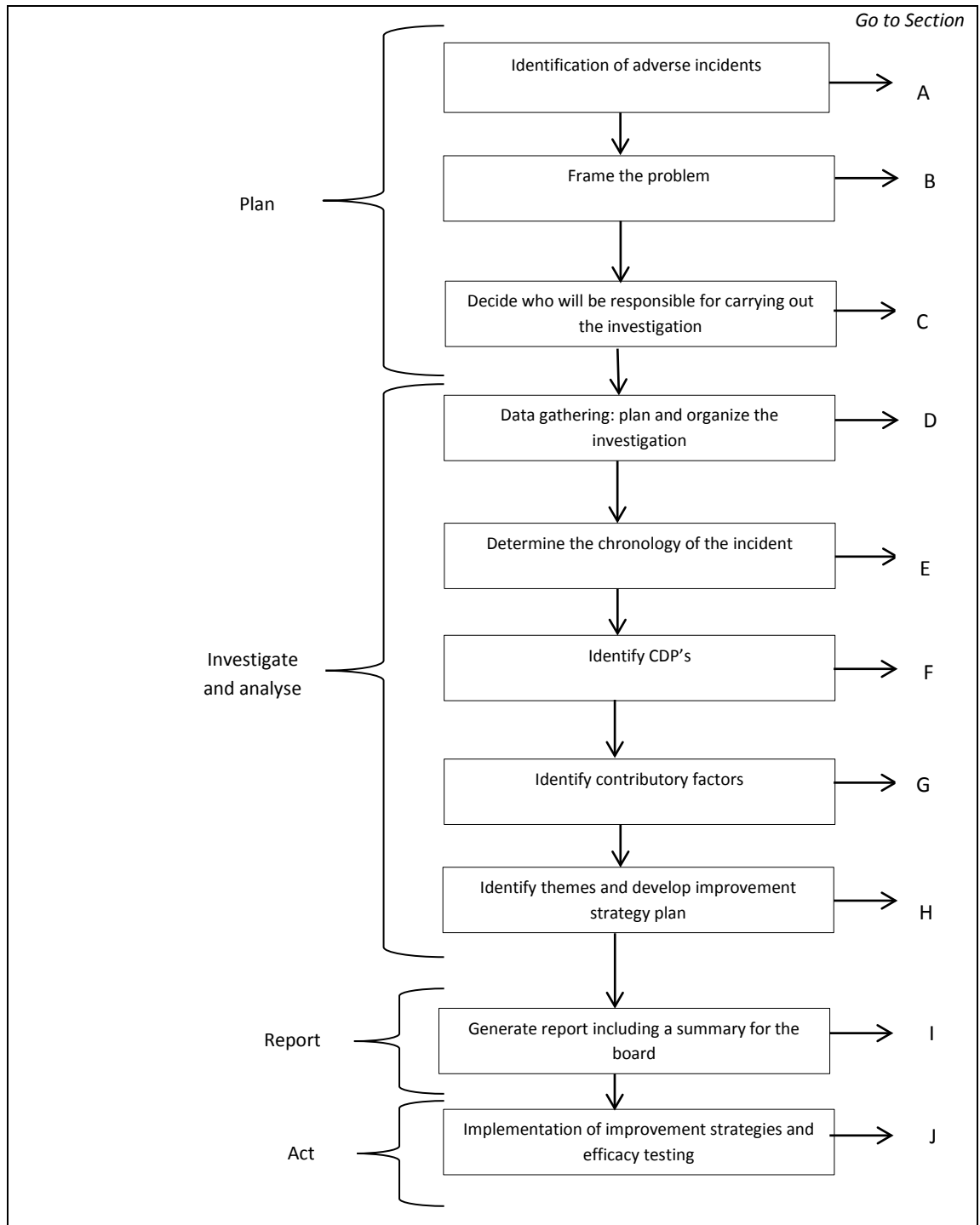- Investigation and analysis
- Report
- Action

Fig 7.4: Investigative process

This structured approach ensures that there is a comprehensive investigation of reported incidents. In the Free State we have adopted the investigative approach that is proposed by Vincent et al [291], who begin by identifying care management problems then examine the contributory factors to unsafe care before they determine the influence of the organisational and corporate culture on adverse events. This approach ensures that there is a comprehensive investigation of the reported incidents from the coal face to the corporate level in the system.

The major difficulty with the implementation of this investigative framework is the time, the skills and the costs that are required. In a resource-constrained environment this challenge can slow down or corrupt the processes and lead to incomplete or badly investigated incidents and inappropriate or late interventions.

7.2.6 Intervention framework

The interventions to improve patient safety are closely linked to the investigations so that the nature and causes of reported incidents can be determined. It is therefore not surprising that the intervention part of the framework places heavy emphasis on the causes of unsafe care. We have used a framework developed by Reason [220] in order to define the type of intervention and where it should be targeted. The framework illustrated in Figure 7.5 recognises that all incidents emanate from organisational decisions, an unsafe workplace, staff providing unsafe care or a lack of incident-prevention policies, protocols and guidelines or a combination of these. This incident causality model developed by Reason [220], also means that interventions aimed at improving patient safety will, after they have been revealed by the investigations, be directed at the same areas or combination of areas that have been identified.
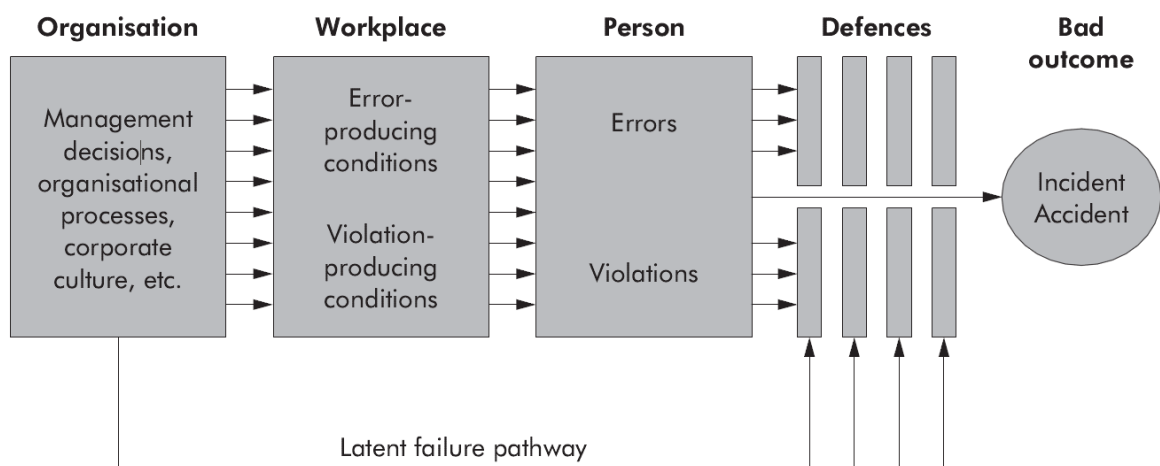
Fig 7.5: Reason's framework for organisational incidents

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Evidence exists that human beings and their inability to deal with continuity of care gaps are contributors to a large number of incidents [132,265,292].There is, however, evidence that demonstrates that systems failure is responsible for the majority of unsafe care incidents [62,176]. It is therefore important in the management of incidents to be able to distinguish between human factors and system factors that have contributed toward the incident. There is also a tendency to immediately suspend the personnel that is involved in the incident while an incident is being investigated. This often impulsive suspension of personnel has been found to be very costly and demoralising, especially where there are already staff shortages. A more cost-effective and humane solution has been to temporarily transfer the involved individuals to other sections under supervision until the investigations have been completed.

The incident decision tree [235], illustrated in Figure 7.6 was developed by the NHS in order to deal with the fate of health professionals that are involved in incidents and also to separate human failures from system failures. This log-frame was adapted from the culpability tree that is used in other high-risk industries such as aviation, nuclear and petrochemical.

Figure 7.6: Incident decision tree

The incident decision tree is an algorithm that seeks to determine the four key features of a reported incident in order to determine the extent of human factor involvement. These features are in the form of tests that comprise of a set of questions which are answerable by a "yes" or a "no", Depending on the answer a further set of questions follows until a final verdict is reached. The features that are being tested for in the incident decision tree are:

a. Deliberate Harm Test: This determines if the actions and consequences were intended;
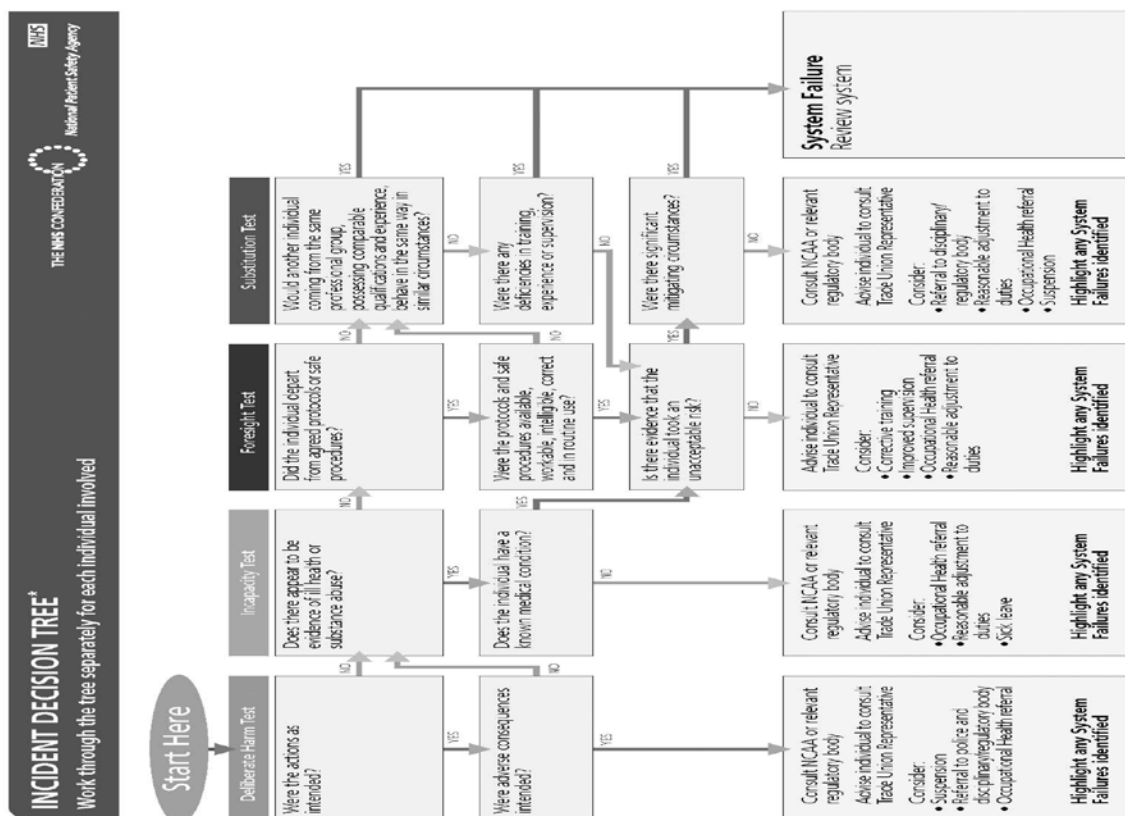b. Incapacity Test: Determines if the professional is on drugs or has a medical condition that would have contributed to his or her behaviour
c. Foresight Test: Determines if there was a deviation from protocols and guidelines, whether these were in use and available, and whether there was unacceptable risk taking
d. Substitution Test: Determines if another professional having similar qualifications and experience would have responded in a similar fashion to the incident or not

In the absence of deliberate harm and incapacity and where there was good foresight and personnel acted appropriately, the reported incident is deemed to be a system failure. The failure of any of the tests posed indicates human failure and the appropriate sanctions are recommended. It is, however, important to note that the causes of many incidents are usually a combination of human and system failure. This means that in cases where human failure has been identified, a need to determine the contribution of systems still exists. It is also important to note that the decision tree has to be applied to all the personnel involved on an individual basis in order to formulate appropriate interventions aimed at improving patient safety.

In closing the loop of the model, it is important to note that in the implementation of alleviative or preventative interventions both at a system level and human level, the quality planning and improving framework was used. The Plan, Do, Study, Act or PDSA framework that we started with is again utilised for the implementation of these key interventions. The patient safety interventions will have an impact on the number, type, severity and the risk profile of the reported incidents.

7.3 Putting the model together

In 2001 the Free State was one of the first provinces in South Africa to adopt and enrol its public sector hospitals into the COHSASA facility accreditation programme. This enrolment came out of the realisation that the quality of health care services that was provided by some of these hospitals was sub-standard. This programme resulted in increased awareness of and enthusiasm for quality improvement and a number of our hospitals have achieved accreditation status. Despite these achievements, it was noticeable that there was an increase in the frequency and numbers of legal claims against the department based on clinical incidents and complaints.

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At the time when there was consideration of implementing an incident reporting system in the Free State, there was: an increase in the backlog of unresolved disciplinary cases; an increase in the infant mortality rate; and increase in the under-5 and maternal mortality rates. This meant that despite our best efforts to improve quality, the Department of Health was still faced with mounting complaints of unsafe care and unrelenting negative media attention. This situation, therefore, called for a major intervention in order to improve patient safety and health care quality.

Some of the key processes apart from the incident reporting system that were put in place as part of the patient safety improvement programme on which this model is based included the following:

- Conversion from the pre-research incident reporting and management system to the AIMS-related system;
- Implementation of management interventions aimed at improving patient safety and overall quality of health care; and
- Implementation of interventions for climate and safety culture improvement.

7.3.1 Conversion from the paper-based incident reporting and management system to AIMS

This was one of the most important intervention steps in the research and represents some of the fundamental mind-set shifts that are part of this effort to improve patient safety. The paper-based incident reporting system is the system that the Free State Department of Health had been using prior to the introduction of AIMS in January 2008. This system had been in use since the years leading up to 2003, when it was formally recorded as a departmental policy. We will focus on the following key features of the conversion:

- Philosophical approach;
- Reporting, investigation and management of incidents; and
- Structures put in place to manage incidents

7.3.2 Philosophical approach

The underlying philosophy of the paper-based incident reporting and management system was to establish that an incident had occurred, to determine who was responsible for it and then take the appropriate disciplinary action to punish the culprit. This philosophical stance was drawn from the approach espoused by the statutory or professional bodies such as the South African Nursing Council (SANC) and the Health Professions Council of South Africa (HPCSA), that incidents and adverse events occur as a result of negligence by professionals, and that once such negligence has been apportioned to the right individual, then appropriate punitive action is the acceptable remedy for the situation.

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SANC sees its main role as protecting the members of the public in matters involving nursing health care services. The Nursing Act and Regulations [294,295] exist to define practice standards and what is unprofessional and punishable behaviour. The HPCSA, through the Health Professions Act [296] defines its role as setting and maintaining educational and professional standards and exists primarily to protect the members of the public against unprofessional behaviour by doctors and other professionals. This is also evident in the Professional Conduct Matters Report of 2012, that the council is very active in disciplining professionals for what could be described as medical errors [297].

This approach, which does not fully consider the fact that incidents and adverse events occur as a result of interactions between complex human behaviour, technology, socio-cultural factors and procedural and organisational failures [10], has been found to have many shortcomings. This person-centred approach endorses the view that incidents and adverse events occur as a result of carelessness, inattention and negligence by professionals in the course of providing health care services and inadvertently also the view that the systems that have been put in place for health care delivery are perfect and, therefore cannot, be blamed for any adverse event.

The iconic "To err is human: creating a safer health system" report [71] asserts that human error is inevitable, because human beings are fallible and errors in health care are in many instances a product of organisational and system shortfalls. The advocates of the systems approach [298,299,300] insist that analysis of incidents and adverse events using the approaches that have been used in the numerous disasters of other sectors and industries will provide long-lasting lessons for the health care sector and, if the systems approach is appropriately used, it will improve patient safety.

AIMS is part of the philosophical approach that advocates for the collection of data from incidents and adverse events, subjects it to a detailed analysis in order to determine the systems, technology, human and organisational factors that are responsible for them, and then develop interventions to correct these shortfalls. This was the first and the most important philosophical shift or mind-set shift that the Free State Department of Health had to undergo before the implementation of AIMS. This mind-set shift was achieved through a series of workshops at provincial and district levels, whose aim was to address the core issues embedded in this systems approach.

Some of the issues that were discussed in the workshops included, but were not limited to: the following:

- Anonymous reporting of incidents;
- Reporting and just culture;
- Unprocessed disciplinary cases; and
- Dealing with the legal system and the professional bodies

Although these issues were discussed and assurances given to individuals that they would not be punished as a result of reporting incidents and adverse events, this assurance needs to be given on a continuous basis.

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This new approach was seen to be developmental and supportive of the reporting of incidents and adverse events and as a platform by others to voice their displeasure at the health care systems.

7.3.3 Reporting, investigation and management of incidents

These are the processes that are undertaken to minimise the negative impact of incidents and adverse events to all the parties that are involved and includes rehabilitative care. The processes extend from the clinical site where the incident occurs to the highest level in the organisation.

The era of the paper-based incident reporting system was characterised by an absence of guidelines and protocols for responding to incidents and adverse events. The response was largely left to the treating clinicians together with the managerial personnel to respond to the incident. This resulted in a varied and ad hoc response by the various personnel and facilities to the incidents.

This inconsistent way of dealing with incidents and adverse events led much dissatisfaction from families and patients who were victims of unsafe health care practices. This meant that enquiries and complaints by patients and their families were inadequately responded to and this led to lawsuits and other retaliatory actions by despondent members of the public. The introduction of AMCu also brought with it the standardised manner of responding to incidents and adverse events, which was adapted from the Harvard hospitals consensus statement [301].

One of the key factors in the response that in many instances influences the final decision of whether the victim of the incident or adverse event will accept the final outcome or will take the department to court is communication. This refers to communication with the patient, family, and other clinicians; how open, empathetic and factual it is; its timing and how it is perceived by the patients and family. In many instances, if the family and patients feel ignored, that information is being hidden from them, that officials are not honest or empathetic; they will become angry and will be confrontational and retaliatory in their approach. Training, standardisation and development of these communication skills is crucial for the successful management of these adverse events.

During the era of the paper-based system the management of adverse events and clinical governance was given to committees that comprised individuals who had an interest in them for various reasons. Not all these individuals were decision makers at institutional level; they were instead mainly nurses who were patient advocates by profession and used whatever little influence they had to advance the case for patient safety and, by all accounts, these advocates remained largely ignored.

These voices that were located in many committees at hospital, district or even at provincial level had no direct channel to the leadership of the organisation. The issues of patient safety were largely seen as a medico-legal issue and not a strategic priority for the organisation at all. They were not part of the strategic or operational plans of the department and there was no mention of patient safety and quality in the

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performance agreements that were signed by senior managers dealing with clinical issues.

In order to change this situation and elevate this important subject of patient safety and health care quality to a higher level in the organisation, the following initiatives were undertaken:

- Member of the Executive Council for Health (Provincial Minister for Health) was convinced to approve a submission that declared an amnesty on all outstanding disciplinary cases and to declare that new reported incidents were to be treated using the revised developmental approach.
- The Head of Department of Health signed a declaration that encouraged officials to report incidents and adverse events and that stated that no one would be punished for reporting incidents. This declaration was also adopting the just culture, which encourages individuals to be professionally responsible and accountable for their patients but adopts a system-based approach towards managing incidents and adverse events.
- Patient safety indicators made their way into the strategic plans of the department and the performance agreements of senior leadership of the organisation have patient safety as one of the key performance indicators.
- CEOs of hospitals and district managers are now compulsory members of the local, district and provincial adverse event and clinical governance structures. This means that they can implement the recommendations that are results of the deliberations made by these structures, where they are directly involved.

These initiatives have ensured that patient safety and quality of health care have taken their place amongst the strategic priorities of the Free State Department of Health and this has happened as part of the implementation of the AMCu interventions.

The additional details of the structures and the processes that were reformed as part of this patient safety programme are described in detail in Chapter 4. The incident reporting and management structures that were linked to the paper-based reporting system were abandoned when the new reporting and management structures that were conducive to the effective implementation of AIMS, were introduced.

7.4 Implementation of management interventions aimed at improving patient safety and overall quality of health care:

The management interventions aimed at improving patient safety and overall quality emanate from the discussion, investigation and finalisation of each incident at the various levels (institutional, district and provincial). In order to illustrate this further, let us use the following incident as an example:

Incident No: 1768   Date: 2008/11/05

"Patient starved for prolonged period due to operation being cancelled. Patient was kept NPO from 22H00 on 2008/11/04.   After 16:00 on 2008/11/05 the theatre

informed the ward staff that the operation was cancelled due to time constraints. Case was rescheduled for 2008/11/06".

The above-mentioned incident was classified as an adverse event as the patient was harmed [unjustified prolonged starvation, anxiety of cancelled procedure]; it was a system error due to poor planning and communication between the theatre and the ward and was attributed to the clinical personnel in charge of patient care.

The recommended interventions to improve patient safety and health care quality were:

- Develop and implement a booking and cancellation protocol for theatre patients;
- Communicate with patients all the time to explain unanticipated delays;
- Improve communication between theatre and surgical holding ward; and
- Improve patient scheduling in theatre.

These interventions were then entrusted with CEOs to implement in their hospitals in order to prevent a similar incident from occurring.

In the above discussions we have outlined the process that was undertaken by the Free State Province in developing a patient safety programme. We have provided detailed discussions on the various approaches and decisions that were adopted at the various stages of development of the model. More importantly we have provided the various frameworks that form the scientific and theoretical basis for the model that has been developed and implemented in the Free State province. We also firmly believe that this model works and the successful implementation of the interventions and the results that were reported for the research project prove that.

In the following section 7.5 we now put all the different components or frameworks of the model so that it can be viewed in its entirety. A basic simplified version of the model is represented by Figure 7.7.

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Figure 7.7: Free State patient safety risk reduction model

The above illustration outlines the various components of the model and how they are inter-linked. The planning framework was used to determine what interventions need to be put in place in order to improve patient safety. The key intervention that emanated from this process was the implementation of an incident reporting system. The main product of this part of the model is the reported incidents.

The reported incidents are then subjected to the classification process that was described in detail in the classification framework discussions. The product of the classification process is the detailed classification of the incidents into broad and sub-categories. The next step in the development of the model is the risk-assessment process using the SAC rating tables. The results of this risk assessment will be the risk ratings of the various reported incidents.

The reported incidents that have been rated as having an extreme- or high risk is subjected to a root cause analysis by an external multi-disciplinary team of trained experts. Included in this group there are also the complex DOCI incidents that are subjected to both the root cause analysis and the incidents decision tree. The reported incidents that are rated as moderate or minor risk are handed over to the institution for a quick routine internal investigation.

The investigations will reveal the causes of these reported incidents and the developed interventions will be specifically aimed at addressing them in a comprehensive and sustainable manner.

In broad terms there are three types of interventions: those that are aimed at addressing the system defects; those that are aimed at addressing human errors; and a combination of the above.

In order to develop effective interventions it is important to distinguish between system defect and human errors as human beings will be involved in many of these incidents irrespective of the root cause. The incident decision tree analysis is a tool that provides for this differentiation between human error and system defect. It is, however, important that all the personnel involved in the incident are subjected to this process, so that there is fairness in the manner of addressing events and also for determining the different interventions required for each individual.

7.5 Lessons learned

There are several factors which the author believes were important for the success of the study and the patient safety improvement programme in the Free State. The identification of these factors is based on the author's experience in managing this research project and the many discussions that have occurred between the author and key officials in the Free State Department of Health. The following factors were identified as key learning points in the implementation of the patient safety programme in the Free State Department of Health:

7.5.1 Political and administrative support

There was considerable support for this programme by both the political and administration leadership in the Free State Department of Health. This support was based on the premise that the patient safety programme would save lives and improve the overall health outcomes for the province. Improving health outcomes is one of the more important and recognised goals of many health systems.

This leadership support was demonstrated by the endorsement of the following 2 key decisions by both the MEC and HOD for Health in the Free State:

- Granting of amnesty and the scrapping of all misconduct cases that were in process prior to the implementation of the study in 2007.
- Approval to adopt the "just culture" as an approach to managing incidents and adverse events.

The endorsement of these decisions gave professionals sufficient confidence that while they would be held accountable for their professional conduct, they would not be punished for reporting incidents. The declaration of patient safety as a key priority by the Minister of Health in 2010, further landed support for this study and the patient safety programme.

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7.5.2 Health care services delivery crisis

The poor health outcomes that were prevalent at the beginning of the study in 2008; the high number and severity of adverse events that were reported ; and the high settlement fees for the lawsuits against the Free State Department of Health convinced everyone that drastic and serious action needed to under-taken to address this crisis. This crisis in service delivery provided an excellent point of entry for the study proposal aimed at improving patient safety and health outcomes. This was one of the key success factors for the implementation of the patient safety programme.

7.5.3 Focusing on health outcomes

The new political administration that was inducted in 2009, presented a long term strategic approach that placed more emphasis on outcomes rather than inputs, outputs and processes across the various sector service delivery programmes. In the health sector this meant focusing on the improvement of health outcomes including morbidity and mortality rates. This had a synergistic effect on the study and the patient safety programme in the Free State.

7.5.4 Training, communication and feedback

The training workshops that were conducted in 2007 to provide a theoretical background to the patient safety programme; to address patient safety operational challenges and to discuss the importance of implementing a patient safety programme in all hospitals in the province, made a huge impression on the clinical staff on the ground. These training sessions provided an in-depth understanding of the patient safety challenges and practical solutions to address them. It also became apparent that these training sessions played a major role in the motivation of both management and clinical personnel in hospitals.

The communication networks that were developed through the structures and meetings that were established in order to drive the patient safety programme, assisted in the dissemination of key information between different parties during the study. These communication channels were used to update key officials in the state of patient safety in the province, new policy initiatives on patient safety and sharing best practices between different branches of the department.

The regular feed-back that was provided to facilities on the classification, analysis and investigation of their reported incidents further served to motivate the personnel. These feed-back sessions also provided specific recommendations on how some of the reported incidents can be addressed. The role of communication in keeping people informed; addressing queries and supporting the implementers on the ground cannot be over-emphasised.

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7.6 Conclusion

The development of a hospital-based patient-safety risk-reduction model for the Free State is one of the most important outputs of this research project. In the above section, we have attempted to describe in detail the theoretical underpinnings of the Free State approach, the key decisions that were taken that have a bearing on the "model", the development of the safety and just culture within the organisation and the processes that this entailed. The researcher and the management of the Free State Department of Health are convinced that this model has indeed reduced patient safety risks at its hospitals. We also believe that this model can, with a few adaptations, be used successfully by any province or country that is providing health care in a resource-constrained environment.

CHAPTER 8: Study recommendations

8.1 Introduction:

This chapter is specifically devoted to the presentation of the study recommendations. A variety of recommendations will be made in this section; some will be based on what can be done additionally in the province or the country in order to get the maximum benefits from the findings of the study. There will also be specific patient safety recommendations that are directed at the Free State Department of Health, who will be tasked with their implementation. Other recommendations will address design and methodological issues in order to support future studies in this area of knowledge.

8.2   High-level recommendations:

8.2.1 Free State province to continue to invest in AIMS

The successful demonstration that the computerised incident reporting system can be implemented in a developing country setting and that it can make a meaningful contribution towards the development of a patient safety programme gives a clear signal to the Free State Department of Health that it should continue to invest in a system of this nature. This recommendation is not necessarily promoting the specific system known as AIMS [68]. Any generic reporting system that has the same basic properties as the system that was used in this study can be implemented. The province may use the technical specifications of AIMS in order to search for an equivalent but more cost-effective product on the open market. It would also be useful and user friendly if new features such as cell phone alerts were incorporated into the product, given the widespread use of cell phone technology in South Africa.

8.2.2 Extend use of similar system to other provinces

The successful testing of the reporting system in the Free State also means that other provinces could invest in similar systems in order to improve patient safety in the whole of South Africa. It has been demonstrated in other countries such as the USA that once a reporting system has been tested successfully in several hospitals it can be extended to others without great difficulty [302]. The extension of an incident reporting system could easily be co-ordinated by the national ministry, which could address the funding, policy and inter-linking of the different provinces. This project could well be the beginning of the establishment of a national incident reporting system that has been established in other countries such as USA, UK and Australia [303,304,305]. This process should, according to the researcher, be preceded by proper planning, policy development, funding, communication and rigorous project management.

This is potentially one of the projects that could be proposed for piloting as part of the implementation of the NHI [306] in the greater South Africa. The prerequisite for funding as part of the NHI programme, however, will depend on a successful demonstration that this system can improve incident reporting, patient safety and the

overall quality of health care services in public hospitals. The results of this study have already demonstrated that such outcomes can be achieved.

8.2.3 Extend investment to emergency medical services (EMS) and primary health care (PHC).

This study has largely focused on testing and implementing the incident reporting system at hospitals, but the health system extends beyond this setting. The model for the delivery of health care services in South Africa is the district-based PHC approach [307]. There have been strong indications by senior managers in the health system that a great number of incidents that are seen and reported in hospitals emanate from system defects and human errors in the PHC setting.

It would therefore make sense for the reporting system together with all the accompanying enabling activities to be implemented in the primary health care setting. This would address incidents from their sources and this would assist in providing timely effective interventions. The successful implementation of an incident reporting system at a PHC setting has already been demonstrated by Fernald et al [195].

The emergency medical services (EMS) provide a backbone to the health care system referral networks by connecting the different parts of the system. Emergency patients get transferred from one health care facility to the next in order to provide them with life-saving care. There is strong anecdotal evidence that a large number of unreported incidents occur when patients are in transit between hospitals, home or clinics and community health centres before they reach hospitals.

Trzeciak et al [248] have identified the increasingly over-crowded emergency or casualty units in hospitals as one of the main reasons for the increased risks for unsafe care in the emergency medical services, and propose a number of interventions to alleviate the problem. Implementing an incident reporting system in the emergency medical services (EMS) will certainly ensure that incidents are reported and that effective interventions to improve patient safety can be implemented.

The Free State Provincial Department of Health has already extended the incident reporting system to both the community health centres and the emergency medical services. The results for this expansion will be published at an appropriate time in the future.

8.2.4 Develop provincial and national policies on patient safety

The lack of patient safety policies at provincial and national levels was clearly articulated in Chapter 1. During the process of implementing and testing the incident reporting system, the development of the Free State patient safety risk reduction model, the Free State patient safety policy emerged as one of the products. This policy covers a wide area of patient safety processes including: reporting, classification, investigation, analysis, risk assessment and responding to incidents.

This comprehensive provincial policy on patient safety will be shared with other provinces and the national ministry to develop its own. The experiences and expertise gained through this research programme will be volunteered to address these policy defects at a national level and in other provinces. These patient safety policies have been demonstrated in many countries as forming the basis for empowering managers and health professionals in the provision of safe health care.

8.2.5 Epidemiological studies and patient safety

This study is based on the implementation of a reporting system, as a patient safety intervention and is therefore more of an operational study rather than an epidemiological study. The key difference between these two lies in the purpose and the methodology. The methodology followed in our study was extensively discussed in Chapter 4 and will therefore not be repeated here. In order to study the epidemiology of incidents and adverse events, there are several methodologies that have been recommended and these include:

- Retrospective medical record reviews
- Ethnographic studies
- Prospective medical record reviews

Epidemiological studies [79,80,81,82,83,84] are characterised by the measurement of adverse event rates as well as other dimensions of patient safety and a comparison of these rates between various countries. According to Shojania et al [274], it is, however, not possible to measure adverse event rates from a reporting system because: first, you rely on the reported number and kind of adverse events rather than the actual number and kind of adverse events; what is not reported is excluded from the numerator. Second, unless there is a mechanism for separating the adverse events from hazards and near misses, it becomes difficult to accurately measure adverse event rates. Finally, there is also difficulty in determining the denominator for this calculation, in the absence of accurate information about the total number of actual incidents.

It is, however, important for any country to get a sense of the scale of the problem of adverse events in order to mobilise key stakeholders and resources towards quality improvement and patient safety in the same way that the USA [71], Australian [305], UK [10] and other studies were used. It is therefore recommended that an epidemiological study similar to those that were conducted in the USA and UK is conducted in order to bring national focus and interest in patient safety issues. This would particularly be useful immediately after the publication of this report and the possible interest that its content may generate. An epidemiological type of study would follow a different methodology than the one used in this particular study.

8.3 Model-based recommendations

The development of a hospital risk-reduction model for the Free State was one of the key aims of this study. The model that clearly demonstrates how the set of interventions centred around an incident reporting system was used to develop a

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patient safety programme. The successful development of the risk-reduction model set out in the previous chapter is a clear demonstration that, given a similar set of circumstances and contexts, different provinces and countries can use the same model to implement a patient safety programme. Our confidence is derived from the fact that the model is premised on frameworks that have been tried and tested elsewhere, that are based on rigorous thought processes about health system functions and has been proven to work in the Free State. It is, however, important that when provinces or countries use the model that they ensure that the necessary province-related- and country-related adaptations are made.

The lessons learned during the implementation of this patient safety programme are discussed in detail in Chapter 7.

8.4 Design, methodology and further research recommendations

The scope of this study was not aimed at performing a very detailed classification of all the reported incident types, including the duty of care incidents. It has already been indicated that duty of care incidents are by their very nature complex and difficult to classify, unless a detailed investigation of each incident has been conducted by experts. Unless the context, the task requirements and as the skills and competence of the involved personnel are fully understood these incidents cannot be fully classified. This investigation will provide additional insights regarding the nature, causes and possible interventions at both clinical- and policy level.

It is therefore recommended that all the incidents classified as duty of care incidents be further analysed to determine their nature and causes. This kind of study will need to be undertaken as soon as possible, because of the valuable insights that it will provide for necessary patient safety interventions.

The study made use of various surveys in order to determine the effectiveness of various interventions related to patient satisfaction, safety culture and safety climate. Colla et al [309] however, warn us that there are too many of these surveys on the market and that a study of them uncovered that there were significant variances with respect to the strengths of psychometric testing of the different survey tools and that there was often no relationship between the survey results and other health outcomes of the facility. This limitation, therefore, means that these factors need to be taken into account before the surveys are implemented and in the interpretation of their results.

The suggestion and conclusion by Hutchinson et al [239] that increased incident reporting rates by institutions is an indication that those institutions are developing a more positive safety culture is an idea that is intuitive and needs to be explored and tested at an institutional level in the Free State Province to confirm its validity. It is therefore also recommended that the Free State further explore and undertake a research project of this nature because if it can be proven that increased incident reporting is a key performance indicator of a positive safety culture; the monitoring of

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a safety culture will then be carried out through incident reporting rates, for which the facility CEO can be held accountable

8.5 Specific operational recommendations:

In the process of the analysis and interpretation of the results of the various surveys, there were specific areas of concern that gave an indication of health system challenges. Considering that each survey was aimed at eliciting specific responses from the Free State health system, these recommendations are therefore specific to Free State hospitals and are aimed at improving patient safety and overall health care quality. These identified health system challenges are not an indication that the patient safety interventions that are part of the study have failed. These recommendations have already been discussed and agreed upon with the Free State Department of Health and are in the process of being implemented.

There are several researchers who argue that in order to reach sustainable improvement in patient safety from an extended health care platform, the introduction of an incident reporting system alone may not be sufficient.[261,262] These researchers insist that other culture improvement measures such as leadership walk-abouts for patient safety are necessary [261,262]. It is therefore recommended that the Free State Department of Health considers implementing additional interventions such as leadership walk-abouts in order to observe meaningful changes in patient safety

8.5.1 AIMS survey: Recommendations

The overall perceptions of personnel of the effectiveness of AIMS as a reporting system have been positive. These positive personnel perceptions also extended to the question of whether the electronic computerised reporting system was superior to the paper-based system that was in place in the Free State prior to the research. There were, however, serious concerns that were raised with respect to what was perceived as poor managerial support and poor feed-back on incidents reported to AIMS. Ironically this lack of feedback is also identified as an area of poor perception in the safety climate survey. In order to address these challenges, it is therefore recommended that:

1. Management ensures that patient safety becomes regarded as one on the strategic objectives at each hospital;
2. The achievement of patient safety should be reflected in the performance agreements of key hospital and corporate executives; and
3. The leadership patient safety walk-abouts are an excellent vehicle for the hospital executives to assert themselves as champions of patient safety and to provide the necessary feedback on reported patient safety incidents.

8.5.2   Safety climate survey: Recommendations

The overall responses to the safety climate as reported in Chapter 5 appear to be positive. The following interventions are however recommended in order to address the identified challenges:

1. The findings of this research in general and this survey specifically need to be shared with a wider range of key stakeholders in the department, including executive leadership, hospital CEOs, district managers, heads of clinical services and heads of nursing and governance structures. Front-line personnel, medical officers and nursing personnel need to be involved.

2. An effort has to be made to train facility leadership as well as medical officers and nursing personnel in charge of units to listen and address concerns of other health professionals and provide feed-back to them on how the various reported incidents were managed and resolved. This lack of feedback is a lost learning opportunity that negates the usefulness of a reporting system.

3. The briefing between transferring clinicians is standard practice, and there are already indications that that policies, guidelines and protocols are not being followed. An effort to encourage this important safety practice at a ward unit level and between units and facilities has to be made in order to ensure patient safety is improved.

4. There is agreement among senior department officials that a formal investigation has to be undertaken in order to understand the reasons why personnel on the ground are complaining about the lack of availability of clinical leadership at the critical times when their support is required by the junior clinical personnel on the ground. The findings of this investigation should lead to specific sustainable policy and clinical interventions. The investigation should also answer some of the following key questions: are the findings due to a shortage of personnel, lack of leadership and clinical governance training or are they due to fraudulent practices, such as "moonlighting" or all of these?

8.5.3   Safety culture survey: Recommendations

The majority of the findings as reported in Chapter 5 are positive for the successful implementation of patient safety culture. There are, however, areas that need urgent attention patient safety culture is to be improved. The following interventions, which are also a product of joint discussions with the Free State department of Health, are therefore recommended:

1. An effort must be made to create a situation that allows professionals on the ground to be able to ask key questions to their supervisors when clinical incidents occur. This will enable all the key stakeholders to bring matters that affect patient safety into the open in order for these matters to be addressed comprehensively.

2. Regular feedback needs to be provided to the units that have reported incidents and adverse events in order to ensure that they understand how these were managed and resolved. Units also need to get information about

incidents and adverse events that have happened to other units in order to learn from these unwanted incidents.

3. Institutional managers need to inculcate a spirit of cooperation instead of competition between the various units in a hospital. The different units have to be motivated to work for and with one another instead of against each other. When one unit is overwhelmed with patients, the staff of those units that are less busy should be redeployed to where they are required. This will certainly improve the patient safety culture.

4. The efforts aimed at reducing the anxiety associated with the reporting of incidents and adverse events at the coalface have to be intensified. These efforts need to be part of the implementation of a just culture, led by the organisation's leadership.

The recommendations cited above could be used as key discussion points during the management and leadership walk-abouts at various institutions in order to improve the climate of safety and the safety culture over time as already described above.

8.5.4 Patient satisfaction survey: Recommendations

There appears to be an overall increase in patient satisfaction as reported in Chapter 5, during the implementation of the research project. It is, however, recommended that the Free State Department of Health should pay attention to the following aspects of service delivery in order to improve patient satisfaction:

1. Improve the quantity and clarity of information provided to patients on admission, during their stay and upon discharge from hospitals;
2. Motivate and encourage staff to improve their attitudes through various incentives;
3. Investigate the reasons for poor perceptions about the quality and quantity of food provided to patients;
4. Improve the procedures related to the discharge of patients and these include follow up, reviews and down referral; and
5. Congratulate leadership, management and personnel on their achievement and encourage the holders of these positions to maintain the standards in the areas of good performance.

The recommendations that are presented above are aimed ensuring that the health system in the Free State and the country South Africa as well as other interested parties are able to extract value from the research results. It is believed that if these recommendations are implemented after adaptation to different environments, will contribute to the improvement of patient safety and overall quality of health care services.

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