# MANAGEMENT OF REPORTED PATIENT RELATED SERIOUS ADVERSE EVENTS (PRSAE) IN A CENTRAL HOSPITAL IN THE GAUTENG PROVINCE

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## DECLARATION

I, Mathabo Primrose Mathebula, declare that this research report is my own work. It is being submitted for the degree of Master Public Health in the field of Hospital Management at the University of the Witwatersrand, Johannesburg, South Africa. It has not been submitted before any degree or for any examination at this stage or any other University.

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**Mathabo Primrose Mathebula** **Date**

## DEDICATION

In my final step of having this report developed I would like to dedicate it to the following:

- To My Creator, my God who remained my Pillar of strength to continue even when I had all reasons not to complete the course.
- To my dear Late Mother Nosisa who together with my father Tebatso have been my support and encouraged me to complete this project.
- My beloved Late (brother Mothusi, sister Thakane, niece Mahlape and nephew Mpho).
- My dearest children: son Tsundzuka, daughter N'tsakisi and niece: Khopotso who sacrificed and allowed me space to complete my course whilst encouraging me.

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- Lastly, specific roles played by my husband; Hlengani and Bakoena.

## ABSTRACT

**Background:** Patient Related Serious Adverse Events (PRSAEs) are likely to occur in a tertiary institution where highly specialised types of treatments are being provided and warrant high levels of expertise. The patients' disease profiles are complicated and often for better outcomes require urgent interventions. It is mandatory that health professionals report all PRSAEs as soon as they occur but often an incident of a PRSAE got to be detected by management either through media query, complaint, a medico-legal claim or even as enquiry from Health Professional Bodies [such as Health Professional Council of South Africa (HPCSA), South African Nursing Council (SANC), South African Pharmacy Council (SAPC)]. By properly managing reported PRSAEs, it may be possible to develop and to put strategies that can minimise PRSAEs. This can also ensure that employees report PRSAEs occurrence, as part of their daily work. However, this would require an understanding of the factors that might be associated with PRSAEs in an institution.

**Aim:** To describe the factors associated with patient-related adverse events in the central hospital in the Gauteng Province [Steve Biko Academic Hospital (SBAH)] during a two-year study period (01 January 2016 to 31 December 2017) and management of these events by the management of that Hospital.

**Methodology:** The setting of this study was SBAH. A retrospective study design was used. Routinely collected data from the PRSAEs register (Quality Assurance division) was used as primary source of data. In addition, other sources of information (such as Complaint register, Media queries and published articles, Medico-legal claim records of SBAH, Mortality & Morbidity Meeting minutes and known enquiries related to cases against the professionals when they were performing duties in SBAH were used as secondary sources for the study.

Approval from Gauteng Department of Health Research Monitoring Directorate and Chief Executive Officer of Steve Biko Academic Hospital, Post-Graduate Research Committee of the Faculty of Health Science of the University of Witwatersrand as well as Research Ethics Committees of the Universities of Witwatersrand and Pretoria were sought before commencement of the study. After all necessary approvals were obtained, the research data were collected, analysed and reported on.

**Results:** Records of 390 participants were used for analysis. It was noted that there

was 25% reduction in PRSAEs from 2016 (224) to 2017 (166). The majority of the events were classified as medium (55%) and high (41%) risk categories and few in the low (3%) and extreme categories. Although the numbers were almost equal in medium and high-risk categories in 2016, there was a significant reduction in the number in high risk categories in 2017.

The majority of the subjects were in the middle age group (21-70 years) with no significant difference between male and female subjects. The majority of the PRSAEs happened in Medicine, followed by Operating theatres, Surgery, and Psychiatry. The main clinical conditions of these subjects included Oncology, Psychiatry, Surgical gastroenterology and trauma.

*Health professional factors* were identified as the most important contributory factors. Abscondment of patients was found to be one of the major *Patient factors*. Malfunctioning of lifts was the major factor in the *Administration* category.

The investigation period of the majority of the PRSAEs were completed within a reasonable time (median 8 days), with a significant reduction from 2016 to 2017. Although the majority of the four intervals [namely intervals between (a) Dates of Incidence and Reporting, (b) Dates of Reporting and Submission of written report (c) Dates of Submission of written report and SAE Committee meetings, and (d) Dates of SAE Committee meetings and Closure] were short, in few cases the interval became long, which would require further investigation.

**Conclusion:** It is envisaged that this study would contribute valuable information regarding the causes and effects of PRSAEs in the SBAH. In addition, the findings of this study could stimulate future research to determine reasons for health professional factors and targeted in-service training to prevent them in future.

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## GLOSSARY OF TERMS

Adverse event: Adverse event is always associated with “unintended harm to the patient by an act of commission or omission rather than by the underlying disease or condition of the patient”. (Naessens, Campbell, Huddleston, et al, 2009). It can be associated with the use of a drug in humans, whether or not considered drug related. (NHS, 2012). It is often described as an injury that was caused by medical management rather than the patient’s underlying disease; also called ‘harm’, ‘injury’ or ‘complication’.” (Barnes et al, 2006).

Adverse drug reaction: An adverse drug reaction is “*an appreciably harmful or unpleasant reaction, resulting from an intervention related to the use of a medicinal product, which predicts hazard from future administration and warrants prevention or specific treatment, or alteration of the dosage regimen, or withdrawal of the product.”* (Edwards, Aronson, 2000).

Adverse medical event or error: Adverse medical event or error “*is the one that causes an injury to a patient as the result of a medical intervention rather than the underlying medical condition. It represents an unintentional harm to a patient arising from any aspect of healthcare management*.” (Kessler, 1993)

Life-threatening adverse event: Life-threatening adverse event (or life-threatening suspected adverse reaction) is an adverse event or suspected adverse reaction that is considered "life-threatening" if its occurrence places a patient or subject at immediate risk of death. It does not include an adverse event or suspected adverse reaction that, had it occurred in a more severe form, might have caused death.

Medical errors: Medical errors are mistakes or failures in the process of care. While they have the potential to be harmful, often they are not linked to patient injury. Moreover, when medical errors do lead to adverse events, many are minor in terms of patient harm. (Naessens, et al, 2009)

Serious adverse event: Serious adverse event (or serious suspected adverse reaction) is an adverse event or suspected adverse reaction that may be considered "serious" if it may result in any of the following outcomes: Death, a life-threatening adverse event, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions, or a congenital anomaly/birth defect. (National Quality Forum, 2012)

Suspected adverse reaction: Suspected adverse reaction means any adverse event for which there is a reasonable possibility that the drug caused the adverse event.

Unexpected adverse event (or unexpected suspected adverse reaction): An adverse event or suspected adverse reaction is considered "unexpected" if it is not listed in the investigator brochure or is not listed at the specificity or severity that has been observed; or, if an investigator brochure is not required or available, is not consistent with the risk information described in the general investigational plan or elsewhere in the current application.

## LIST OF ABBREVIATIONS

| | |
|---|---|
| AE | Adverse Event |
| A&E | Accident and Emergency Unit |
| DALY | Disability Adjusted Life Years |
| GP | Gauteng Province |
| GDoH | Gauteng Department of Health |
| NDoH | National Department of Health |
| HPCSA | Health Professional Council of South Africa |
| ICU | Intensive Care Unit |
| NHS | National Health Service |
| PRSAEs | Patient Related Serious Adverse Event(s) |
| SANC | South African Nursing Council |
| SAPC | South African Pharmacy Council |
| SBAH | Steve Biko Academic Hospital |
| SAEs | Serious Adverse Event(s) |

# CHAPTER 1
# INTRODUCTION

The purpose of this study was to describe the factors associated with patient-related serious adverse events in the Steve Biko Academic Hospital (SBAH), a central hospital in the Gauteng Province. This introductory chapter will cover the background to the study, statement of the problem, its aims and objectives and an outline of subsequent chapters.

## 1.1 BACKGROUND

The Domain 2 of The National Standards for the health establishments in South Africa is about patient safety: clinical governance and clinical care, which has six sub-domains that focus on prevention of patient related serious adverse events. The South African Minister of Health, to emphasise this quality standard, further listed three of the Ministerial Priority on quality of care to be those that are to minimise Patient Related Serious Adverse Event(s) (PRSAEs), which are: (a) Patient and Staff Safety and Security, (b) Infection Prevention and Control, and (c) Availability of medicine and supplies. (NDoH, 2011). It is an expected that every health facility in South Africa comply with these set standards. Therefore, a high number of PRSAEs can indicate that the quality of health in a health establishment may be compromised and can affect the accreditation of that particular facility, making it important that intervention strategies should be developed whenever an incident of a PRSAE is reported or discovered. This study was planned in that context to understand the management of reported PRSAEs at a central hospital in the Gauteng Province (SBAH).

As a public entity, the SBAH is expected to follow '*National Policy for patient safety incident reporting and learning in Public Health Sector of South Africa'*. It implies that the SBAH is expected to provide direction for the management of patient safety incidence reporting including provisioning of feedback to patients, families/ support person, clinicians and sharing of learnt lessons to prevent reoccurrence of such harm in the public health sector of South Africa (NDoH, 2016). This policy was developed in accordance with that of the World Health Organization (WHO). It encourages Member States to develop policies that seek to address the patient safety issues

through an effective and sustainable National level patient safety incident reporting and learning system (WHO, 2005).

## 1.2 PROBLEM STATEMENT

PRSAEs could be costly to the state, also affect reputation and public credibility of a health institution, health professionalism, and could result in morbidity and/or mortality of patients. The SBAH is faced with a relatively high number of PRSAE's. A formal research was never conducted to systematically study routinely collected information. Therefore, the SBAH management identified this as one of the priority areas because it would like to improve its services. In that context, the researcher believes that this study would assist the SBAH management with provisioning of valuable information and the outcome of the study would be used by the hospital management to identify areas where improvement of services though appropriate planning and development of specific preventive strategies within the SBAH could be made.

## 1.3 JUSTIFICATION FOR THE STUDY

This study would contribute valuable information on management of reported PRSAEs and establish whether the current strategy is working or needs to be improved or changed. If the management of reported PRSAE is improved, this may encourage further reporting of PRSAEs, and it may enable the employees to learn from an incidence thereby minimising reoccurrence of such incidences. The lessons learnt from this study might also assist in identifying gaps in terms of detecting the common factors that may result in PRSAEs.

## 1.4 RESEARCH QUESTION

What were the factors related to the PRSAEs occurring in the SBAH and how these events were managed by the SBAH management?

## 1.5 AIM AND OBJECTIVES

### 1.5.1 AIM

To describe the factors associated with the PRSAEs in the SBAH during a two-year study period (01 January 2016 to 31 December 2017) and management of these events by SBAH management

### 1.5.2 SPECIFIC OBJECTIVES

1. To describe the PRSAEs with respect to different categories (low, medium, high, extreme) in the SBAH during the study period.
2. To describe demographic and clinical profiles of the subjects who experienced PRSAEs during the study period.
3. To describe these events with respect to different factors (Patient, Health professional related and Administration) in the SBAH during the study period.
4. To describe the management process for these events during the study period.

## 1.6 FOLLOWING CHAPTERS

The background to the research has been outlined and discussed. Subsequently, research question and objectives were defined in this first chapter. A brief outline of the following chapters is described below.

**Chapter Two: Literature Review**: The purpose of the literature review is to review related literature and to discuss concepts related to factors associated with PRSAEs.

**Chapter Three: Research Methodology:** The chapter describes the research methodology, study design, setting and scope and data management techniques used in this study.

**Chapter Four: Presentation of Results**: This chapter deals with an analysis of the data collected for this study relating to its aim and objectives.

**Chapter Five: Discussion**: Findings from the review of the literature are included in this chapter with the results obtained from the analysis in order to address the aims and objectives of the study.

**Chapter Six: Conclusions and Recommendations:** The chapter is the last part of the report and derives conclusions from the research related to the objectives of this study, makes recommendations and highlights the areas for future research in the field of PRSAEs.

# CHAPTER 2
# REVIEW OF LITERATURE

This chapter discusses the appropriate and relevant literature on the PRSAEs. In addition to published literature, information from various unpublished sources are also reviewed.

## 2.1 INTRODUCTION

Iatrogenic injury often occurs from the poor design and fault in the health care delivery system. The detection and analysis of serious adverse events, both individually and in the organization, can reveal organizational, systemic, and environmental problems (Aspden, Corrigan, Wolcott, et al, 2004). The National Patient Safety Agency of the National Health Services in the United Kingdom (NHS) developed a '*seven steps model'* to address adverse events and improve patient safety (NHS, 2004).

**Table 2.1 Seven-step patient safety model**

| Steps | Descriptions |
|---|---|
| **Step 1** | Build a safety culture: Create a culture that is open and fair |
| **Step 2** | Lead and support your staff: Establish a clear and strong focus on patient safety throughout your organization |
| **Step 3** | Integrate your risk management activity: Develop systems and processes to manage your risks and identify and assess things that could go wrong |
| **Step 4** | Promote reporting: Ensure your staff can easily report incidents locally and nationally |
| **Step 5** | Involve and communicate with patients and the public: Develop ways to communicate openly with and listen to patients |
| **Step 6** | Learn and share safety lessons: Encourage staff to use root cause analysis to learn how and why incidents happen |
| **Step 7** | Implement solutions to prevent harm: Embed lessons through changes to practice, processes or systems |

Source: NHS, 2004

Lapses in patient safety are a major health care quality problem. The majority of these lapses are often preventable and are unintended consequences of a highly complex and imperfect health care delivery system. However, a few of these lapses are related to negligence or professional misconduct (Kizer, Stegun, 2005) and if identified, steps could be taken to avoid them in future. Wilson, Runciman, Gibberd,

et al (1995) identified adverse events in 16.6% of admissions, half of which were considered preventable in Australia; they estimated that adverse events accounted for 7.1 additional bed days.

Using the "disability-adjusted life years" (DALYs), the impact of the adverse events can be assessed. Jha, Larizgoitia, Audera-Lopez, et al (2013) found that adverse events resulted in 23 million DALYs lost per year. This emphasizes the importance of investing in improving the quality and safety of health care systems, especially in a middle income country like South Africa.

Patient Related Serious Adverse Events are unintended outcome that follows treatment intervention(s) by a health professional, resulting in a serious outcome. Different authors defined PRSAEs, as events that are somehow harmful to a patient following an intervention of some kind by a health provider. (Kessler, 1993; Edwards, Aronson, 2000; Barnes et al, 2006; Naessens, Campbell, Huddleston, et al, 2009; National Quality Forum, 2012; NHS, 2012). During clinical trials, PRSAEs must be reported and classified as serious or minor, expected or unexpected, and study-related, possibly study-related, or not study-related. These reports must include patient information, adverse event or product problem, suspect products, initial reporter, and manufacturer details. (Stone, Rizvi, Sudhir, et al, 2011). However, reporting of other PRSAEs are usually not so stringent.

There is a direct link between PRSAEs and patient safety. Patient safety is a good measure of quality of health care provisioning by health facilities. Therefore, incidences of reported PRSAEs would give an indication of the quality of health care that a health institution provides. When measuring patient safety, it is important to differentiate between medical errors and adverse events with harm to patients. Moreover, not all adverse events are preventable, nor are they always the result of medical errors. (Naessens, et al, 2009). Patient safety may be compromised because of a surgical procedure that went wrong. For example, a significant proportion of reported adverse events in operations theatre in a hospital, in the United Kingdom, was unintentional (Khorsandi, Skounas, Beatson, et al, 2012).

Although adverse medical events can be costly to both patients and institutions, their complete elimination may be impossible, given the complexity of modern healthcare

systems and technology. Their severity, frequency and number can provide a good indication of the healthcare institution's quality of health care provision. Therefore, a proper record of serious adverse events would be informative. Questions to be answered for information gathering could include (a) which of serious adverse events are preventable, (b) if everything humanly possible being done to reduce the incidence of the identified avoidable conditions (Kessler, 1993). The answers would influence issues of medical liability and might also significantly affect reimbursement or healthcare services in South Africa and elsewhere.

An Australian healthcare study identified adverse events costed the Australian healthcare system AU$4.7 billion a year. Adverse events also result in huge personal cost to the affected individuals, both patients and staff. (Vincent, Neale, Woloshynowych, et al, 2001). Similar figures for South Africa is not known, except Medico-legal claims (approximately R 10 million per annum from the SBAH (Personal communication, Director of Finance, SBAH).

## 2.2 CLASSIFICATION OF SERIOUS ADVERSE EVENTS

The Patient related adverse events are classified into the following categories Bateman, 2008) (Table 2.3):

**Table 2.3 Classification of adverse events**

| Safety Assessment Codes | Description | Category |
|---|---|---|
| Safety Assessment Code 1 (SAC1) | An incident leading to permanent disability or death | extreme |
| Safety Assessment Code 2 (SAC2) | A fairly sever incident, which results in temporary disability. | high |
| Safety Assessment Code 3 (SAC3): | Incidents without disabilities | medium |
| Safety Assessment Code 4 (SAC4) | Incidents considered as 'near misses'. | low |

Patient related adverse event can also be further defined and categorized as serious, unexpected, suspected, life-threatening, medical error and near miss according to the severity of the outcome.

An adverse event may indicate a poor-quality care. They are used widely in healthcare quality measurement and improvement activities. Even traditional medical quality improvement mechanisms such as mortality and morbidity meetings are used for identification and examination of adverse events, and to learn for instituting change practice in ways that would make such events less likely in future and hence improve the quality of health care. An adverse event is a happening, incident, or set of circumstances which exhibits three key characteristics to some degree (Walshe, 2000):

**Table 2.2 Key characteristics of circumstances associated with adverse events**

| | |
|---|---|
| *Negativity*: | An event which is, by its very nature, undesirable, untoward, or detrimental to the healthcare process or to the patient. This is a theme common to all definitions |
| *Patient involvement/ impact:* | Some way involves or have some negative impact or potential impact on a patient or patients.<br>The wider definitions of AE include occurrences in which there is no actual effect on any patient, though there is the potential for harm. More restrictive definitions often only include events where the patient has suffered some definable and identifiable ill effect from the event |
| *Causation* | Some indication that the event is a result of some part of the healthcare process (either through commission or omission), rather than a result of events outside the healthcare process, such as patients' own actions or the natural progression of the disease. Again, definitions vary, with some accepting events as adverse events with little or no evidence of causation, while others insist on strong and direct evidence of causation. |

Source: Walshe, 2000

## 2.3 REPORTING OF OCCURRENCES OF ADVERSE EVENTS

There are many ways to detect adverse events through reporting systems, document review, automated surveillance of clinical data, and monitoring of patient progress. These approaches are ultimately complementary and require a broad range of data elements covering demographic information, signs and symptoms, medications, test results, diagnoses, therapies, and outcomes. (Aspden, et al, 2004). To improve

patient safety, it is essential to report adverse and near miss events to identify failure at system level. (Tevis, Schmocker, Kennedy, 2016)

Policy of the Gauteng Department of Health (GDoH) stipulates that all adverse events reports should be reported within six hours and the final report should be sent to the chief executive officer (CEO) of a hospital within seven days of its occurrence. The CEO would then send it to the district/ provincial adverse event committees within 14 days after the incident. The policy further stipulates that all meetings will be held monthly by the relevant committees. The establishment and constitution of institutional, districts and provincial adverse events committees are guided by the provincial policy document. Responsibilities, authority and functions of the adverse events committees in terms of classifications and analysis of reported adverse events are important outcomes of reporting system. The process includes classification of adverse events into types or severity, identification of related factors and risks, proposing interventions and recommendations, and ensuring dissemination of the results to relevant stakeholders (GDoH, 2015).

Adverse event registration would be first step in assessing quality and safety of care. Compliance to adverse event registration in daily practice might be difficult but it is key to optimal monitoring of quality of care. (van der Starre, van Dijk, Tibboel, 2012). Reporting of occurrences of adverse events is the first and crucial step in the management and reduction of PRSEAs. For better interventions, it is also important to have adverse event reported, as soon as they occur or discovered. (Kessler, 1993).

The World Health Organization (WHO) suggested following requirements for successful adverse events reporting systems (WHO, 2005): (a) objective of the system, (b) who should report, (c) on what to be reported, (d) mechanism to receive report and data management, (e) method to classify and make sense of reported events, (f) capacity to disseminate findings, (g) technical infrastructure and (h) data security.

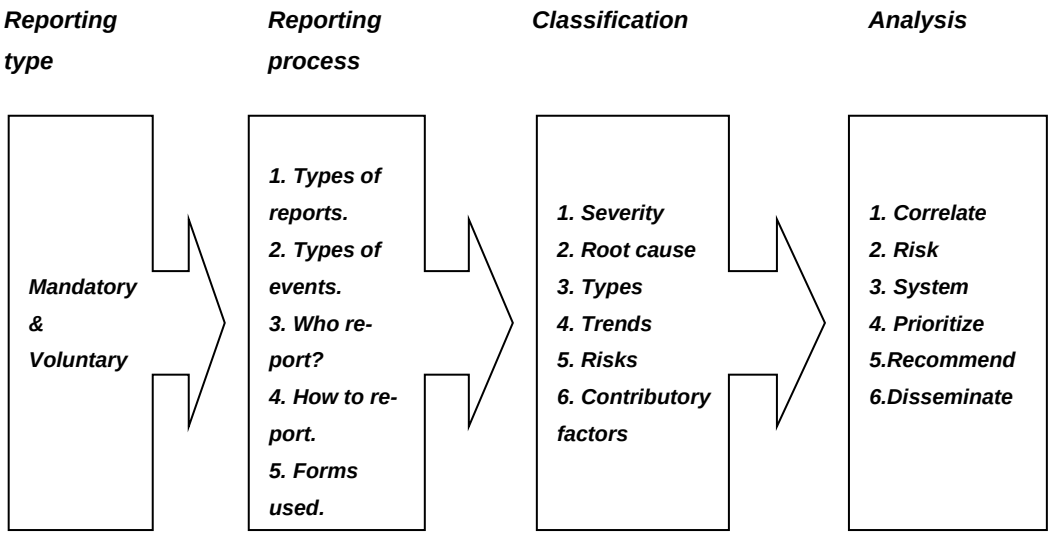


**Figure 2.1 Adverse events reporting system**
(WHO, 2005)

Although there is no national reporting of patient related serious adverse events in the United States, they are one of the leading causes of morbidity and mortality. Some States require reporting of some types of PRSAEs. However, it is widely agreed that, such events are grossly underreported due to the lack of clarity about what is to be reported. In a study done at different institutions in the USA, it was found that: around 38% of identified events were provider-reported events; nearly 43% of them were related to skin integrity, 23% to medication, 21% to falls, 1.8% to equipment and 37% miscellaneous issues. Interestingly, patients with adverse events identified by one method were not usually identified using another method. Only 97 (6.2%) of hospitalizations with patient safety indicators (PSI) also had a provider-reported event and only 10.5% of provider-reported events had a PSI. (Naessens, et al, 2009). The results of the study demonstrated the need for improvement in the quality of incident reporting. In order to standardize reporting process, utilization of standardized reporting systems would be ideal. This would minimize time and resources required. However, this would require appropriate training of staff involved with standardized reporting systems (Khorsandi, et al, 2012). Although a standardized reporting format is used in public hospitals in the Gauteng Province, no systematic analysis of its relevance was seldom studied.

In addition to standardized reporting systems managed by health providers, a system of collecting patients' and their relatives' reported adverse events could be of great benefit. In a survey conducted with patients who were discharged from Massachusetts hospitals, it was concluded that many patients could identify care-related PRSAEs; however, patients' response to questions about the sequelae of the events provided limited additional information for physicians to use in gauging the presence and severity of the event. Therefore, patient reports that often get presented as complaints can only complement other incident-detection methods by providing information that is credible and unavailable from other sources. (Zhu, Stuver, Epstein, et al, 2011).

According to the study conducted at King Edward VIII Hospital maternity unit in Durban on adverse events, most patients who experienced adverse events had temporary disability (SAC2) and death (SAC1) and accounted for 17.7% of the total reported adverse events (Matsaseng & Moodley, 2005). The results of a pilot study on the seriousness of adverse events conducted by COHSASA in hospitals in the Free State Province revealed that 8.5% of reported incidents were serious (defined as SAC1: Safety Assessment Code and 1 is an incident leading to permanent disability or death) which is high compared to 4% for Australia and USA. (Bateman, 2008). The results of this pilot study further indicated that the overall SAC2 (fairly severe incident which results in temporary disability) incidents at hospitals in the Free State Province is significantly high (21%) as compared to 5% for Australia and USA (Bateman, 2008). A similar study should be conducted in all public hospitals in South Africa.

In the study conducted on reasons for poor reporting of adverse events by registrars as well as the impact of interventions, it was found that reasons for poor reporting were: 38% of registrars' lack of knowledge about how to submit adverse event and 35% of registrars mentioned lack of time to submit. The interventions included education of registrars about importance of reporting adverse events and near misses as well as simplification of reporting process, led to the reporting of adverse event by registrars increased by 230%. (Tevis, et al, 2016)

Many patients suffer significant harm because of multiple small failures that accumulate throughout their care, rather than a single dramatic failure at one point in

time. (Vincent et al, 2001). However, Baines, Langelaan, de Bruijne (2015) proposed that study of fewer records of these patients would be enough to obtain as much information as possible and to identify trends and if safety improvements would be possible on patient safety. This may not specifically eliminate the SAEs for the total hospital population, but assist in management of SAEs in high risk areas.

## 2.4 FACTORS RELATED TO ADVERSE EVENTS

These factors can broadly be grouped into two groups: Health system related factors and patient related factors.

### 2.4.1 HEALTH SYSTEM RELATED FACTORS

PRSAEs occur due to multiple factors: some adverse events may be new or unanticipated, due to (i) changing technologies. (ii) Systems failures—such as poor management decisions, dysfunctional corporate cultures, poor communication, inadequate resources, poor staffing, poor documentation, or a lack of safeguards and check points—generally facilitate human errors. (iii) Human errors (which might be knowledge-based, skill-based, fatigue-based, or might result from a failure to follow rules, technical mistakes, and/or an inability to cope with the complexities or demands of the healthcare system) (Kessler, 1993).

For example, in an emergency, adverse events can occur very quickly and may result in serious complications, which might even be fatal. When patients need to be referred, response time, availability of transport (ambulance on site) as well as the presence of skilled health professionals, often determines the outcome for them (Meda, Houton, De Bouwer, et al, 2008). Any delay in referral could turn it into an adverse event.

Human errors is often associated with PRSAES. For example, in the USA, hospitals adverse events rate is lower in non-teaching hospitals than in teaching hospitals as these hospitals often deal with more complex and severely ill patients as well provision of training for health care providers. Dynan, Goudie, Brady (2017) found in a teaching hospital in the USA several adverse events involving registrars, which might be attributed to their lack of experience, work overload, poor judgment, case

complexity. This implies that teaching hospitals might have higher rate of occurrence due to high turnover of registrars and medical officers in a place like the SBAH. Adequate training of health professionals also plays an important role in reduction of human errors thereby adverse events as documented in studied conducted in the King Edward VIII Hospital in Durban (Matsaseng & Moodley 2005), in Gugu District in Zimbabwe (Majoko, Nystrom, Munjaja, et al, 2005) and in Australia (Beaves, Jenkins, Wallace, 2007).

In addition, administrative factors (such as timely availability of emergency transport) also play a contributory role to the increase in reported adverse events as found in the Gugu Mission hospital in Zimbabwe (Majoko, et al., 2005). Patients' fall from hospital beds linked to shortage of staff, constitute one of the most common PRSAE across the world (Mion, Chandler, Waters, et al, 2012). Drug shortages could also result in serious adverse events as it can pose a serious challenge for health care institutions, often interfering with patient care (McLaughlin, Kotis, Thomson, et al, 2013). It is unclear what health systems factors might have an influence on PRSAEs in the Gauteng Province.

### 2.4.2 PATIENT RELATED FACTORS

Various patient factors (such as demographics, socio-economic conditions) were studied to determine their association with SAEs. For example, age (geriatrics), race (Caucasians), funder (public insurance), poor socio-economic conditions were found to be positively associated with adverse events (Dynan, et al, 2017).

For example, Mion, et al, (2012) studied 784 patients in a teaching hospital in the USA and found age (geriatrics), ethnicity (black), drugs (antipsychotic agents, opiates, or a diuretic non-antihypertensive agent) were more likely to sustain a SAE such as fall.

The health and well-being of patients could be negatively influenced by socio-economic conditions of patients and their families. When strategies are developed to reduce adverse events in a hospital, socio-demographic profiles of patients who were involved should be taken into considerations especially in rural areas (Couillet, Serhier, Tachfouti, et al, 2007). Although attendance at antenatal

clinics are known to reduce adverse events, antenatal services are often underutilized by patients due to socio-economic and cultural factors. For example, antenatal clinic attendance remained low in Burkina Faso and Morocco, although it is free; multi-gravidity was cited as one of the reason for non-utilization, which might be linked to increased domestic workload among them (Couillet, et al, 2007; Meda, et al., 2008). Findings from these studies suggest that patient related factors might play an important role in avoidance of adverse events and they should be studied simultaneously with health system factors.

Patients in the intensive care unit (ICU) are more likely than other hospitalized patients to experience medical errors, due to the complexity of their conditions, need for urgent interventions, and considerable workload fluctuation. Thus, the risk of medical errors associated with ICU admission deserves continuous attention. (Garrouste-Orgeas, Timsit, Soufir, et al, 2008). The critical care units are highly dependent on high technologically sophisticated services especially in a teaching hospital and therefore more likely to be associated with adverse events (Dyan, Goudie, Brady, 2017). Therefore, patients in ICU, operating theatre should receive special attention in any SAEs management plan.

## 2.5 INTERVENTIONAL MANAGEMENT

Interventional management of reported and discovered PRSAE is the next step that can reduce incidences of PRSAEs and thus improving patient safety and quality of care. To manage and reduce PRSAEs, it is essential to establish the causes/ or factors contributing to the occurrence of the common adverse events. Occurrences of clinical serious adverse events might be due to systems failures, human error, negligence, rare complications. These events have physical and psychological effects to patients, their families and staff, and are common in the health care system. The way the leadership within the health care establishment deals with clinical serious adverse events can either positively or negatively differentiate one health establishment from the others. The differentiation is terms of institutional culture of safety, advanced planning for adverse events, balanced prioritization of patients, families, staff members, and institutional needs; how actions taken immediately and ultimately bring empathy, support, resolution, learning, and improvement. (Conway et al, 2011).

The management of serious adverse event is to support two processes namely: (a) proactive preparation of a plan for managing serious adverse events, and (b) reactive emergency response of an organization/ institution that has no plan. It is advisable that every health care institution must develop a clinical serious adverse event management plan before there is a need to use it. (Conway et al, 2011). The same should be applied in all South African institutions

The risk of poor response to serious adverse events include loss of trust, absence of healing, no learning, no improvement, mixed messages about what the institutional priorities are, increased likelihood of medico-legal claims, and media queries. The proper ways of responding to serious adverse events immediacy, transparency, apology, and accountability. The priorities of response are the patient and family, staff members especially those at the front line of care and the harm; and the organization (Conway et al, 2011).

The ultimate strategy of managing serious adverse events is avoiding the harm and occurrence of a serious adverse event. The key steps in managing serious adverse events include avoidance, preparation to manage, recognition, containing, and resolving a serious adverse event, as well as benefiting by learning from it. (Conway et al, 2010). An institutional quality improvement plan of PRSAEs is expected to be associated with a decrease of serious adverse events. (de Jong, Molinari, de Lattre et al, 2013). The challenge, however remains with designing a system that compensates injury, correctly identifies medical error, and learns from adverse events to build systems that eliminate errors. (Sohn, 2013)

# CHAPTER 3
# RESEARCH METHODOLOGY

The methodology for this study was selected based on its aims and objectives. In this chapter the following would be discussed: setting, scope, and study design and research tools.

## 3.1 STUDY DESIGN

A retrospective study design was used through reviewing of existing data collected routinely in the hospital.

## 3.2 SETTING AND SCOPE

The study was conducted in Steve Biko Academic Hospital for a period of two years: (01 January 2016 to 31 December 2017). It is one of the four central hospitals in Gauteng Province located in the City of Tshwane. It is an academic hospital, a training platform for students (undergraduates and post-graduates) from many institutions of higher learning mainly: University of Pretoria, Tshwane University of Technology, S.G. Lourens Nursing College, as well as other private and public colleges and hospitals.

## 3.3 STUDY POPULATION AND SAMPLE

The study population included all reported PRSAEs as per the Serious Event register for a period of two years (01 January 2016 to 31 December 2017) at the SBAH. Approximately 60-70 PRSAES reported every year. Therefore, the approximate number in two years was expected to be 120 (approximately).

## 3.4 DATA MANAGEMENT

### 3.4.1 VARIABLES

The data included following variables (Table 3.1).

**Table 3.1 List of variables**

| Objectives | Tools | Variables |
|---|---|---|
| 1 | 1 | Number of adverse events per category, seriousness of adverse events as described in Table 1.1 |
| 2. | 2 | Demographic and Clinical factors<br>Demographic profile: age, gender<br>Clinical profile (diagnoses) |
| 3 | 3 | Factors associated with SAE<br>Patient related; Health Professional related; Administration |
| 4 | 4 | Management process with respect to SAEs<br>Interval between (1) Interval between Dates of Incidence and Reporting (2) Interval between Dates of Reporting and Submission of written report (3) Interval between Dates of Submission of written report and SAE Committee meetings (4) Interval between Dates of SAE Committee meetings and Closure and (5) Total Interval between Dates of Incidence and Closure<br>Outcome of the meeting for SAEs |

The reporting of SAEs in the SBAH follows the steps mentioned below:

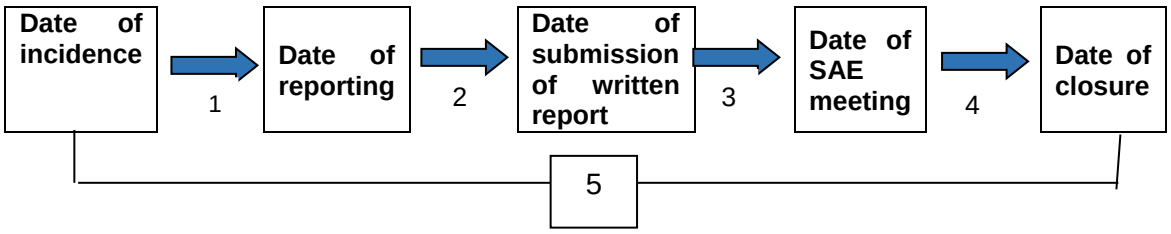


**Figure 3.1 Management process for SAEs in SBAH**

### 3.4.2 STUDY INSTRUMENTS

Data collection sheets are attached (Appendix B) which are based on the objectives of the study (Table 3.1)

### 3.4.3 DATA COLLECTION

Routinely collected data from the PRSAEs register (Quality Assurance division) was used as primary source of data. In addition, other sources (such as Complaint register, Media queries and published articles, Medico-legal claim records of SBAH, Mortality & Morbidity Meeting minutes and known enquiries related to cases against the professionals when they were performing duties in SBAH) were used to ensure inclusion of all PRASAEs (Table 3.2). In case of missing data (for objectives 2 and 3), secondary sources of information (such as patients file) were used. (Table 3.2)

**Table 3.2 Data collection**

| Objectives | Tools | Primary source | Secondary source |
|---|---|---|---|
| 1 | 1 | Patient Related Serious Adverse Events register | Complaint register, Media queries and published articles, Medico-legal claim records of SBAH, Mortality & Morbidity Meeting minutes and known enquiries related to cases against the professionals when they were performing duties in SBAH) |
| 2. | 2 | | Patients' file |
| 3 | 3 | | Patients' file |
| 4 | 4 | | Patients' file |

### 3.4.4 DATA ANALYSIS

The MS Excel software was used to capture and the NCSS statistical software were used to analyse the data (NCSS, 2017). The following descriptive statistical tests were used:

- Nominal and Ordinal variables (such as ethnicity): Proportions and percentages.
- Continuous variables with normal distribution (such as age): mean and standard deviation
- Continuous variables without normal distribution: median and interquartile range.

Trend analysis was done for two years (twenty-four months) to establish whether there was any trend (increase or decrease) during the study period.

In addition, analytical statistics were utilized to compare data (a) among five

departments (Medicine, Surgery, Paediatrics, Obstetrics and Gynaecology, Critical Care, Operating theatre and Accident and Emergency) and (b) two years.

- Nominal and Ordinal variables (such as race): Chi-square test.
- Continuous variables with normal distribution (such as age): t-test and ANOVA
- Continuous variables without normal distribution: Mann Whitney's U test

The significance of the statistics was calculated at 95% confidence levels. A personal computer was used to capture the data.

### 3.5 ETHICAL CONSIDERATIONS

No patient names were listed in the database for the study; special numbers were assigned against each patient related serious adverse event without any reference to their identity or name. There was no need to obtain the individual patients' informed consent, as the study was conducted using existing records.

Approval from Gauteng Department of Health Research Monitoring Directorate and Chief Executive Officer of Steve Biko Academic Hospital to conduct the study were obtained. Approval from the Post-Graduate Research Committee of the Faculty of Health Science of the University of Witwatersrand as well as Research Ethics Committees of the Universities of Witwatersrand and Pretoria were also obtained (Appendix A). After all necessary approvals were obtained, the research data were collected, analysed and reported on.

# CHAPTER 4
# RESULTS

The results obtained from the analysis of data are described in this chapter. There were 224 and 166 reported cases in 2016 and 2017 respectively.

## 4.1 NUMBER OF ADVERSE EVENTS PER CATEGORY

The total number of adverse events in different risk categories are described in Table 4.1. There was a significant difference in terms of these categories between the two years with a significant reduction in number of extreme and low cases in 2017 (Chi-square test, $p<0.001$). (Figure 4.1) However there was an increase in medium risk cases during the period.

**Table 4.1 Risk categories (n=390)**

| Risk categories | 2016 | 2017 | Total |
|---|---|---|---|
| **Low** | 10 (4%) | 0 (0%) | 10 (3%) |
| **Medium** | 100 (45%) | 117 (70%) | 217 (55%) |
| **High** | 112 (50%) | 49 (30%) | 161 (41%) |
| **Extreme** | 2 (1%) | 0 | 2 (1%) |
| **Total** | **224 (100%)** | **166 (100%)** | **390 (100%)** |

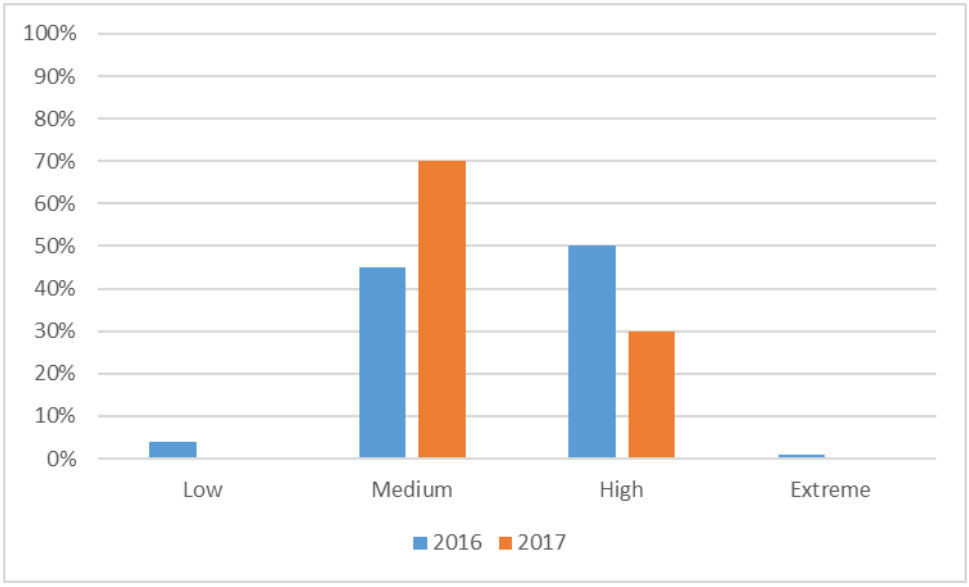


**Figure 4.1 Different risk categories**

## 4.2 DEMOGRAPHIC PROFILE

### 4.2.1 AGE

The age distribution of the subjects is described in Table 4.2. The age of the subjects was not normally distributed (Figure 4.2). Therefore, the age is reported in median and inter-quartile range (IQR). There is no significant difference in age between the two years of study (Mann Whitney's U test, p<0.7).

**Table 4.2 Age distribution of the subjects (n=390)**

| Age in years | 2016 | 2017 | Total |
|---|---|---|---|
| **Median** | 42 | 43 | 42 |
| **IQR** | 26-61 | 23-64 | 26-62 |
| **minimum** | 0.1 | 0.1 | 0.1 |
| **maximum** | 89 | 84 | 89 |

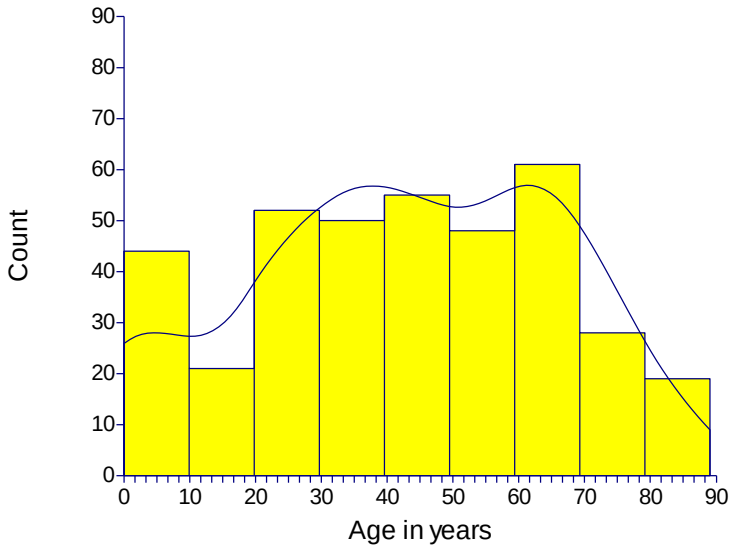


**Figure 4.2 Age distribution of the subjects**

The subjects were stratified according to the different age groups in Table 4.3.

**Table 4.3 Age group of the subjects (n=390)**

| | 2016 | | 2017 | | Total | |
|---|---|---|---|---|---|---|
| **Age group in years** | **n** | **%** | **n** | **%** | **n** | **%** |
| **0 - 1** | 10 | 4.6% | 18 | 10.6% | 28 | 7.2% |
| **1 - 10** | 12 | 5.5% | 6 | 3.7% | 18 | 4.7% |
| **11 - 20** | 15 | 6.5% | 7 | 4.3% | 22 | 5.6% |
| **21 - 30** | 34 | 15.2% | 23 | 13.7% | 57 | 14.6% |
| **31 - 40** | 34 | 15.2% | 22 | 13.0% | 56 | 14.3% |
| **41 - 50** | 31 | 13.8% | 21 | 12.4% | 51 | 13.2% |
| **51 - 60** | 32 | 14.3% | 20 | 11.8% | 52 | 13.2% |
| **61-70** | 36 | 16.1% | 28 | 16.8% | 64 | 16.4% |
| **71 - 80** | 12 | 5.5% | 16 | 9.9% | 29 | 7.4% |
| **81 -90** | 7 | 3.2% | 6 | 3.7% | 13 | 3.4% |
| **Total** | **224** | **100%** | **166** | **100.0%** | **390** | **100.0%** |

The majority of the subjects were in the middle age group (21-70 Years).

### 4.2.2 GENDER

The gender distribution of the subjects is described in Table 4.4. There is no significant difference in gender between the two years of study (Chi-square test. $p<0.7$)

**Table 4.4 Gender distribution of the subjects (n=390)**

| **Gender** | **2016** | **2017** | **Total** |
|---|---|---|---|
| **Female** | 107 (48%) | 75 (45%) | 182 (47%) |
| **Male** | 117 (52%) | 91 (55%) | 208 (53%) |
| **Total** | **224 (100%)** | **166 (100%)** | **390 (100%)** |

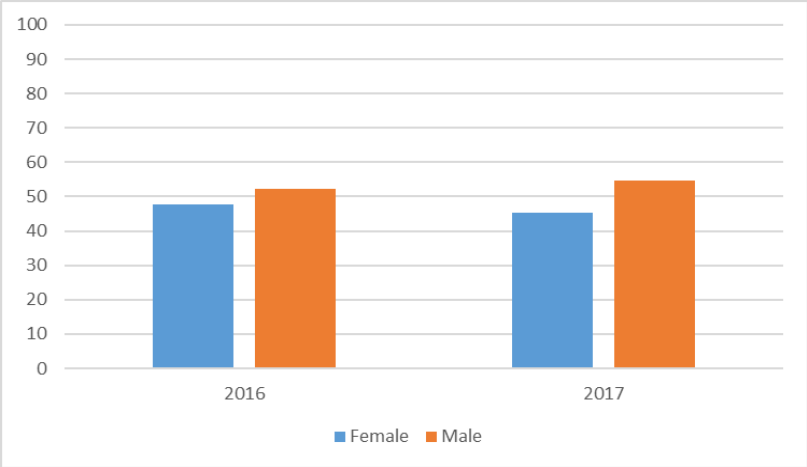


**Figure 4.3 Gender distribution of the subjects**

## 4.3 CLINICAL PROFILE OF THE SUBJECTS

### 4.3.1 PLACE OF OCCURRENCE OF PRSAEs

The subjects were classified according to the places of occurrence (Table 4.5).

**Table 4.5 Place of occurrence of Serious adverse events (n=390)**

| | 2016 | | 2017 | | Total | |
|---|---|---|---|---|---|---|
| | N | % | n | % | n | % |
| **A&E** | 6 | 2.7% | 3 | 1.8% | 9 | 2.3% |
| **Medicine** | 65 | 29.0% | 51 | 30.7% | 116 | 29.7% |
| **Psychiatry** | 28 | 12.5% | 11 | 6.6% | 39 | 10.0% |
| **O&G** | 9 | 4.0% | 4 | 2.4% | 13 | 3.3% |
| **Paediatrics** | 3 | 1.3% | 1 | 0.6% | 14 | 3.6% |
| **Surgery** | 41 | 18.3% | 29 | 17.5% | 75 | 19.2% |
| **Theatre** | 58 | 25.9% | 56 | 33.7% | 114 | 29.2% |
| **Nuclear medicine** | 0 | 0.0% | 1 | 0.6% | 1 | 0.3% |
| **Pharmacy** | 2 | 0.9% | 1 | 0.6% | 3 | 0.8% |
| **ICUs** | 7 | 3.1% | 8 | 4.8% | 15 | 3.8% |
| | | | | | | |
| **Family** | 5 | 2.2% | 1 | 0.6% | 6 | 1.5% |
| | | | | | | |
| **Total** | **224** | **100%** | **166** | **100%** | **390** | **100%** |

The result showed that the majority of the SAEs happened in Medicine (29.7%), followed by Operating theatre (29.2%), Surgery (19.2%) and Psychiatry (10%) (Figure 4.4).

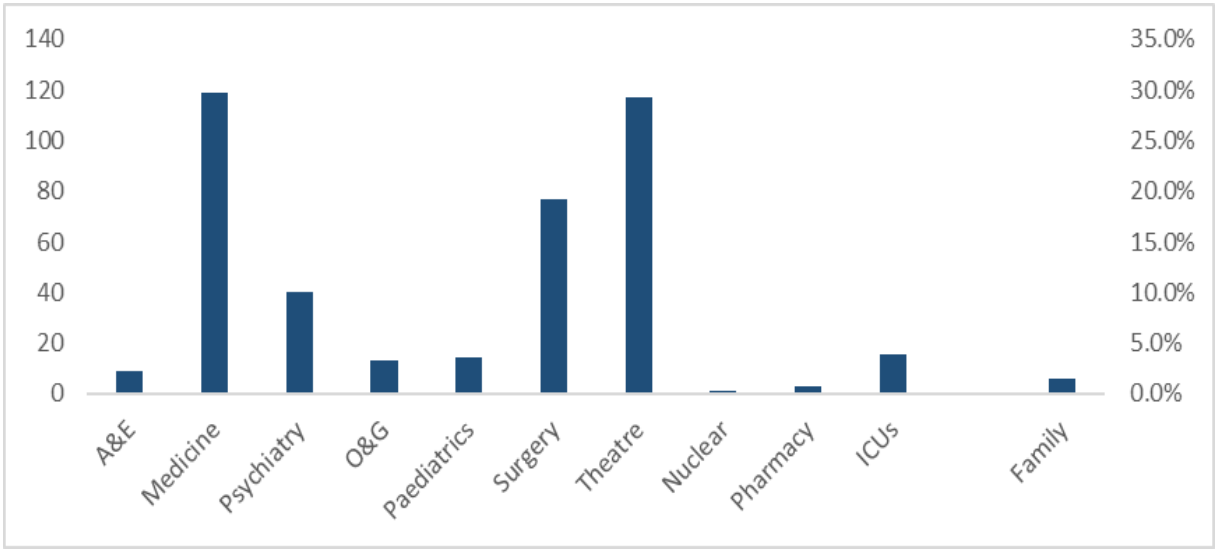


**Figure 4.4 Place of occurrence of PRSAEs (n=390)**

### 4.3.2 CLINICAL CONDITIONS OF SUBJECTS INVOLVED WITH PRSAEs

The subjects were stratified according to the initial diagnoses (Table 4.6). the majority of the subjects had Medical (43.8%) and Surgical (40%) conditions. Oncology (12%), Psychiatry (10%), Surgical Gastroenterology (10%) and Trauma (9%) were the main clinical disciplines associated with these patients.

**Table 4.6 Clinical conditions of subjects involved with PRSAEs (n=390)**

| **Clinical conditions** | **2016** | **2017** | **Total** |
|---|---|---|---|
| **Medical conditions** | **104 (46.4%)** | **67 (40.4%)** | **171 (43.8%)** |
| Cardiology | 12 | 9 | 21 |
| Endocrinology | 4 | 3 | 7 |
| Neurology | 9 | 3 | 12 |
| Oncology | 27 | 18 | 45 |
| Pulmonology | 4 | 2 | 6 |
| Nephrology | 6 | 5 | 11 |
| Internal Medicine | 14 | 16 | 30 |
| Psychiatry | 28 | 11 | 39 |
| **O&G conditions** | **12 (5.4%)** | **9 (5.4%)** | **21 (5.4%)** |
| Obstetrics | 3 | 4 | 7 |
| Gynaecology | 9 | 5 | 14 |
| **Paediatric conditions** | **15 (6.7%)** | **18 (10.8%)** | **33 (8.5%)** |
| Neonatology | 7 | 6 | 13 |
| Paediatric | 8 | 12 | 20 |
| **Surgical conditions** | **86 (38.4%)** | **70 (42.2%)** | **156 (40.0%)** |
| ENT/ Maxillofacial | 3 | 0 | 3 |
| Ophthalmology | 1 | 0 | 1 |
| Breast | 2 | 1 | 3 |
| Orthopaedics | 7 | 1 | 8 |
| Gastroenterology | 20 | 14 | 34 |
| Plastic | 2 | 0 | 2 |
| Cardiothoracic | 12 | 12 | 24 |
| Transplant | 0 | 1 | 1 |
| Trauma | 22 | 18 | 40 |
| Urology | 5 | 3 | 8 |
| Vascular | 1 | 2 | 3 |
| General Surgery | 11 | 18 | 29 |
| **Other non-medical** | **7 (3.1%)** | **2 (1.2%)** | **9 (2.3%)** |
| Pharmacy | 3 | 1 | 4 |
| Lift | 2 | 0 | 2 |
| Family Members | 2 | 1 | 3 |
| | | | |
| **Total** | **224 (100%)** | **166 (100%)** | **390 (100%)** |

## 4.4 FACTORS ASSOCIATED SERIOUS ADVERSE EVENTS

Factors associated with PRSAEs are described in Table 4.7. There was no significant difference between the two years in terms of various categories of SAEs (Chi-square test, p=0.1).

**Table 4.7 Factors associated with PRSAEs**

| Factors | 2016 | 2017 | Total |
|---|---|---|---|
| **Patient** | 43 (19%) | 24 (14%) | 67 (17%) |
| **Health professional** | 177 (79%) | 136 (82%) | 313 (80%) |
| **Administration** | 4 (2%) | 6 (4%) | 10 (3%) |
| **Total** | **224 (100%)** | **166 (100%)** | **390 (100%)** |

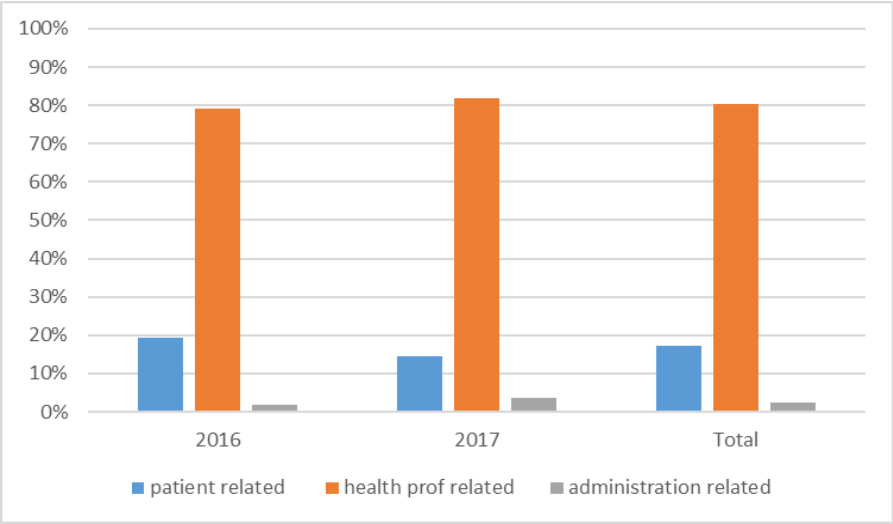


**Figure 4.5 Factors associated with PRSAEs**

### 4.4.1 PATIENT FACTORS

The factors associated with patients are listed in the Table 4.8, abscondment of the patients (76%, 51) remained one of the major factors. The majority of abscondments happened in Surgery (22, 44%) and Medical wards (14, 28%).

**Table 4.8 Patient factors**

| Factors | 2016 | 2017 | Total |
|---|---|---|---|
| **Suicide Attempt** | 0 | 2 | 2 |
| **Abscondment** | 34 | 17 | 51 |
| **Addiction to alcohol** | 1 | 0 | 1 |
| **Addiction to drug** | 1 | 0 | 1 |
| **Aggressiveness** | 4 | 3 | 7 |
| **Injury to Self** | 3 | 2 | 5 |
| **Total** | **43** | **24** | **67** |

### 4.4.2 FACTORS ASSOCIATED WITH HEALTH PROFESSIONALS

The factors associated with health professionals are listed in the Table 4.9. History of falls (50%, 157) and deaths (36%, 112) are the leading factors. The majority of falls had occurred in Medical (83, 52%), Surgical (40, 25%) and Psychiatric (15, 10%) wards.

The history of falls was not directly associated with age; [Median 55 years, IQR (44-66 years]. Only 20% of these subjects were more than 70 years. The majority of deaths occurred in the operating theatre (106, 95%).

**Table 4.9 Factors associated with health professionals**

| Health professional related | 2016 | 2017 | Total |
|---|---|---|---|
| **Blood Transfusion** | 3 | 1 | 4 |
| **Error in feeding** | 4 | 4 | 8 |
| **Error in treatment** | 9 | 5 | 14 |
| **Reaction to treatment** | 0 | 4 | 4 |
| **Fall** | 98 | 59 | 157 |
| **Injury to patients** | 3 | 0 | 3 |
| **missing swab** | 0 | 1 | 1 |
| **needle** | 2 | 2 | 4 |
| **patient injury** | 1 | 4 | 5 |
| **pressure sore** | 0 | 1 | 1 |
| **death** | 57 | 55 | 112 |
| **Total** | **177** | **136** | **313** |

### 4.4.3 ADMINISTRATIVE FACTORS

The factors associated with Administration are listed in the Table 4.10. Malfunctioning of lifts (5, 50%) was the major factor in this category.

**Table 4.10 Factors associated with administration**

| Factors | 2016 | 2017 | Total |
|---|---|---|---|
| **Lift** | 3 | 2 | 5 |
| **Misidentification of patients** | 0 | 1 | 1 |
| **Stealing of patients' possession** | 1 | 3 | 4 |
| **Total** | **4** | **6** | **10** |

## 4.5 TIME PERIOD

The reporting of SAEs follows the steps mentioned below (Figure 4.6):

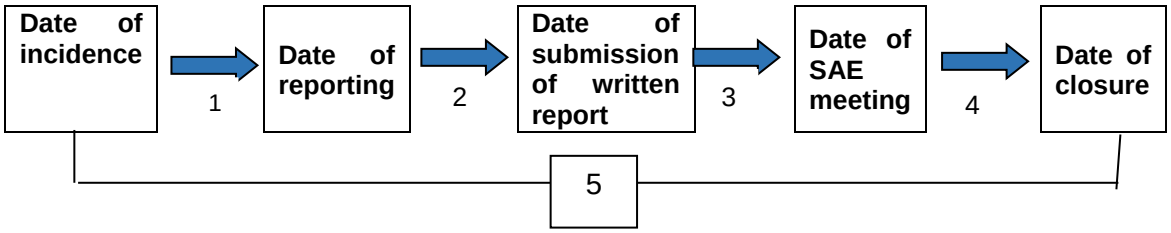


**Figure 4.6 Process of management of SAEs**

Following intervals were calculated:

(1) Interval between Dates of Incidence and Reporting

(2) Interval between Dates of Reporting and Submission of written report

(3) Interval between Dates of Submission of written report and SAE Committee meetings

(4) Interval between Dates of SAE Committee meetings and Closure

(5) Interval between Dates of Incidence and Closure

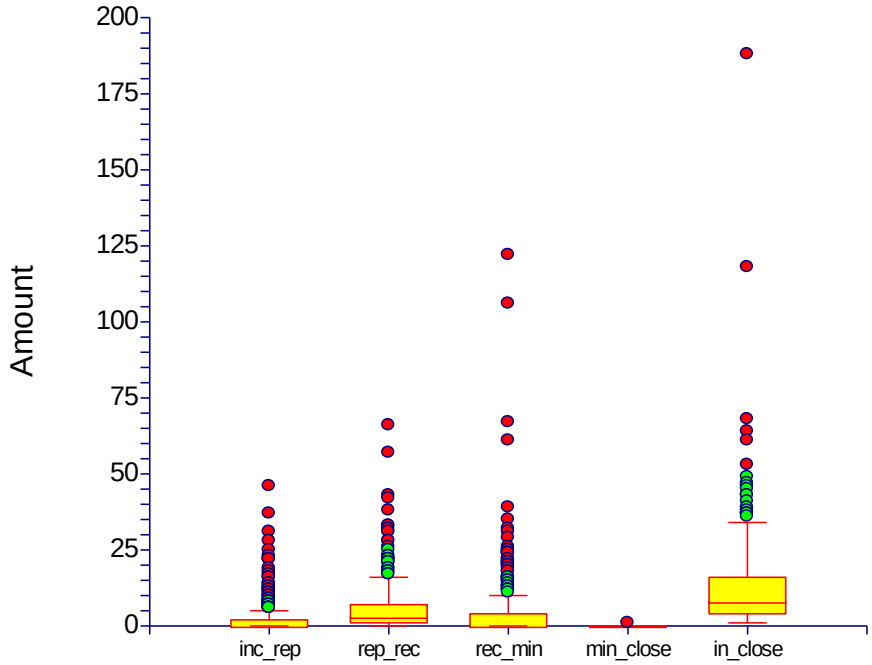


**Figure 4.7 Incidence to closure in days**

### 4.5.1 INCIDENCE TO REPORT INTERVAL

The '*Incidence to Report'* interval is described in Table 4.11. The data was not normally distributed (Figure 4.8). Therefore, the interval is reported in median and inter-quartile range (IQR). There was significant increase in the '*Incidence to Report*' interval from 2016 to 2017 (Mann Whitney's U test, p<0.001).

**Table 4.11 Incidence to report interval (n=390)**

| Interval in days | 2016 | 2017 | Total |
|---|---|---|---|
| **Median** | 0 | 2 | 2 |
| **IQR** | 0 | 0-5 | 0-2 |
| **minimum** | 0 | 0 | 0 |
| **maximum** | 46 | 37 | 46 |

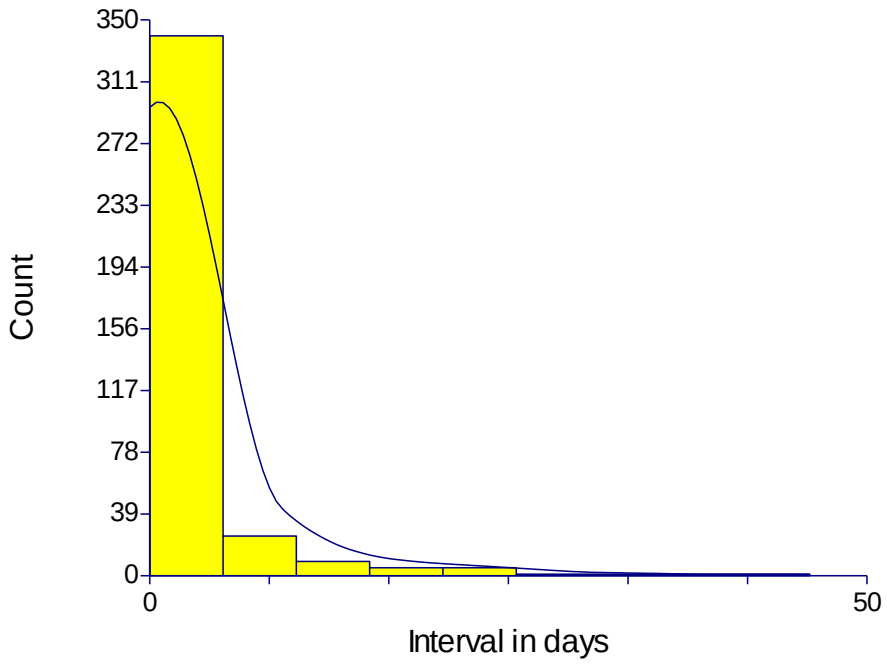


**Figure 4.8 Incidence to report interval in days**

### 4.5.2 REPORT TO SUBMISSION OF WRITTEN REPORT INTERVAL

The interval between '*Reporting'* and '*Submission of written report'* is described in Table 4.12. The data were not normally distributed (Figure 4.9). Therefore, the interval is also reported in median and inter-quartile range (IQR). There was significant reduction in this interval period from 2016 to 2017 (Mann Whitney's U test, $p<0.001$).

**Table 4.12 Report to Submission of written report interval (n=390)**

| **Interval in days** | **2016** | **2017** | **Total** |
|---|---|---|---|
| **Median** | 4 | 1 | 3 |
| **IQR** | 2-10 | 0-6 | 1-7 |
| **minimum** | 0 | 0 | 0 |
| **maximum** | 66 | 23 | 66 |

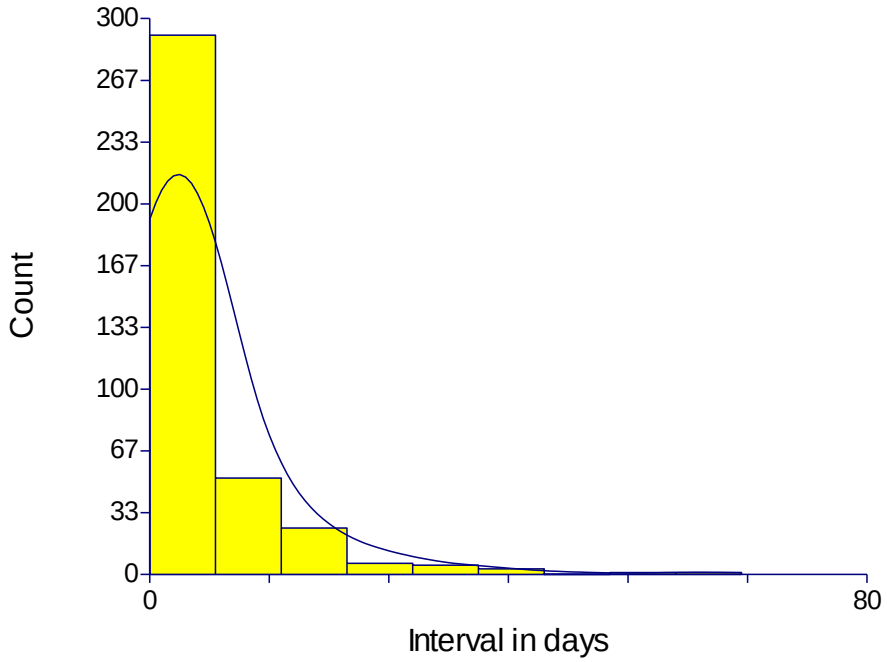


**Figure 4.9 Report to Submission of written report interval (n=390)**

### 4.5.3 SUBMISSION OF WRITTEN REPORT TO MEETING INTERVAL

The interval between '*Submission of written report'* to '*SAE meetings'* is described in Table 4.13. The data was not normally distributed (Figure 4.10). Therefore, the interval is also reported in median and inter-quartile range (IQR). There was significant reduction in this interval from 2016 to 2017 (Mann Whitney's U test, $p<0.001$).

**Table 4.13 Submission of written report to Meeting interval (n=390)**

| **Interval in days** | **2016** | **2017** | **Total** |
|---|---|---|---|
| **Median** | 2 | 0 | 0 |
| **IQR** | 0-7 | 0 | 0-4 |
| **minimum** | 0 | 0 | 0 |
| **maximum** | 122 | 25 | 122 |

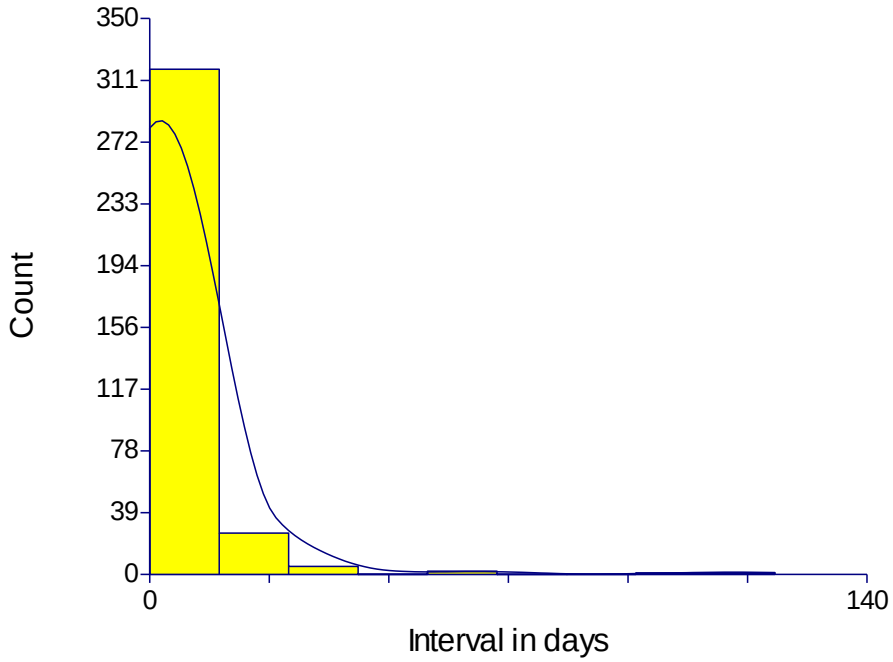


**Figure 4.10 Submission of written report to Meeting interval (n=390)**

### 4.5.4 SAE MEETING TO CLOSURE INTERVAL

The '*SAE meeting'* to '*Closure*' interval is described in Table 4.14. The data was not normally distributed (Figure 4.11). Therefore, the interval is reported in median and inter-quartile range (IQR). There were no significant changes in this interval from 2016 to 2017 (Mann Whitney's U test, p<0.001).

**Table 4.14 SAE Meeting to Closure interval (n=390)**

| Interval in days | 2016 | 2017 | Total |
|---|---|---|---|
| **Median** | 0 | 0 | 0 |
| **IQR** | 0 | 0 | 0-0 |
| **minimum** | 0 | 0 | 0 |
| **maximum** | 1 | 0 | 1 |

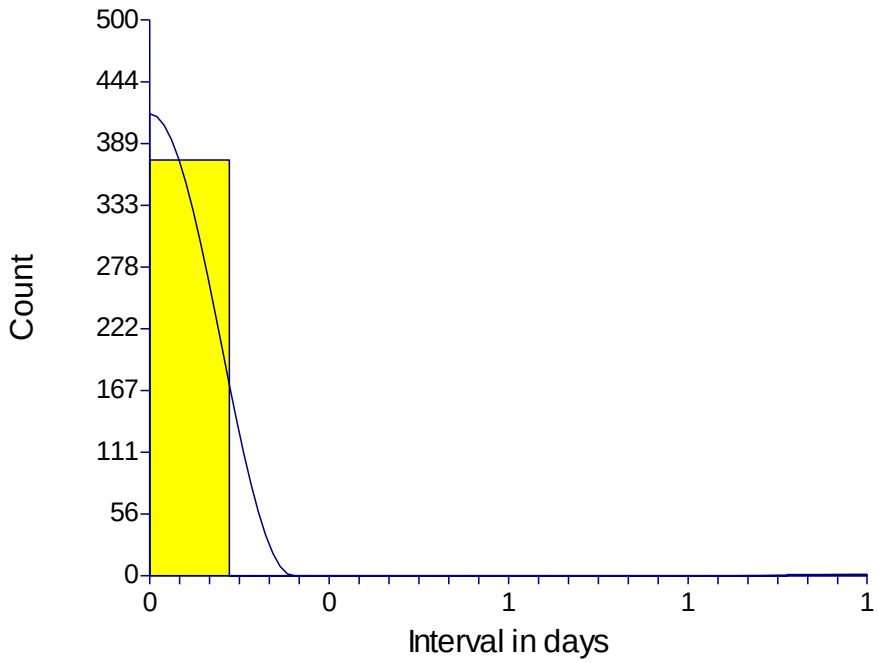


**Figure 4.11 SAE Meeting to Closure interval in days (n=390)**

### 4.5.5 INCIDENCE TO CLOSURE INTERVAL

The 'I*ncidence*' to '*Report'* interval is described in Table 4.15. The data was not normally distributed (Figure 4.12). Therefore, the interval is reported in median and inter-quartile range (IQR). There was a significant reduction in the Total SAE management time (from *Incidence* to *Closure*) from 2016 to 2017 (Mann Whitney's U test, p<0.0001). The closure time exceeds 100 days in two cases in 2016, one was associated with fall, and the other one was associated with error in treatment.

**Table 4.15 Incidence to Closure interval (n=390)**

| **Interval in days** | **2016** | **2017** | **Total** |
|---|---|---|---|
| **Median** | 10 | 7 | 8 |
| **IQR** | 5-19 | 4-12 | 4-16 |
| **minimum** | 1 | 1 | 1 |
| **maximum** | 188 | 43 | 188 |

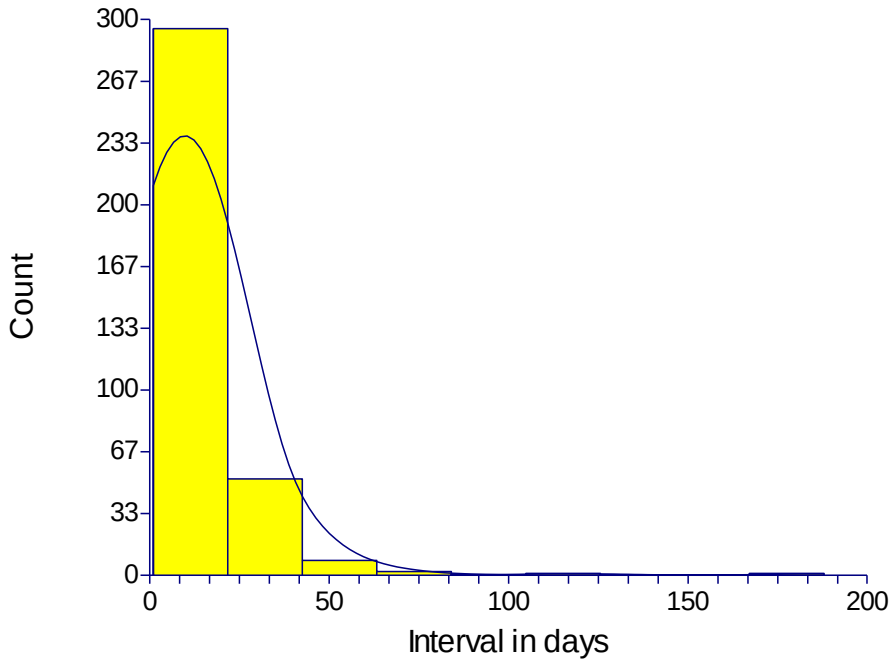


**Figure 4.12 Incidence to Closure interval in days (n=390)**

## 4.6 OUTCOME

The outcomes of the SAE meetings in terms of measures to be taken for prevention of similar incidences are described in Table 4.16. It implies that with the majority of the reported cases no further actions were taken.

**Table 4.16 Outcome of SAE meetings**

| Outcome | Extreme | High | Low | Medium | Total |
|---|---|---|---|---|---|
| **In-service training given to nurses** | 0 | 0 | 0 | 1 | 1 (1%) |
| **No disciplinary action** | 1 (100%) | 155 (99%) | 10 (100%) | 205 (98%) | 371 (98%) |
| **Referred to Labour relations** | 0 | 1 (1%) | 0 | 2 | 3 (1%) |
| **Total** | **1 (100%)** | **156 (1%)** | **10 (100%)** | **208 (1000%)** | **375 (100%)** |

# CHAPTER 5

# DISCUSSION

In this chapter, results obtained from the analysis of the data were discussed and compared with those from other published studies.

## 5.1 INTRODUCTION

It is noted that there hasn't been a similar study conducted in any of South African hospitals. Therefore, this study is quite unique and hope to stimulate further research in this area. The Steve Biko Academic Hospital strives to be the provider of highest quality; hence it is important to have a study like this that assesses elements of quality. Patient safety and low adverse event rates are a signal of potentially high-quality care and therefore it remains as one of South African National Ministry's quality priority. Domain 2 of the National Core Standards for Health Establishments (NDoH, 2011) also is related to this standard.

## 5.2 DIFFERENT CATEGORIES OF PATIENT-RELATED SERIOUS ADVERSE EVENTS

The SBAH being a teaching hospital that provides complex types of services. It is expected that it would have a higher rate of serious adverse events. Teaching hospitals are expected to have higher rates of SAEs (Trevis, et al, 2016). This also implies slower adverse event rate reduction as compared to the non-teaching hospital because of the high registrars' (inexperienced) turnover (Dynan, et al, 2017). However, SBAH has demonstrated 25% reduction in PRSAEs from 2016 to 2017 which is commendable, and the majority of this reduction is of high-risk category. However, there may still be a possibility of under reporting, but this probability is weakened by the fact that even the rating of the PRSAE had improved with less serious ones reported in the same period of reporting less PRSAEs even though more medium PRASEs were reported.

The SBAH also has significantly more hospital beds (845) and higher numbers of the hospital bed is expected to be positively associated with the adverse event rate.

(Dynan, et al, 2017). The rate of PRASAEs in other hospitals of similar size is not known and it might be interesting to compare them in future.

Reduction in rate and severity of PRSAEs might signify that: the intervention strategies that have been developed over time are starting to bear fruit. These strategies can be summarized as follows using the framework developed by the United Kingdom's NHS National Patient Safety Agency (NHS, 2004)

**Table 5.1 SBAH strategy to address Patient Related Serious Adverse Events**

| Steps | Descriptions |
|---|---|
| **Step 1** | An open and fair culture was created in the SBAH, which resulted in being judged as best quality public hospital in South Africa (Matshili and Makhubu**,** 2018). |
| **Step 2** | A clear and strong focus on patient safety was established through the Quality Assurance Department which reports directly to the office of the Chief Executive Officer as well as a performance indicator with most monitoring elements in the monthly Quality Assurance Committee meetings. |
| **Step 3** | A quality improvement Plan (QIP) was developed to manage risks as per National Core Standards for Health Establishment assessment results. SBAH Quality Assurance Committee's predetermined performance indicators have been monitored monthly) |
| **Step 4** | All staff members and even patients and their families were encouraged to report these incidents as evidenced by complaints numbers & resolution rate and monthly meeting of SAE and Complaints Committee. |
| **Step 5** | Regular communication was done with patients as well as their family members. This resulted in even family members reporting the adverse events even if they were minor incidents. Regular redress meetings take place with affected families and patients, in addition, morbidity and mortality meetings have been organized monthly. |
| **Step 6** | Staff are encouraged to use root cause analysis to learn how and why incidents happen |
| **Step 7** | The SBAH management has been embedding lessons through changes to its practice, processes or systems |

The results demonstrated that with interventions and having a systemic approach to patient safety, it is possible to reduce the number as well seriousness of PRSAEs.

## 5.3 DEMOGRAPHIC AND CLINICAL PROFILES OF THE SUBJECTS

**DEMOGRAPHIC PROFILE**

Socio-demographic profiles of patients might play an indirect role for patients involved with SAEs (Couillet, et al, 2007). Even though incidences of PRSAEs is higher between ages of 60-70 years, statistically there was no significant difference in age between the two years of study. It is worth taking extra care of this age group as an intervention strategy as they constitute a high-risk category (Mion, et al, 2012).

Even though ethnicity was not considered in this study, SBAH happen to be in the Capital City of South Africa; it, therefore, caters for a sizeable number of people from all ethnic groups including Caucasians. Because of their historical socio-economic status, Caucasians tend to live longer and therefore, they might be more prone to PRSAEs. This should be considered in the future studies. The main-users of the SBAH are public funding dependent and poor socio-economic condition. That puts the hospital at a higher risk of having increase patients who are prone to have SAEs (Mion, et al, 2012). There was no difference in gender of the subjects which was like the findings of study (Mion, et al, 2012).

**CLINICAL PROFILES**

Patients' fall from hospital beds linked to shortage of staff, constitute one of the most common PRSAE across the world (Mion, et al, 2012). This study also reported a significant number of falls (157, 40%), which was higher than reported elsewhere (23%) (Naessens, et al, 2009). Many oncology patients, (11%, 45) were found to have SAEs of which 34 (75%) of them were due to fall. This might be due to the exposure to the chemotherapy. Thirty four (10%) patients were from the Psychiatry ward, 14 of them (35%) associated with fall, and 4 (11%) of them demonstrated aggressive behaviour that required restraining. For both patient groups, it might be due to effect of medicines that they were on, both of which would require further study.

In the Surgical wards, the most important PRSAE were operating theatres or procedure related deaths (106) which was 94% of the total deaths (n=112). Twenty

(18%) of them were related to Gastroenterology Surgery, 15 (13%) with congenital malformation, and 26 (23%) of them were related to Cardiothoracic surgeries. This would require further investigation through improved clinical governance, as a significant proportion of reported adverse events in hospital operations theatres was found to be unintentional (Khorsandi, et al, 2012).

Although the ICUs were expected to have more mortality related SAEs, there were fewer than expected in comparison to the other studies (Garrouste-Orgeas, et al, 2008; Dyan, et al, 2017).

There were few SAEs (3.3%) in the Obstetrics and Gynaecology Unit, in comparison to other hospitals in South Africa such as King Edward VIII Hospital maternity unit in Durban (17.7% of the total reported adverse events) (Matsaseng & Moodley, 2005).

## 5.4 DIFFERENT FACTORS ASSOCIATED WITH PATIENT-RELATED SERIOUS ADVERSE EVENTS

Patient related factors might play an important role in avoidance of adverse events and they should be studied simultaneously with health system factors (Couillet, et al, 2007; Meda, et al, 2008). Patients were found to be associated with 67 (17%) cases over the two years, with 19% (43/224) incidences in 2016 and 14% (24/166) in 2017. This illustrate that patient causal factor was reduced by 5%. Majority of these events (51, 6%) were due to patients absconding from the hospital. They were ultimately found and brought back to their respective wards. However, the fact that they left without being ready for discharge was still regarded as PRSAEs. It was established without quantifying that in this study root cause of these abscondment might be social, mainly drug and other addictions as hospital do not allow smoking, drinking or use of any illegal drug in its premises.

The majority, contributing 313 (80%) of the 390 reported of PRSAEs cases, were associated with treatment provided by staff members who care for patients, hence they were classified as health professional factor in this study. It is evident that they were unintended outcome of treatments (making them adverse events) and were not due to negligence but rather expected/ known complications of treatment. Dynan, et al (2017), in a study among registrars in Internal Medicine department in a hospital in

the USA, found that lack of experience, work overload, poor judgment and case complexity could play important role. This might be the applicable to the SBAH, which is a teaching hospital with services driven by registrars as well as responsible for management of highly complex medical conditions. In addition, other health professional factors (such as knowledge, skill, fatigue, or failure to follow rules, technical mistakes, and/or an inability to cope with the complexities or demands of the healthcare system) might play a role (Kessler, 1993). In this study, these factors were not assessed.

In this study, Administrative factors pay a small role (10, 3%). Malfunctioning of lift is the main administration factor and even though there were no recorded SAEs, there were near misses that included patients' family members struck with the lifts. They were listed as PRSAE for hospital management to be on the alert of a potential SAE cause and to develop intervention strategies.

## 5.5 THE MANAGEMENT PROCESS FOR THESE EVENTS

The investigation of the majority of the PRSAEs were completed within a reasonable time (median 8 days), with a significant reduction from 2016 to 2017. Although all steps of the *Serious Adverse Event Management Policy* algorithm developed by the Gauteng Department of Health were followed accordingly, in 5% cases (20/390), the submission of final reports were longer than stipulated 25 days (GDoH, 2013). This would require further investigation.

It is interesting to note that no further action had to be taken in most of cases (371, 98%), and this can be postulated to the fact that investigations to PRSAE were not due to medical negligence but rather as true unintended outcomes as per the definition of adverse event (Walshe, 2000).

Still, the SBAH management should develop focussed in-service training programme embedding lessons based on the PRSAE reports for changing practice, processes or systems as proposed in other studies (Matsaseng & Moodley 2005; Majoko, et al, 2005; Beaves, et al, 2007; Khorsandi, et al, 2012).

## 5.6 POSSIBLE LIMITATIONS

The possible limitations to this study include:

- Poor reporting of PRSAEs might result in non-representative sample, not being representative of the actual picture (such as 25% reduction in PRSAES from 2016 to 2017). Hence, in addition to the SAE register, different data sources (such as Medico-legal cases or claims records and complaints register, compliments records, media queries & articles) were utilized to minimise this limitation. In addition, the information deduced from the *systems of SBAH rating of services and complaint management* was used.
- The study has not explored details of the listed causal factors associated with the PRSAEs and therefore, could not provide more insight into the problem in specific areas (such as death in operating theatre, falls, abscondment) which would require further studies.

# CHAPTER 6
# CONCLUSION AND RECOMMENDATIONS

In this chapter, recommendations obtained from this study were assessed in relation to the aims and objectives of the study, so that appropriate conclusions can be drawn. The limitations of the study are listed. Based on the findings of the study, appropriate recommendations and suggestions for future research are included.

## 6.1 CONCLUSIONS RELATED TO THE AIMS OF THE STUDY

This was a cross-sectional retrospective study for assessment of patient-related adverse events in Steve Biko Academic Hospital, a central in the Gauteng Province during two-year study period (01 January 2016 to 31 December 2017). Records of 390 participants were used for analysis.

### 6.1.1 PATIENT-RELATED SERIOUS ADVERSE EVENTS WITH RESPECT TO DIFFERENT CATEGORIES

There was 25% reduction in PRSAEs from 2016 (224) to 2017 (166). The majority of the events were medium (55%) and high (41%) risk categories and few in the low (3%) and 1% extreme categories. Although the numbers were almost equal in medium and high-risk categories in 2016, there was a significant reduction in the number of high risk categories in 2017.

### 6.1.2 DEMOGRAPHIC AND CLINICAL PROFILES OF THE SUBJECTS

The majority of the subjects were in the middle age group (21-70 years) with no significant difference between male and female subjects. The majority of the SAEs happened in Medicine, followed by Operating theatre, Surgery, and Psychiatry. The main clinical disciplines of these subjects included Oncology, Psychiatry, Surgical Gastroenterology and Trauma.

### 6.1.3 DIFFERENT FACTORS ASSOCIATED WITH PATIENT RELATED ADVERSE EVENTS

*Health professional* factors were identified as the most important contributory factors. Abscondment of the patients being of the major *Patient factors.* History of falls and deaths were the leading *health professional* factors. Malfunctioning of lifts was the major factor in the *Administration* category.

### 6.1.4 THE MANAGEMENT PROCESS FOR THESE EVENTS

The investigation of the majority of the PRSAEs were completed within a reasonable time (median 8 days), with a significant reduction from 2016 to 2017. Although the majority of the four intervals [namely intervals between (a) Dates of Incidence and Reporting, (b) Dates of Reporting and Submission of written report (c) Dates of submission of written report and SAE Committee meetings, and (d) Dates of SAE Committee meetings and Closure] were short, in some cases interval became long, which would require further investigation.

## 6.2 RECOMMENDATIONS

Based on the findings of this study, it is recommended that SBAH management zoom into the main contributor of PRSAE and develop interventions after establishing the causal effects. It is recommended that management immediately institute NHS' seven-step patient safety model. Furthermore, the SBAH management should put in place strategies to ensure monitoring of the implementation of the SAEs policy in terms of reporting of all categories of SAEs to avoid any underreporting.

The study results indicated a high number of abscondment, and falls, which would require improved vigilance from ward staff. It is recommended that the SBAH management should improve safety and security services throughout the hospital.

This study revealed that the majority of deaths occurred were procedure-related/ in operating theatre, which should be addressed through Clinical Governance Committee. The clinical audits should be made compulsory or mandatory in operating theatre, where structured peer reviews by a team of clinician examines the

existing practices against acceptable standards. In addition, a range of audit topics such as quality of patient care, development of staff and improved management should be used for in-service training. The Hospital should enforce Safe Surgery Project by making it a policy. The management team should address the main PRSAEs such as falls, abscondment and deaths of procedure-related/ operating theatre and attempt to find out effective remedial measures.

### 6.2.1 FOLLOW-UP AND FUTURE RESEARCH

A detailed qualitative study is required to study these PRSAEs and identified causal factors to generate hypotheses for further studies. In addition, the in-service programmes should be evaluated to determine its effectiveness in management of PRSAEs. The induction and in-service training programmes of all health professional trainees should include management of SAEs.

Follow up study should be conducted using root cause analysis to learn how and why incidents happen. An implementation research study embedding lessons through changes to practice, processes or systems should also be done.

### 6.2.2 PLAN FOR UTILISATION AND DISSEMINATION OF RESULTS

The SBAH management team for its continuous quality improvement strategies would hopefully utilize the study report. The report confirmed that the current strategies that are meant to minimise PRSAEs were effective as there is a 25% reduction in PRSAEs. It would also be reported to The Gauteng Department of Health who might also be interested in their possible utilisation in service improvement planning.

## 6.3 SUMMARY AND CONCLUSIONS

This cross-sectional study for assessment of patient-related adverse events in Steve Biko Academic Hospital studied records of 390 subjects.

There was a decrease of 25% on PRSAEs from 2016 to 2017. Most importantly, the study findings showed that treatment related unintended outcome, here classified as

"health professional factors" played a significant role on the occurrence PRSAs in the hospital and that the majority of the reported PRSAEs were of medium or high-risk category. They were mainly procedure –related or occurred in Operating Theatre besides patients' falls. Only a negligible number of cases were found to be due to negligence rather than real treatment related complications. Therefore, only few ended up with disciplinary action being taken. It is therefore critical that the SBAH management urgently intervene and address identified health professional factors, especially those that may be preventable.

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