ASSESSMENT OF REPORTED IN-PATIENT ADVERSE EVENTS:

RETROSPECTIVE STUDY OF REPORTED ADVERSE EVENTS AT THE FREE STATE PSYCHIATRY COMPLEX FROM 2008-2010

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DECLARATION

I, Jacoline Qhali, 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. It has not been submitted before any degree or for any examination at this or any other University.

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DEDICATION

For the development of this research I feel a deep sense of gratitude to:

The Almighty for His mercy and blessings in my lifetime;

My husband Shuping for his continuous support and love; my children, Shawn, Thato, Nthatisi and Lebo, for supporting my travels and involvement outside the home and for giving me a reason to strive to be the best I can.

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ABSTRACT

Background: Although the Free State Psychiatry Complex has collected information on adverse events, the reporting processes have not been consistent, systematic or transparent and this information was not used in the planning process. In addition, there is also a perception that the rate of adverse events is increasing, that these adverse events are not managed adequately and the extent of the problem could not be determined. It was for this reason that this study was found to be necessary to investigate further on patterns of serious adverse event occurrence, to put the arguments to a scientific test and be certain about the extent to which contributory factors were associated with the occurrence of these events in the Free State Psychiatry Complex.

Aim: The aim of the study was to describe the inpatient-related adverse events and factors contributing to these adverse events reported at the Free State Psychiatry Complex in order to develop effective strategies to prevent and reduce these adverse events.

Methodology: This was a cross sectional study design based on a retrospective review of records of patients who were involved in these adverse events. The study was undertaken at Free State Psychiatric Complex which is a specialized Mental Health Care Establishment from 1 April 2008 to 31 March 2010. All records of reported adverse events of all inpatients at Free State Psychiatry Complex were reviewed and no sampling was done. The study included review of routinely collected hospital information on patients' records and registers and from the Advance Incident Management System (AIMS).

Results: There were 419 Serious Adverse Events reported during 1 April 2008 to 31 March 2010. The most commonly reported SAE's included Aggressor-Aggressor, Aggression-victim, Behaviour/Human Performance, Accident/occupational health and safety and falls. The Aggression related adverse event type was one of the most common types of SAE's, constituting 40% of the Serious Adverse Events reported. The Behaviour /Human Performance adverse event type was second in frequency.

Other common SAE's reported during the study period included Medication, Pressure ulcer, Clinical Management and Organisation Management. These Serious Adverse Events occurred in 5% of the inpatients at Free State Psychiatry Complex and the findings showed an increase rate of 3.3%. Although more than 80% of the adverse events gave rise to moderate disability, 2% caused permanent disabling injuries and 2% led to death. However, only 15% of the SAE's caused minor harm to patients. The most Serious Adverse Events occurred in the months of March, December and November which indicate that seasonal changes are associated with increased risk for Serious Adverse Events. Most SAE's happened during the day-shift which might be ascribed to the organisational routines such as medication rounds, handover periods and mealtimes.

Human and System Adverse Event Error Types accounted for more than 70% of these SAE's. The study revealed a positive relationship between the patients in the Intellectual disability and Psycho-geriatric specialities and Accident/occupational health and safety as well as falls related adverse event types. There was also a positive correlation between male patients in the age group of 9-38 in the Acute and Forensic Specialities and Aggression- as well Behaviour Performance related Adverse Event Types. The patients diagnosed with Schizophrenia, Substance Induced Psychosis and Intellectual Disability was mostly associated with an increased risk for Serious Adverse Events. The results showed that co-morbidity, the patient's disease profile, age, admission classification, organisational routines and seasonal changes are associated are contributory factors too Serious Adverse Events. It supports the premise that human and system errors as well as the profile of the patient are contributing to SAE's.

Conclusion: Safety issues in mental health are unique and are in that way different to the safety issues in medical care. Both the patient population and the environment make patient safety in mental health unique. The uniqueness is associated more with the diagnosis, the patient population and with the mental health setting. SAE's included Aggressor-aggression, Aggressor-victim, Behavior Performance (absconding, self-harm, suicide); Occupational health and safety, falls and other injuries are particularly prominent to mental health patients. Although patient safety in mental

health was considered a field of importance, there is still a lack of awareness of the issues as well as a shortage of research and readily available information to guide patient safety systems, practices, policies, and care delivery in mental health. Work is required to establish a clear definition, set priorities, and develop strategies for responding to patient safety concerns. Models of quality improvement are being utilized in psychiatry hospitals but the need for evidenced-based quality improvement models for inpatient psychiatric care still exist. Findings from my study showed that Serious Adverse Events are prevalent in Free State Psychiatry Complex and factors significantly associates with the frequency of aggression-, behavior/occupational health and safety and falls related adverse event types. Advancing a quality and safety research agenda for inpatient psychiatric care will guide practice, improve care, and help ensure efficient and effective care. Complicated problems such as the provision of acute psychiatric hospital services require solutions that incorporate depth of understanding the complexities of acute mental illness as well as changes in prevailing attitudes and systems.

This study has also highlighted that Serious Adverse Events are contributed by a varied set of contributing and interacting elements, including patient factors, human factors, system factors, and environmental factors. A complex interaction between the mental health environment and the diagnosis/patient population was found which differentiates patient safety from other health sectors is. Understanding this interaction and its relationship to patient safety is very important. It is believed that research in scientific advances, systems analysis, education and development, dissemination of guidelines and improved standard of practice is required for reduction of SAE's (Leappe et al. 1991)

This was the first study to systematically evaluate adverse events in a mental health establishment in the Free State province. The researcher hopes that the Department of Health in the Free State Province would utilise the findings of this study to review and to improve the safety programmes on the care, treatment and rehabilitation of the mental health care services.

TABLE OF CONTENTS

LIST OF TABLES

DEFINITION OF TERMS

Adverse event refers to any unexpected, unwanted event or circumstance that could have or did lead to unintended or unexpected harm, loss or damage. It includes all possible medico-legal events (WHO Draft guidelines for adverse event reporting and learning systems, 2005).

Serious Adverse event refers to any event which causes death, permanent damage, birth defects, or requires hospitalization is considered an SAE.

Adverse drug event: An adverse event related to a medication (Localio, Weaver, Lanks et al. 1996).

Error refers to the failure of planned sequence of mental and physical activities to achieve its intended outcome when these failures cannot be attributed to chance (Reason, 2000).

Principle Adverse event types include

Accident/occupational Health: Classify incidents related to accidents, occupational health and safety or the physical environment and staff incidents. For example a needle stick injury/ exposure to a hazardous substance /a patient sustain an injury of unknown origin / a wet or slippery floor surface.

Aggression-aggressor: Classify the details of the aggressive person (or the perpetrator) of an aggressive incident.

Aggression-victim: Classify the victim of an aggressive episode, if there was an outcome for the victim.

Behaviour/human performance: Classify the details of behavior or human performance incidents. For example: patient deliberately self-harming / absconding patient.

Medication/IV fluid, nutrition: Classify the details related to medication or intravenous fluid incidents for example: medication prescribing errors / nurse administers a medication with the intent of asking the clinician for a prescription later / incorrect intravenous fluid infusion rates.

Falls: Classify the details related to a fall for example: a patient was found on the floor and it could not be confirmed that a fall took place / a disorientated patient fell while ambulating after forgetting to use their walking frame.

Clinical management: Classify the details related to the clinical management of the subject.

Pressure ulcer: Defined as any lesion caused by unrelieved pressure resulting in damage of underlying tissue.

Organisation management: Classify the details of any incident involving the provision of patient, staff and visitor services or the organizational management of the health care institution, for example: no hospital beds available / inadequate staff supervision / insufficient staff for workload (COHSASSA, 2007).

Human factors: The study of inter-relationships between humans, the tools they use, and the environment in which they live (The American Psychiatric Association Task Force Report, 2002).

Patient related Adverse events factors: such as socio-demographic profile (age, gender, ethnicity), and clinical profile (Admission classification, diagnosis according to DSM IV).

System factors related to adverse events refer to are policies, equipment, staffing, education/training, communication, information (FSPC Institutional Policy PCG 136, 2006).

Individual factors in the context of this study include /adverse event error types include human, system, inappropriate behavior, at risk behavior, patient idiosyncratic response.

"Safety Assessment Code refers to a method of determining whether any further action is required concerning an event and the probability of occurring again and events are graded as:

SAC1. Extreme: Patients with death unrelated to natural cause of the illness and differing from the immediate expected outcome of the patient management.

SAC 2: Major: Patients with major permanent loss of function unrelated to the natural course of the illness and differing from the immediate expected outcome of the patient management.
SAC 3: Moderate: Patients with permanent lessening of bodily functioning unrelated to the natural course of the illness and differing from the expected outcome of the patient management.
SAC 4: Minor: Patients requiring increased level of care including: Review and evaluation, additional investigations and referral to another unit" (COHSASSA, 2007).

Safety: To be free from accidental injury (Localio, Weaver, Lanks et al. 1996).

Safe environment refers to an environment that is free from accidental injuries (Free State Psychiatry Complex Policy PCG 136 2006)

System refers to a set of interdependent elements interacting to achieve a common aim. Element may be both human and non-human (Reason, 2000).

Admission Classification refers to:
Voluntary care: Patients who are able to give informed consent for treatment, care and rehabilitation**.**
Assisted Care: Patients unable to make informed decisions, is not in contact with the reality but does not refuse treatment and rehabilitation.
Involuntary Care: Patient who is unable to make informed decisions, is not in contact with reality but refuse treatment, care and rehabilitation.
Forensic Patients include Psychiatric assessments ('30-day observations'**)**: Criminal defendants are referred by the courts for evaluations of triability and criminal responsibility as well as Criminal defendants that have been found to be mentally ill and not trial-able are certified for an indefinite period and admitted to this hospital

Psychiatry Services/speciality in this context refers to the following range of services:

Acute Care services for Affective for patients that require assessment, therapy and other interventions for non-psychotic disorders and for the admission and treatment of serious psychiatric disorders, such as Schizophrenia, and Bipolar affective disorder that cause or are associated with behaviours that are dangerous to the patients or others, suicide risk and vulnerability that requires the containment of a ward.

Long-term Psychiatry services for treatment of patients who cannot be easily discharged because their illness is too severe to be managed in the community and more intensive therapeutic interventions are required. Despite ongoing symptoms or behaviour difficulties they do not warrant containment in a high or medium care ward.

Psycho-geriatric services for patients above 60 years who cannot be easily discharged because their illness is too severe to be managed in the community and more intensive therapeutic interventions are required. Despite ongoing symptoms or behaviour difficulties they do not warrant containment in a high or medium care ward.

Forensic Psychiatry services for the assessment of defendants referred by the courts, and Treatment and Rehabilitation of forensic patients.

Persons with intellectual Disabilities for the assessment care and treatment of patients with intellectual disabilities (FSPC Revitalization document, 2012)

DSM 1V Diagnosis include Schizophrenia, Schizophrenia with medical condition, Major Depression, Bipolar Mood Disorder, Substance Induced Psychosis, Mental Retardation, Psychosis due to medical condition and Mental Retardation with medical conditions.

Patient means mental health service users, consumers, clients.

Patient safety refers as the reduction and mitigation of unsafe acts within the health care system as well as to the use of best practices shown to lead to optimal patient outcomes (Davies, Herbert & Hoffman, 2003).

Dual Diagnosis: It describes the presence of two or more disorders at the same time. For example, a person may suffer substance abuse as well as bipolar disorder.

(American Psychiatric Association, Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition)

Mental health refers to those diagnoses covered in the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, Text Revision (DSM-IV-TR, American Psychiatric Association [APA], 1997).

Aggression refers to any behaviour in which the patient places their hands on one another with the intention of causing harm. (Steadman et al.1998).

Violence is defined as threats with a weapon in hand, sexual assaults and assaults resulting in injury (Monahan et al. 2010).

Diagnostic and Statistical Manual of Mental Disorders ((DSM-IV), Fourth Edition refer to a manual in which Psychiatric Diagnoses are categorized by the Diagnostic and Statistical Manual of Mental Disorders, 4th. Edition. The manual is published by the American Psychiatric Association and covers all mental health disorders for both children and adults. It also lists known causes of these disorders, statistics in terms of gender, age at onset, and prognosis as well as some research concerning the optimal treatment approaches (The American Psychiatric Association)

Specialized Mental Health Establishment: A facility designated and registered in terms of the Mental Health Care Act 17 of 2002 to render mental health care services.

Regional Hospital: Is a specialist hospital that is rendering Level 11 or secondary services in terms of South African National Health system.

District Hospital: Is a hospital rendering Level 1 care within the District Health system.

LIST OF ABBREVIATIONS

AIMS	Advance Incident Monitoring System
AE	Adverse Event
APA	American Psychiatric Association
CEO	Chief Executive Officer
COHSASSA	Council Of Health Standard of South Africa
DHS	District Health Services
DSM 1V	Diagnostic and Statistical Manual of Mental Disorders.
FSPC	Free State Psychiatry Complex
IAEC	Institutional Adverse Events Commit-tee
NPSA	National Patient Safety Agency
PHC	Primary Health Care
SAC	Safety Assessment Code
SAE	Serious Adverse Event
USA	United States of America
WHF	World Health Forum
WHO	World Health Organisation

CHAPTER 1

INTRODUCTION

The purpose of this study was to describe the pattern of Serious Adverse Events and contributory factors affecting the patients at Free State Psychiatry Complex. This information will be used to understand the common features in Serious Adverse Event patterns and contributory factors of patients at Free State Psychiatry Complex. This introductory chapter covers the background to the study, statement of the problem, its aims and objectives and an outline of the subsequent chapters.

1.1 Background

Patient safety in the hospital environment has become a global and regional issue of immense importance in both first and third world contexts. About 50% of healthcare errors are considered preventable and with an estimated average of 10% of all inpatients visits resulting in some form of unintended harm. This made the need of safety clear. Although adverse events in medicine have been studied for several decades, but it is only recently that they began to use it as a guide to improve quality. The first studies of adverse events focused on specific undesirable situations but did not have long-term repercussions. It was not until the mid-1970s that the California Medical Association decided to analyze the importance of adverse events in a study that reviewed the histories of 20 864 admissions. The review reported a rate of adverse events of 4.6% and evidence of negligence in 0.8% of cases. (Pere Rebasa, Laura Mora, Alexis Luna et al. 2008).

In South Africa patient safety is included in the National Core Standards and is one of the Ministerial priorities for 2010/2015. Initiatives are being taken throughout the sector to reduce the impact of adverse events. Recently the Free State Provincial Compliance Unit issued a policy guideline on adverse events to provide guidance on processes and systems for organizational reporting, management and investigation of incidents, accidents and hazards. Changes have been introduced to improve

complaints processes and to ensure health professionals retain their competence as part of a comprehensive bill to address safety and quality in the health sector. Medical errors reported in Psychiatry units only received worldwide attention from the eighties when an investigative series in the Hartford Courant in the USA reported 142 deaths that occurred during seclusion and restraint in psychiatric facilities. Since then, safety in Psychiatry units was brought into the national discussion in the United States of America SA resulting in a patient safety project being established by the American Psychiatric Association (APA) Task Force Team on Patient Safety. (American Psychiatric Association Task Force Report on Patient Safety, 2002). However, the situation is different in developing countries like South Africa where no formal studies have been done, although the Mental Health Care Act was legislated in 2002 which legislates for the protection and safety of psychiatric patients.

Free State Province

The Free State Department of Health (FSDH) provides health services based on the District Health System (DHS). There are five districts; namely, Motheo, Xhariep, Thabo Mofutsanyane, Fezile Dabi and Lejweleputswa (see Figure 1). In each district, District hospitals refer patients if required to a Regional hospital. According to the DHS, the entry level for health care services PHC facilities which are made of clinics and community health centers (see Figure 2). District hospitals, which form part of the DHS, accept referrals from the PHC facilities for further management. District hospitals refer to the regional and specialized hospitals patients that need specialist health care services (Gorgen, Kirsch-Wok, et al. 2004).

Figure 1: Free State Province Districts

The Free State Psychiatry Complex (FSPC) is an 870-bed specialized Mental Health hospital situated in the Motheo District in the capital city of the Free State Province namely, Bloemfontein (Figure 1). The hospital is designated as a Psychiatry Hospital in terms of the Mental Health Care Act, (Act 17 of 220). It is regarded as a specialized Psychiatric hospital and is included in program 4 of the Provincial Department of Health. The focus of the Free State Psychiatry is on the delivery of mental health and substance abuse services. The total planned population to be served by the Free State Psychiatric Complex is 2 855 152. The Free State Psychiatric Complex is located in the Motheo District Municipality. It provides inpatient services for the Forensic, Acute, Long-term, Psychogeriatric and for the persons with Intellectual Disabilities.

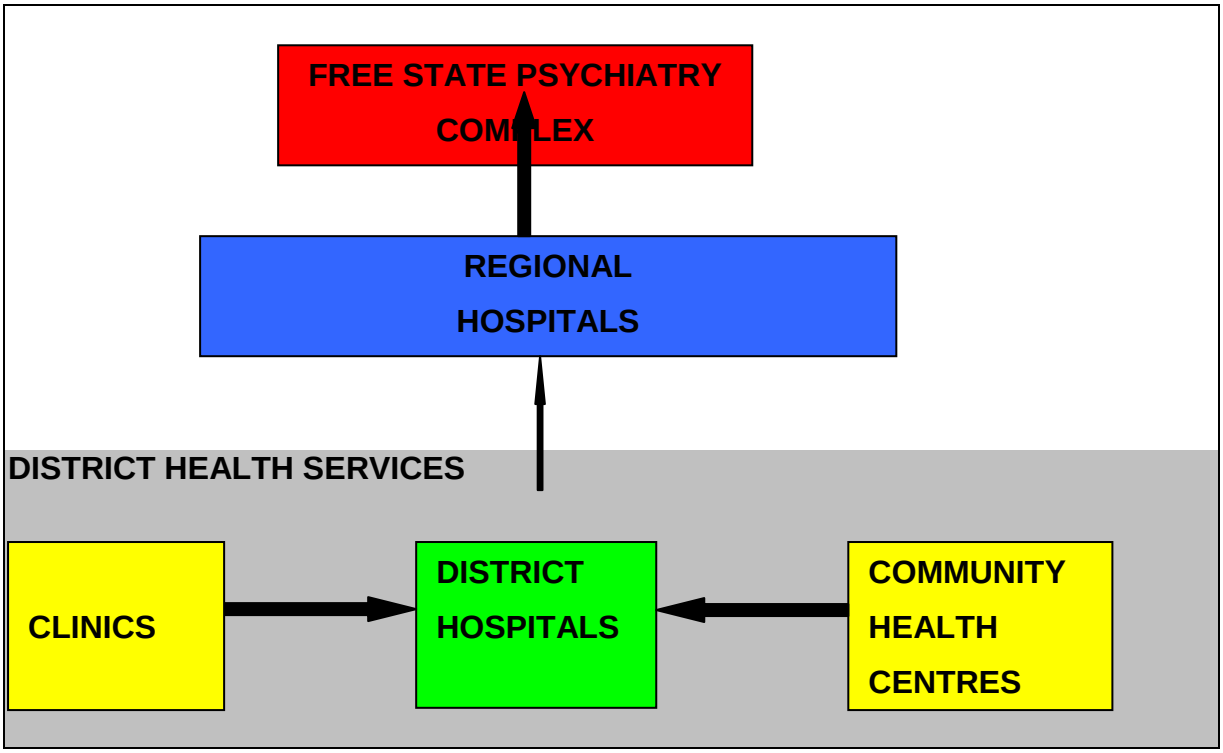

Figure 2: Free State province health referral system flow diagram

Justification for the study

Recent research findings indicate the lack of clear evidence on the nature and types of adverse events in psychiatry services and the need for further investigation on patterns of adverse occurrence and determination particularly in relation to preventability (Bates, Miller, Cullin et al.1999; Zhan & Miller, 2003). Although the Free State Psychiatry Complex has collected information on adverse events, the reporting processes have not been consistent, systematic or transparent and this information was not used in the planning process. In addition, there is also a perception that the rate of adverse events is increasing, that these events are not managed adequately and the extent of the problem could not be determined. It was for this reason that this study was found to be necessary to investigate further on patterns of serious adverse event occurrence, to put the arguments to a scientific test and be certain about the extent to which contributory factors were associated with the occurrence of these events. It will support the development of targeted strategies to prevent and reduce adverse events thereby enhancing patient safety. The findings of the research will be presented to the Provincial Hospital Services Directorate and it is envisaged that this methodology could be utilised in other hospitals that are rendering mental health

care services.

1.3 Research question

What are the reported inpatient-related adverse events and contributing factors related to these adverse events at the Free State Psychiatry Complex?

1.3 Study objectives

1.4.1 Broad Objective

To describe the inpatient-related adverse events and factors contributing to these events reported at the Free State Psychiatry Complex during a two year study period from 1 April 2008 to 31 March 2010.

1.4.2 Specific Objectives

1. To describe the inpatient related adverse events reported at the Free State Psychiatry Complex in terms of adverse event numbers, occurrence, type, date and time of adverse event**,** and Safety Assessment Code (SAC).
2. To describe the patient factors related to adverse events such as Socio-demographic and clinical profile (age, sex, gender, diagnosis, admission classification, Psychiatry specialty and different wards).
3. To describe the individual factors related to adverse events such as human error, system error, inappropriate behavior, at risk behavior, patient idiosyncratic response and no error detected

1.5 Subsequent chapters of the report

So far, the background to the research has been discussed and the 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 was to review pertinent literature and to discuss concepts related to adverse events and related factors reported in hospitals in South Africa and elsewhere.

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 aims and objectives.

Chapter Five: Discussion:

The findings from the review of the literature are incorporated 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:

This constitutes the last chapter of the report and derives conclusions from the research related to the objectives of this study, makes recommendations and advocates areas for future research in the field of adverse event reported at a Specialized Mental Health Hospital.

CHAPTER 2

LITERATURE REVIEW

In this chapter, relevant literature on patient related adverse events are discussed. In addition to published literature, information from various unpublished sources is also reviewed.

2.1 Introduction and background

There has been a steady increase in the number of medico-legal litigations against healthcare provider's worldwide (Brennan, Leappe, Laird, et al.1991). Furthermore, there has been an increase in monetary damages awarded to plaintiffs, indicating that at the minimum, errors in the medical care are responsible for adverse events. The situation in the Free State Province is not different in this regard. It is therefore essential to assess the quality of care provided, so that all errors due to medical interventions can be kept to the bare minimum. Despite the efforts implemented to reduce morbidity and mortality in the medical care including the introduction of antibiotics, aseptic techniques during surgical procedures, advances in medical technology and improvements in skills training and education of health personnel, adverse events still occur and result in huge personal loss to the affected individual and attendant staff (Thompson and Pretlove, 2002).

A cross sectional study in the Mayo Clinic Rochester hospital revealed that nearly 43% of provider reported adverse events were related to skin integrity events, 23% classified as medication events, 21% as falls, 1.8% related to equipment functioning and 37% miscellaneous events (Naessens, Campbell, Huddleston et al. 2009). The Free State Department of Health Aims Report (2011) showed that out of 1540 Principle adverse events that were reported, 7 was for Accident/Occupational Health & Safety, 6 for Aggression-Aggressor, 5 for Aggression-Victim, 18 for Behavior/human performance, 6 for Building/fitting/fix, 73 for Clinical Management, 3 for documentation, 11 for fall, 1 for Medication/fluid, 1 for nutrition, 13 for organizations/ Management /service, 2 for pathology/laboratory, 9 for ulcers and 3 for Poor Clinical Management . The review of the literature suggests that aggressive and violent assaults

are one of the most common types of events leading to patient safety incident reports (National Patient Safety Agency Report, 2006). Based on their analysis of nearly 45,000 incidents from 116 organizations in England and Wales, the National Patient Safety Agency Report (2006) reported 10,467 incidents of disruptive and aggressive behaviour constituting 23.4% of reports. The Clinical Indemnity Scheme Report (2009) highlighted the fact that the adverse event type related to the category of violence, harassment and aggression are rated the highest (35.5%) followed by 30.6% of events relating to slips trips and falls.

Previous studies have explored an association between aggression and mental illness (Linaker and Busch-Iversen, 1995). Severe psychopathology is still thought to be a major source of inpatient aggression and a strong association between thought disorders and violent behaviour was found (Nijiman H, Evers C and Merchelbach, et al. 2002). The Royal College of Psychiatrists (1998) further elaborated in their study that young men with psychiatric illness and a history of substance abuse are most likely to be violent. Fall rates and fall-related injuries were found to be generally higher among psycho geriatric populations. Hence accidental falls are a serious safety concern for mental health service providers (Gillespie Lesley D, Ian D Cameron, Geoff R Murray, et al. 2008).

The study previously cited (Braithwaite, Westbrook, Robertson, et al. 2011) showed that 3%-16% of hospitalized patients suffer harm from adverse treatment. The significance of adverse events problems is noted by Davids, Lee & Briant (2001) in New Zealand, in Australia as well as in the United Kingdom and the United States of America. It is also important to note, however that the majority of the Serious Adverse Events reported resulted in no harm (65.5%) or low moderate disability (81%) or minor harm to patients (15%), only 2% of SAE's involved death and severe harm to hospitals. Incidents of self-harm were the most likely to result in death (NPSA, 2006). A study conducted at King Edward Hospital, Durban revealed that adverse events occurred in 11.7% of admissions and 52% are avoidable. The majority of adverse events were minor (disability lasting less than 6 months). Mortality accounted for 17.7% of adverse events and 2.1% of all admissions (Matsaseng & Moodley, 2005).

The study previously cited (Braithwaite, et al. 2011) support other findings that structural, process and the profile of patients are contributing to adverse events. Organizational routines such as medication rounds, handover periods or mealtimes may be generally the result of adverse events happening more frequently during the dayshift than during night shift (Carmel and Hunter, 1993 and Vanderslott, 1998). A study in Durban, South Africa further revealed that poor judgment, inadequate use of diagnostic facilities and admission to an inappropriate surgical ward have been incriminated as the main reasons for undetected injuries (Chan, Ainscow, Sikorski, 1980). System related factors such as staffing and nurse skills also influence the frequency of patient falls in Psychiatry Hospitals (Thomas, Studdert, Runciman et al. 2000). It is found in Australia that the psychiatric patients who were involuntarily admitted accounted for 79% of all patient related adverse events (Benvesniste, et al. 2005). Although previous studies have generally not focused on adverse drug effects, results were consistent with previous studies in which drug identity checking errors and wrong dose administration were reported as among the most frequent type of errors (Hiroto & Yamazumi, 2003). A study done in New York showed that 10% of patients experienced an injury due to drugs that resulted in disability or prolonged stay in hospital (Bates, Miller, Cullin et al. 1999). Knowledge of how the prevalence and severity of adverse effects vary for different antipsychotics allows clinicians to reduce the occurrence of these effects. A review is needed for the range of adverse effects associated with antipsychotics and their clinical impact and an overview of the various sources of data on adverse effects and their relative strengths and weaknesses must be given

The relative risk of choking is 31 times higher for Organic disorders and 23 times higher for Schizophrenia (Ruschena, et al. 2003). Patients with schizophrenia or intellectual disabilities often have swallowing abnormalities, which correlate with the high incidence of congenital deformities occurring in this population (Cooper-Brown, Copelard, Daily, et al. 2008). It is also argued by Matsen, Fodstad and Boijoli (2008) that organic mental disorders such as intellectual disabilities carry a higher choking risk. The Medico-Legal laboratory in Bloemfontein, Free State reported 20 choking related deaths in the Free State between 2005 and 2008, of which 11 cases were in individuals aged 15 and older (Liebenberg, personal communication, 2009). As the complexity of care increases on inpatient units, so too does the likelihood of patient

safety incidents. Adverse events are also occurring more frequently amongst patients over the age of 65 years and injury and musculoskeletal related incidents are high in this age group according to a previous study done in New Zealand Public Hospitals (Davis et al. 2001). Adverse events are found more in admissions amongst the elderly patients with Schizophrenia, more likely amongst non-whites and in females who live in urban countries than in admissions without Schizophrenia. Risk factors associated with increased risk for adverse events were: presence of co-existing illness, complexity of the disease or treatment, surgical intervention in the operating room, elderly patients, the location where care is provided, less time spent with each patient and the sickest patients entering the hospital through the emergency room (Vincent, Neal and Woloshynowych, 2001).

Reflecting the known burden of comorbid medical conditions in persons with Schizophrenia, admissions for patients with Schizophrenia had a substantially higher prevalence of chronic obstructive pulmonary disease, diabetes mellitus, AIDS and substance abuse compared with those for patients without Schizophrenia. Admissions for patients with a secondary diagnosis of Schizophrenia were also more likely to be at a teaching hospital and a trauma center than those for patients without Schizophrenia, and three quarters of hospitalizations for patients with Schizophrenia were admitted through the emergency department (Gail, Daumit & Hopkins, 2006). The Regional Health Forum report (2008) revealed that the hospital admission rates for Schizophrenia and Schizoaffective patients are clearly increased in summer. The frequency of adverse events increased with age, the presence of co-existing illnesses, and severity of the illness on admission (Matsaseng & Moodley, 2005).

Communication, supervision, education and training deficiencies were established as the root causes of adverse events and therefore clinical risk management should aim at more than avoiding litigation and must be integrated with clinical audit and other quality assurance activities (Vincent, 1997). It is believed that research in specific causes, scientific advances, systems analysis, education and development, dissemination of guidelines and improved standard of practice is required for reduction of adverse events (Leappe et al. 1991).

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CHAPTER 3

METHODOLOGY

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

3.1 Introduction and background

This project was approved by the Human Research Ethics Committee of the University of the Witwatersrand. It was also authorised by the Chief Executive Officer of the Free State Psychiatry Complex.

3.2 Study design

The study design was a cross sectional study based on a retrospective record review.

3.3 Study setting

The study setting was all the inpatient wards at the Free State Psychiatry Complex. The Hospital Complex is the only Psychiatry Hospital in the Free State Province and is situated in Bloemfontein in the Motheo Region. The Hospital has a bed capacity of 827 beds. There are 32 wards further divided into 9 female wards, 2 mixed gender- and 19 male wards. The wards have a maximum bed capacity of 30 and a minimum of 10. More than 70 percent of the patients are Black. The Staff establishment consists of 1406 posts of which 1030 are filled. Clinical posts are 565 in total and consist of 6 medical specialist, 3 medical officers, 3 medical interns), psychologists and 33 Allied Health Support services that include social workers, occupational therapists, physiotherapists and 490 nurses. Thirty registrars are rendering services at this hospital but are they are on the staff establishment of Universitas Central Hospital. Maintenance and other support staff are 465 in total.

3.4 Study scope

The study involved reported adverse events of all inpatients at the Free State Psychiatry Complex.

3.5 Study period

The study period was two years (1 April 2008- 31 March 2010).

3.6 Study population and sampling

The Study population included all the records of in-patients who were involved in reported adverse events during the two year study period period 1 April 2008 to 31 March 2010. The entire study population was included and subsequently, no sampling was done.

3.7 Data management

3.7.1 Variables

The following variables were measured during the two study years

Table 3.1, Variables

Adverse events description	Adverse Event Types: Aggression-aggressor, aggression-victim, falls, clinical management, behavior/human performance, pressure ulcer, Accident / occupational health and safety, Medication / IV fluid and organization management. Time, month, year, safety assessment code
Patient factors	Age, ethnicity, gender, admission classification, DSM IV diagnosis, wards, psychiatry services/specialties.
Individual factors	Human error, system error, inappropriate behavior, at risk

	behavior, patient idiosyncratic response

3.7.2 Data collection

The data was first extracted from the adverse events register, then from the AIMS report followed by the admission register over the study period 1 April 2008 to 31 March 2010. The data that was used for this study has been collected routinely and captured electronically. The information was exported to the MS excel based data collection tools (Appendix A) designed for this study.

3.7.3 Data analysis

Extraction sheets were used to store data and SAS Version 9.1.3 to analyze data. Variables were grouped and coded. Analysis was done using tables of frequency, graphs and histograms

The following descriptive statistics were reported:

- Continuous variables (normally distributed): standard deviation;
- Continuous variables (not normally distributed): median and inter-quartile range, and
- Nominal and ordinal variables (such as ethnicity): proportions.

The formally comparative analysis was used: Adverse event types were compared and described against the following variables:

(a) Age groups; (b) wards; (c) gender; (d) diagnosis; (e) components of psychiatry services, (f) admission classification; (g) safety assessment code; (h) adverse event type; (i) time, (j) month; (k) year.

All data was captured in MS excel software. Subsequently, data was exported to SAS Version 9.1.3 software for analysis (NCSS, 2007).

3.8 Pilot study

No pilot study was done as the data used for this study was routinely collected.

3.9 Ethical considerations

No intervention was done as a part of this study. The permission to conduct this study was obtained from the Free State Department of Health (Appendix A). The project was also approved by the Human Research Ethics Committee (Medical) of the University of the Witwatersrand (Appendix A). Confidentiality and anonymity was maintained at all times in the processes of collection, capturing, and reporting of the information.

CHAPTER 4
4.0 RESULTS

The results obtained from the analysis of data are described in this chapter.

4.1 Description of serious adverse events

There were 419 SAE's reported during this period (Table *4.1).* There was a significant increase in SAE's from 2008/09 to 2009/2010 (Chi-square test, p =0.04).

Table 4.1, Period in which Serious Adverse Events were reported (n = 419).

Period	Admissions	Frequency (%)
Period 1 (Apr 2008- Mar 2009)*	8682	147(1.7)
Period 2 (Apr 2009-Mar 2010)	8252	272(3.3)
Total	16 934	419(5.0)

4.1.2 Principal types of serious adverse events

The most common Serious Adverse Events types reported during the study period are categorised by using the AIMS Categories. It is outlined in Table 4.2.
The majority of serious adverse event types reported were Aggression related (40%), followed by Behaviour/human performance adverse event type (28%). Other common Serious Adverse Events reported during the study period included Accident/occupational health and safety (16%), falls (13%), Pressure ulcer (6%), Clinical Management (1%), Organisation Management service (1%) and Medication There was a significant (12%-18%). A significant decrease was found in falls (47%-11%) and in Aggression-victim adverse event types (24%-15%). A significant increase was also found in Aggressor-aggression (17%-24%) and in Accident/Occupational health and safety adverse events. It is found in the analysis that there was a statistical significant difference in adverse event types for the period 2008/09 to 2009/2010 (Chi-square test, p = 0.0156).

Table 4.2, Serious Adverse event types for 2008/09 and 2009/2010

		Years	
Adverse event type	**Total**	**2008/2009**	**2009/2010**
Behaviour / human performance	119(28)	44(30)	75(28)
Aggression – aggressor	91(22)	25(17)	64(24)
Aggression – victim	76(18)	35(24)	42(15)
Accident / occupational health and safety	66(16)	17(12)	49(18)
Fall	53(13)	22(47)	31(11)
Pressure ulcer	8(6)	2(1)	6(2)
Clinical management	4 (1)	2(1)	2(1)
Medication / IV fluid	1(1)	0(0)	1(1)
Organisation management / service	1(1)	0(0)	1(1)
Total	419	147	272

The SAC rating of Serious Adverse Event type is outlined in Table 4.2. Disability was moderate (SAC3) for the majority of patients (81%), followed by a smaller proportion of 15% for minor adverse events (SAC 4). However, it should be noted that 4% of the patients suffered permanent disability or died.

Table 4.3, SAC rating of Serious Adverse Events (n = 419**).**

SAC Ratings	**Total**
SAC 1	4(1)
SAC 2	12(3)
SAC 3	339(81)
SAC 4	64(15)

4.1.2 Psychiatry services and serious adverse events

The majority of adverse events occurred in the Acute Psychiatry services (8.2%), followed by Forensic services (4.5%), the Long term Psychiatry services (2.5%) and Psycho geriatric- and Persons with Intellectual disability services respectively with 1.3% and 1.2%. An increase of Serious Adverse Events was observed in all psychiatric services/specialities with the highest percentage in Psycho-geriatric services

(8%-92%), followed by Persons with Intellectual Disability services (21%-79%), and Forensic Psychiatry- and Acute Psychiatry services respectively from 41%-59%. The summary of the Psychiatry services/specialities is outlined in Table 4.3. There was a significant increase of SAE's in all the services from 2008/09 to 2009/2010 except in Long term psychiatry care (Chi-square test, p =0.0001).

Table 4.4, Adverse events by psychiatric services

Psychiatric Services	**Total admission frequency**	**Total (%) Adverse events N=419**	**2008/09 n=147**	**2009/10 n=272**
Forensic psychiatry	3106	141(4.5)	58 (41)	83 (59)
Person with intellectual disability	10214	125(1.2)	26(21)	98(79)
Long-term psychiatry	2859	69(2.45)	32(46)	37(54)
Acute psychiatry	864	71(8.2)	29(41)	42(60)
Psycho-geriatric	1028	13 (1.3)	1(8)	12(92)
Total	**18071**	**419**	**147**	**272**

4.1.3 In-patient wards and serious adverse events

The majority of Serious Adverse Events were reported in Block A, an acute Psychiatry ward (14%), followed by Block B, a forensic psychiatry admission ward (10%), and A-West, a Long term Psychiatry ward (9%). A markedly high increase of Serious Adverse Events was observed in Block B (4.75%-12.87%) and in 1e ward, (2.04%-9.19%) during the two year study period. The summary is outlined in Table 4.3.

Table 4.5, Serious Adverse Events reported in the 7 top wards.

Ward	Total (%) N=419	2008/09 n=147	2009/10 n=272
Block A	58(14)	22(38)	36(61)
Block B	42(10)	7(17)	35(83)
Block D	28(7)	13(46)	15(54)
A-East	12	7(58)	5(42)
A-West	36(9)	17(47)	19(53)
C-East	24(6)	17(70)	7(30)
C-West	23(5)	9(39)	14(61)

4.1.4 Period of occurrence of serious adverse events

4.1.4.1 Month of occurrence

The majority of Serious Adverse Events were reported in the months of November (3.4%), October and December equally with 3.1% and March (2.9%). An increase in Serious Adverse Events was observed in all months compared with less in the month of March over the two year study period. Table 4.5 illustrates the comparison. The difference in the distribution of adverse for months for period 2008/2009 and 2009/2010 is statistically significant (Chi-Square test, 0.0006)

Table 4.5, Adverse Events by months**.**

Month	Total adverse event frequency	Total admission frequency (%)	Total adverse event rate	2008/09 (%) N=147	2009/10 (%) n-272
January	30	1443	2.1	12(8)	18(7)
February	32	1449	2.2	13(9)	19(7)
March	41	1463	2.8	25(17)	16(6)
April	30	1432	2.1	11(1)	19(7)
May	30	1427	2.1	7(5)	23(8)
June	31	1418	2.2	11(1)	20(0.3)
July	33	1449	2.3	9(6)	24(9)
August	27	1417	1.9	2(1)	25(9)
September	31	1270	2.4	5(3)	26(10)
October	43	1398	3.1	17(12)	26(10)
November	48	1392	3.4	15(10)	33(12)
December	43	1377	3.1	20(14)	23(8)
Total	419			147	272

4.1.4.2 Shift of occurrence

More than 82% of the adverse events were reported during the day and a smaller proportion of 18% at night. The summary is presented in Table 4.6 and Figure 4.1

Table 4.6, **Adverse events by Shifts (n = 419).**

Shift	**Total Frequency (%) N=419**	**2008/09 Frequency (%) N=147**	**2009/10 Frequency (%) N=272**
Morning*	194 (46)	61(31)	133(69)
Afternoon**	152 (35)	52(34)	100(66)
Night***	73 (18)	34(47)	39(53)
Total	419	147	272

*Morning-shift is from 07:00 to 12:59. **Afternoon-shift is from 13:00 to 18:59. *** Night-shift is from 19:00 to 06:59.

4.2 Patients factors related to adverse events

Socio-demographic profiles

4.2.1 Age

The descriptive statistics for age for period 1 and 2 are illustrated in Table 4.7(a) and Table 4.7 summarised the distribution of age groups. The median age of all patients was 37.5 years. The age of patients ranges from 9 minimum to 91 years maximum. A statistically significant association was found for age for the period 2008/2009 and 2009/2010 (Chi-square test, p = 0.0327**)**. There is similarly little evidence of any marked discrepancy between the distributions of adverse events amongst the different age groups. No significant differences could be found for age groups for period 2008/2009 and 2009/2010 (Chi-Square test, p = 0.2861).

Table 4.7(a), Descriptive statistics for age (years) for period 1 and 2

In years	**Total (n=419)**	**Period 1 (n = 140)**	**Period 2 (n = 266)**
Median*	37.5	35	40
Inter-quartile range	28.0 – 49.0	26.5 – 46.0	28.0 – 50.0
Minimum	9	16	9
Maximum	91	91	90

Table 4.7(b) Distribution of age groups* (n = 406).

Age group	Total Frequency (%)	2008/09 Frequency (%)	2009/10 Frequency (%)
9 – 27 years	96 (24%)	37(39)	59(61)
28 – 37 years	107 (26%)	42(39)	65(61)
38 – 48 years	101 (25%)	32(32)	69(68)
49 – 91 years	102 (25%)	29(28)	73(72)
Total	406	140	266

*Different age groups were grouped using the median and inter-quartile range of age

4.2.1.1 SAC rating and age groups

The impact of Serious Adverse Events is assessed by patient disability by age group is and is presented in Table 4.8**.** The great majority of patient's disability according to all groups was moderate, followed by minor disability. Patients in the age group 49-91 years were the most affected by moderate disability (89%) followed by the age group 28-37 (84%).

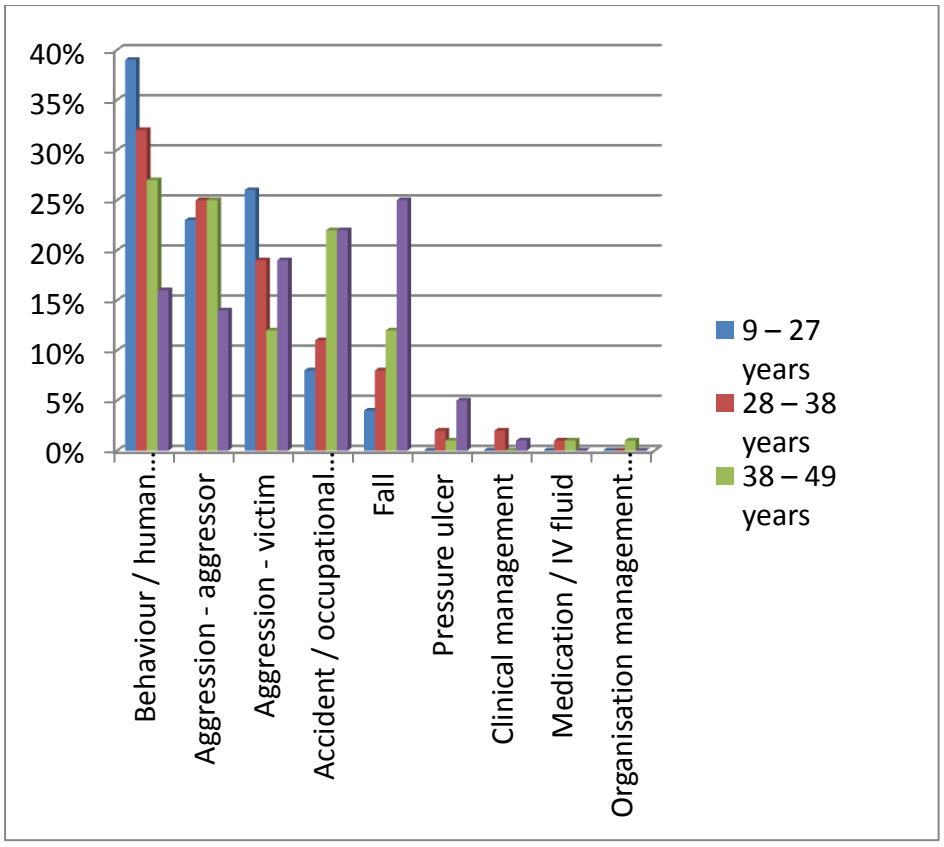
Table 4.8, SAC rating by age groups (n = 406**).**

	Total	**Age group**			
Rating	N	9 – 27 years	28 – 37 years	38 – 48 years	49 – 91 years
SAC 1	4(1)	1(1)	1(1)	0(0)	2(2)
SAC 2	10(2)	2(2)	0(0)	4(4)	4 (4)
SAC 3	330(81)	79(82)	88(84)	70(69)	91(89)
SAC 4	62(15)	14(15)	16(15)	27(27)	5(5)

4.2.1.2 Principal adverse event type and age group

Patients in the age group 9-37 years were more associated with Behaviour/Human performance adverse event type (39%), followed by the age group 28-37 years (32%) and age group 38-48 (27%) . Aggression-Aggressor adverse event type occurred more in the age groups 9-27 and 28–37years compared to patients in age group 49-91 who are mostly victims of aggression, suffered the most Occupational Health and Safety, as well as fall related Serious Adverse Events. The outline of the Principle Adverse Event types is summarised in Figure 4.1.

Figure 4.1, Adverse event type by age groups (n = 406).



4.2.2 Gender

More (85%) males than females (15%) suffered Serious Adverse Events. The distribution of gender is outlined in Table 4.10. No significant differences found for gender for period 2008/2009 and 2009/2010 (Chi-square test, p = 0.32**)**

Table 4.9, Distribution of gender for period 1 and 2 (n = 419).

Gender	Total	2008/09	2009/10
Male	358 (85)	129(36)	229(64)
Female	61 (15)	18(30)	43(70)
Total	410	147	272

4.2.2.1 SAC rating and gender

The SAC rating and gender distribution is summarised in Table 4.10

The male patients suffered more moderate disability (82%) than their female counterparts (77%). Minor Serious Adverse Events were more common in male patients (16%) compared to female patients who suffered more permanent disability or died.

Table 4.10, SAC rating of adverse event by gender (n = 419**).**

		Gender	
Rating	Total	Male (n = 358)	Female (n = 61)
SAC 1	4(1)	4(1)	1(2)
SAC 2	12(3)	1(2)	6(10)
SAC 3	339(81)	294(82)	47(77)
SAC 4	64(15)	57(16)	7(11)
Total	419		

4.2.2.2 Adverse event type and gender

Behaviour/human performance and Aggression related Serious Adverse accounted for more than 70% of reported Serious Adverse Events in male patients. Accident/occupational health and safety- Pressure ulcer- and falls related adverse events were mostly common in female patients (61%). The Adverse Event type and gender distribution is summarised in Table 4.11

Table 4.11, Adverse event type by gender (n = 419).

		Gender	
Adverse event type	**Total**	**Male (n = 358)**	**Female (n = 61)**
Behaviour / human performance	119(28)	111(31)	9(15)
Aggression – aggressor	91(22)	86(24)	4(7)
Aggression – victim	76(18)	64(18)	0(16)
Accident / occupational health and safety	66(16)	50(14)	16(26)
Fall	53(13)	36(10)	19(30)
Pressure ulcer	8(2)	4(1)	3(5)
Clinical management	3(1)	4(1)	1(2)
Medication / IV fluid	2(1)	4(1)	0(0)
Organisation management / service	1(1)	0(0)	0(0)
Total	419		

4.2.3 Ethnicity

Almost 3/4 of adverse events occurred amongst the Black patients (70%), followed by Whites (27%) and Colourds with 3%. The distribution of adverse events by Ethnic group for 2008/2009 and 2009/2010 is summarised in Table 4.12. No significant differences could be found for ethnicity for 2008/2009 and 2009/2010 (Chi-square test, p= 0.10).

Table 4.12, Ethnicity (n = 416).

Ethnicity	**Total**	**2008/2009**	**2009/2010**
Black	290 (70)	97(33)	193(67)
Coloured	15 (3)	9(60)	6(46)
White	111 (27)	39(35)	72(65)
Total	419	145	271

Clinical profiles

4.2.4 Admission classifications

Patients admitted as Assisted Users suffered the most adverse events (40%), followed by State Patients (37%) and Involuntary Users (20%).

Table 4.13, Admission classification (n = 419).

Admission Classification	Total	2008/09	2009/10
Assisted	203 (49)	59(29)	144(71)
Involuntary	70 (17)	29(41)	41(59)
Forensic Patients	146 (35)	59(40)	87(60)
Total	419	147	272

The patients admitted as Assisted Users accounted for 49% of all patients affected by Serious Adverse Events, followed by the Forensic Patients (35%). There was a significant increase in Serious Adverse Events suffered by all admissions classifications with Assisted Users ranking the highest (29%-71%), followed by Forensic Patients (40%-60%). The frequency of adverse events by admission classification for period 1 and 2 is summarised in Table 4.13. A statistical significant association was found for admission classification for period 2008/2009 and 2009/2010 (Chi-Square test, p = 0.01).

4.2.4.1 SAC rating and admission classification

The great majority of patients suffered moderate disability. The Involuntary Users were leading (87%) in terms of moderate disability, followed by Assisted Users (81%). firstly Observant with 100%, Involuntary Users with 87%, Assisted Users with 81% and lastly State Patients with 77%. Minor disability occurred mostly in Forensic Patients compared to Assisted- and Involuntary Users who suffered the most permanent disability (5%) and death. The distribution of SAC and Admission classification is summarised in Table 4.14

Table 4.14, SAC rating of adverse event by admission classification (n = 419).

SAC Rating	Total	Assisted Users	Involuntary Users	Forensic Patients
SAC 1	4(1)	2(1)	2(3)	0%
SAC 2	12(3)	10(5)	0(0)	2(1)
SAC 3	339(80)	164(81)	61(87)	113(78)
SAC 4	64(15)	26(13)	7(10)	31(21)

4.2.4.2 Adverse event type and admission classification

Amongst all patients who were affected by Serious Adverse Events, Forensic patients were leading in terms of Accident/occupational health and safety (78%), Behaviour/human performance adverse event types (59%), Aggression related (52%), followed by Involuntary Users. Assisted Users were leading in terms of falls (24%) and pressure ulcer (3%). The distribution of SAC and Admission classification is summarised in Table 4.15.

Table 4.15, Adverse Event Type by admission classification (n = 419).

Adverse Event Type	**Total (419)**	**Assisted Users**	**Involuntary Users**	**Forensic Patients**
Behaviour / human performance	119(28.4)	37(18)	33(47)	50(52
Aggression – aggressor	91(21.7)	28(14)	12(17)	50(36)
Aggression – victim	76(18.1)	30(15)	13(19)	32(23)
Accident / occupational health and safety	66(15.7)	51(25)	5(7)	11(72)
Fall	53(12.6)	49(24)	5(7)	0(0)
Pressure ulcer	8(1.9)	6(3)	1(1)	1(1)
Clinical management	3(0.7)	2(0.4)	1(1)	0(0)
Medication / IV fluid	1(1)	0(0)	0(0)	1(0)
Organisation management / service	1(1)	0(0)	0(0)	1(1)

4.2.5 Distribution of diagnosis

The most common presenting conditions occurring during the study period are categorised by using the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, DSM-V- and outlined in Table 4.16.The majority (74%) of patients who suffered from Serious Adverse Events were diagnosed with Schizophrenia- and Mental Retardation related conditions. It must also be noted that a significant increase in Serious Adverse Events was observed in patients diagnosed with Mental Retardation with medical condition (7%-15%) and Bipolar Mood Disorder (1%-8%). Substance Induced Psychosis (7%) and Psychosis due to Medical Condition (6%) were the

second most common presenting conditions during the study and no significant changes in totals were observed over the two year study period. More than 25% of patients with dual diagnosis, including Mental retardation with medical condition (11%), Psychosis due to Medical condition (6%), Substance Induced Psychosis (7%) and Schizophrenia with medical condition (2%) suffered Serious Adverse Events. Other common conditions seen during the study period included Bipolar Mood Disorder (6%) and Major Depression (1%). In the analysis a statistical significant difference was found for diagnosis for period 1 compared to period 2. (p = 0.0006).

Table 4.16, Serious Adverse Events by Diagnosis

Diagnosis	**Total**	**2009/09**	**2009/10**
Schizophrenia	147(35)	61(42)	86(32)
Mental retardation	110 (26)	40(28)	70(26)
Mental retardation with medical condition	46(11)	10(7)	36 (13)
Substance induced psychosis	31(7)	15(10)	16(6)
Psychosis due to medical condition	26(6)	9(6)	17(6)
Bipolar mood disorder	24(6)	2(1)	22(8)
Other	21(5)	6(4)	15(6)
Schizophrenia with medical condition	7 (2)	1(1)	6(2)
Major depression	5 (1)	1(1)	4(1)
Total	419	145	272

4.2.5.1 Adverse event type and diagnosis

The most common presenting conditions occurring during the study period are categorised by using the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, DSM-V- and outlined in Table 4.17.

Patients with Major depressive disorders (80%) were mostly associated with Behaviour/human performance adverse event type, followed by those diagnosed with Substance induced psychosis (52%) and Schizophrenia (47%). The Aggression related adverse events type were found more in patients diagnosed with Bipolar Mood Disorder (33%), followed by patients with Psychosis due to medical disorder (31), Schizophrenia (25%) and Mental Retardation with medical disorder (24%). Mental Retardation related accounted more for Accident/occupational health and safety (58%), falls (53%), Pressure Ulcer (11%) and Clinical Management (4%) adverse event types followed by patients diagnosed with Substance Induced Psychosis

4.2.5.2 SAC rating and diagnoses

The majority of patients diagnosed with Mental Retardation suffered moderate disability (91%), followed by patients with Mental Retardation with medical condition (89%), Psychosis due medical condition (88%) and Schizophrenia with medical conditions (86%). Note must be taken that the majority of patients diagnosed with Major Depression suffered minor disability, however also accounted for the majority of permanent disability as well as death. Patients with Mental Retardation related conditions and Psychosis due to medical condition accounted for more than 10% of permanent disability or death.

4.2.6 Adverse events and psychiatry services/specialty

Forensic Psychiatry services were associated with the majority of Serious Adverse Events followed by Persons with Intellectual Disability services (17%). A significant increase in Serious Adverse Events was observed in all the psychiatry services with Psycho-geriatric services leading (8%-92%). Persons with Intellectual Disability area were second (22%-78%) and an increase of 19% was observed in Acute- and Forensic Psychiatry services. Adverse events by Psychiatry Service are outlined in Table 4.17. In the analysis a statistical significant difference was found for psychiatry speciality for period 1 as compared to period 2 ($p = 0.0001$).

Table 4.17, Adverse events by Psychiatry Services (n = 417).

Psychiatry Services	Total	2008/09	2009/10
Acute Psychiatry	71(17)	29(41)	32(59)
Forensic Psychiatry	141(34)	58(41)	83(59)
Persons with Intellectual Disabilities	125(30)	27(22)	98 (78)
Long-term Psychiatry	69(70)	32(46)	37(54)
Psycho-geriatrics	13(3)	1(8)	12(92)

4.2.6.1 SAC rating and psychiatry services/specialty

The great majority of patients suffered Moderate Adverse Events in the Psycho geriatric services (92%), followed by Intellectual Disability Services (86%), Acute Psychiatry services (82%), Forensic services (80%) and Long term Psychiatric services in the minority (70%). Permanent disability was mostly found in Psycho geriatric services (8%), followed by Persons with Intellectual Disability Services (6%). and Acute Psychiatry services with 3%. Although the most minor adverse events occurred in the Acute Psychiatry services, more patients suffered permanent disability (3%) or died (3%). The SAC rating and diagnosis is outlined in Table 4.18

Table 4.18, *SAC* rating by Psychiatry services (n = 419).

		Psychiatry Services				
Rating	**Total**	**Person with intellectual disability**	**Psycho-geriatric**	**Long-term psychiatry**	**Acute psychiatry**	**Forensic psychiatry**
	N	125	13	69	71	141
SAC 1	4(1)	1(1)	0(0)	1(1)	2(3)	0(0)
SAC 2	12(3)	8(6)	1(8)	1(1)	2(3)	0(0)
SAC 3	339(81)	108(86)	12(92)	49(70)	59(82)	113(80)
SAC 4	64(15)	99(7)	0(0)	19(28)	8(49)	29(20)
Total	419					

4.2.6.2 Adverse event type by psychiatry services

Behaviour/human performance adverse events were more prevalent in Acute Psychiatry services (53%) followed by Long term services (51%) and Forensic services (32%). Aggression related adverse even types were mostly associated with Psycho-geriatric (61%), followed by Forensic Psychiatry services (51%) and Acute Psychiatry services with 34%. Patients in the Intellectual disability services suffered the most adverse event types included Accident/occupational health and safety (33%), Falls (34%), Pressure Ulcer (5%) and Clinical Management (3%) followed by those patients in the Psycho-geriatric services Adverse events type by psychiatry services is outlined in Table 4.19

Table 4.19: Adverse event type by Psychiatry services (n = 419**).**

		Psychiatry Services				
Adverse event type	Total	**Person with intellectual disability**	**Psycho-geriatric**	**Long-term psychiatry**	**Acute psychiatry**	**Forensic psychiatry**
	Total	125	13	69	76	141
Behaviour / human performance	119(28)	1(1)	1(8)	35(51)	40(53)	45(32)
Aggression – aggressor	91(21)	13(10)	5(38)	14(20)	11(14)	49(35)
Aggression – victim	76(18)	21(17)	3(23)	6(9)	15(20)	32(23)
Accident / occupational health and safety	66(16)	41(33)	2(15)	8(12)	4(5)	11(8)
Fall	53(13)	43(34)	2(15)	4(6)	6(8)	0(0)
Pressure ulcer	8(2)	1(5)	0(0)	1(1)	0(0)	1(1)
Clinical management	3(1)	3(2)	0(0)	0(0)	1(1)	0(0)
Medication / IV fluid	2(0)	0(0)	0(0)	1(1)	0(0)	1(1)
Organisation management / service	1(0)	0(0)	0(0)	0(0)	0(0)	1(1)
Total	419					

4.2.7 Adverse events reported in the 7 top wards

Patients in Block A suffered the most adverse events (14%), followed by Block B (10%) and A-west with 9%. A significant increase of adverse events was observed in in Block B (5%-13%) compared to C-East and A-West wards where a decrease of more than 5% was observed during the two year study period. Adverse events by wards are outlined in Table 4.21. A statistical significant difference for distribution of adverse events in the wards for period 2008/2009 as compared to 2009/2010 was found (Chi-Square test, p = < 0.0001).

Table 4.20 *A*dverse events by Top 7 wards**.**

Ward	**Total**	**2008/09 n=147**	**2009/10 n=272**
Block A	58(14)	22(15)	36(13)
Block B	42(10)	7(5)	35(13)
Block C	7 (2)	5 (3)	2(1)
Block D	28(7)	13(9)	15(6)
A-west	36(9)	17(12)	19(7)
C-East	24(6)	17(12)	7(3)
C-West	23(5)	9(6)	14(5)
1e	28(7)	3(8)	25(9)

4.2.7.1 SAC rating and top 7 wards

Table 4.21 gives a summary of adverse events reported in the top 7 wards. Patients in ward C-East suffered moderate adverse events (96%) in the majority, followed by Block A (91%) and C-West and ward 1E respectively with 87% and 86%. Patients in Block D ward suffered the most minor adverse events (43%), followed by A-West (31%), Block B (19%), C-West (13%) and 1 E (11%). Patients in Ward A-West suffered more permanent disability and death (6%). Although A-West ward accounted for the second most minor adverse events, patients suffered more permanent disability (3%) or died (3%) compared to other wards.

Table 4.21, SAC rating of adverse event by top 7 wards (n = 239).

Rat-ing	Total	Top 7 wards						
	N 239	1 E	A–west	Block A	Block B	Block D	C–East	C–West
SAC 1	2(1)	0(0)	1(3)	1(2)	0(0)	0(0)	0(0)	0(0)
SAC 2	2(1)	1(4)	1(3)	0(0)	0(0)	0(0)	0(0)	0(0)
SAC 3	193(81)	24(86)	23(64)	53(91)	34(81)	15(57)	23(96)	20(87)
SAC 4	42(18)	3(11)	11(31)	4(7)	8(19)	12(43)	1(4)	3(13)

4.2.7.2 Adverse event type and top 7 wards

Table 4.22 summarises the adverse event types in the top 7 wards. Behaviour/Human adverse events types occurred mostly in A-West (58%), followed by Block A (53%) and ward C-East (42%), Aggression related adverse events type accounted for more than 45% of all adverse event types included patients suffering the most in Block B (76%), followed by Block D and C-West (57% and 56%), C-East (42%),1E and Block A respectively with 38% and 39%. The majority of patients who suffered Accident /occupational health and safety adverse event type, were found in ward 1E (36%), followed by C-East (17%) and A-West (11%). Ward 1E as also more associated with falls (34%) followed by Block A (5%) and A-West (3%).

Table 4.22, Adverse event type by top 7 wards

Adverse event type		Top 7 wards						
	Total	1 E	A–west	Block A	Block B	Block D	C–East	C–west
Behaviour / human performance	89(37)	0(0)	21(58)	31(53)	9(21)	11(39)	10(42)	7(30)
Aggression – aggressor	63(26)	6(21)	5(14)	10(17)	19(45)	7(25)	9(38)	7(30)
Aggression - victim	50(20)	5(18)	4(11)	12(21)	13(31)	9(32)	1(4)	6(26)
Accident / occupational health and safety	23(10)	10(36)	4(11)	2(3)	1(2)	1(4)	4(17)	1(4)
Fall	11(5)	7(25)	1(3)	3(5)	0(0)	0(0)	0(0)	0(0)
Pressure ulcer	1(4)	0(0)	0(0)	0(0)	0(0)	0(0)	0(0)	1(4)
Medication / IV fluid	1(1)	0(0)	0(0)	0(0)	0(0)	0(0)	0(0)	1(4)
Organisation management / service	1(1)	0(0)	1(3)	0(0)	0(0)	0(0)	0(0)	0(0)

4.3 Description of adverse event error types

Human error type accounted for almost half of all error types (45%), followed by system errors (25%) and Inappropriate- and At Risk behaviour respectively with 13% and 12%. Human- and System error types increased with 3% in 2009/2010 compared to a decrease of more than 3% in Patient idiosyncratic response- and inappropriate behaviour error types. Adverse event error types for the period 2008/2009 and 2009/2010 are outlined in Table 4.23

Table 4.23, Adverse event error type (n = 419).

Adverse event error type	Total	2008/09 Frequency n=150	2009/10 Frequency n=269
Human error	187(45)	64(43)	123 (46)
System error	104(25)	34(33)	70(26)
Inappropriate behaviour	54(13)	25(17)	29(11)
At risk behaviour	49(12)	16(11)	33(12)
Patient idiosyncratic response	21(5)	10(7)	11(4)
No error detected	4(0)	1(1)	3(1)

4.3.1 Admission classification and error types

Human and System error types accounted for more than 70% of all the Adverse Event types with Human Errors as the most common (48%). Human errors were found mostly in Involuntary Users (51%), followed by Assisted users (48%) and State Patients (38%). Inappropriate and At Risk behaviour error types were the third most common presenting error type and were mostly associated with Forensic patients (32%) and with Assisted Users (21%). System errors were the second most presenting error type and were found mostly in Forensic patients. Patient idiosyncratic response error types were minimal and occurred more in Assisted Users (5%) and Forensic patients. Adverse event error by admission classification is outlined in Table *4.24.*

Table 4.24, Adverse event error type by admission classification (n = 419).

Adverse Event Error Types	Total	Admission Classification		
		Assisted (n = 203)	Involuntary (n = 70	Forensic Patients (n = 146
Human error	187(45)	97(48)	36(51)	54(37)
System error	104(25)	49(24)	4(26)	39(37)
Inappropriate behaviour	54(13)	18(9)	12(17)	22(16)
At risk behaviour	49(12)	24(12)	2(3)	22(16)
Patient idiosyncratic response	21(5)	10(5)	2(3)	8(6)

4.3.2 Diagnoses and error types

Human and System Error adverse event types accounted for 70% of all reported Serious Adverse Events with Human errors leading (45%) followed by Systems errors (25%). More than 50% of all patients diagnosed with Mental Retardation related disorders and Psychosis due to medical conditions are associated with Human Error types and System Error type were found more in patients diagnosed with Substance Induced Psychosis (42%) and Major Depression (40%). System error types also accounted for more than 50% of patients diagnosed with Schizophrenia related diagnosis. Inappropriate behaviour adverse event errors were more common in patients with dual diagnosis included Mental Retardation related diagnosis (21%); Substance induced psychosis (10%) and Psychosis due to medical condition (12%). At risk behaviour errors were more associated with patients with Major Depression (40%), followed by patients with Schizophrenia related diagnosis (33%) and Mental Retardation related diagnosis (23%). Patient idiosyncratic response adverse event error type was found more common in patients with Mental Retardation related diagnosis (13%) and in patients diagnosed with Psychosis due to medical condition (12%). Adverse Event Error type by diagnosis is outlined in Table 4.25.

Table *4.25:* **Adverse event error type by diagnosis (n = 417).**

		Diagnosis								
Adverse event error type	N	**Mental retardation**	**Mental retardation with medical condition**	**Bipolar mood disorder**	**Schizophrenia**	**Substance induced psychosis**	**Other**	**Psychosis due to medical condition**	**Schizophrenia with medical condition**	**Major depression**
Human error	186(45)	60(55)	24(52)	11(46)	60(41)	8(26)	1(19)	14(54)	3(43)	1(20)
System error	103(25)	24(22)	4(9)	68(25)	40(27)	13(42)	8(38)	4(15)	2(29)	2(40)
Inappropriate behaviour	49(12)	9(8)	6(13)	2(8)	21(14)	3(10)	5(24)	3(12)	0(0)	0(0)
At risk behaviour	54(13)	7(6)	8(17)	3(13)	21(14)	5(16)	4(19)	2(8)	2(29)	2(40)
Patient idiosyncratic response	21(5)	2(6)	3(7)	1(4)	4(3)	2(6)	0(0)	3(12)	0(0)	0(0)

4.3.3 Error type and psychiatry speciality

Table 4.26 gives a summary of adverse event error type by psychiatry services. More than 50% Serious adverse events were due to human errors in the Intellectual disability speciality (56 %), followed by Forensic- and Psycho-geriatric speciality areas (38%). Serious Adverse events due to Systems errors occurred more in the Long term services (30%), followed by Acute and Forensic services with 27% and 26% respectively. Inappropriate behaviour adverse error type was more associated with Acute Psychiatric services (19%) and At risk behaviour with Psych-geriatric services.

Table *4.26*, Adverse event error type by Psychiatry services (n = 419**).**

		Psychiatry services/specialty				
Adverse event error type		**Person with intellectual disability**	**Psycho-geriatric**	**Long-term psychiatry**	**Acute psychiatry**	**Forensic psychiatry**
	Total-419	125	13	69	73	141
Human error	187(45)	70(56)	5(38)	25(36)	34(47)	54(38)
System error	104(25)	24(19)	3(23)	21(30)	20(27)	37(26)
Inappropriate behaviour	54(13)	9(7)	0(0)	10(14)	14(19)	21(15)
At risk behaviour	49(12)	13(10)	5(38)	7(10)	2(3)	23(16)
Patient idiosyncratic response	21(5)	8(6)	0(0)	5(7)	1(2)	8(6)
No error detected	1(4)	3(2)	0(0)	1(1)	0(0)	0(0)

4.3.4 Error type and top 7 wards

Human adverse event error type was found more common in Ward 1E (61%), followed by C-East (54%) and Block A and Block D with 50%. A-West was more associated with Systems Errors (39%), followed by C-East (33%) and Block A and C-West respectively with 26**%.** Inappropriate behaviour error type occurred more in Block A and Block B (21%), followed by A-West (17%) and C-West (13%). Block B was the leading ward in terms of At Risk behaviour error types (31%), followed by C-West (22%) and 1E (11%). Patient idiosyncratic response error type was more associated with patients suffered from Serious Adverse Events in Block D (18%), followed

by 1E (11%) and A-West (6%). Table 4.27 gives a summary of adverse event error types in the top 7 wards.

Table *4.27*: Adverse event error type by top 7 wards

Adverse event error type		**Top 7 wards**						
	Total	1 E	A–West	Block A	Block B	Block D	C–East	C–West
Human error	105(44)	17(61)	11(31)	29(50)	12(29)	14(50)	13(54)	3(39)
System error	60(25)	4(14)	14(39)	15(26)	7(17)	6(21)	8(33)	6(26)
Inappropriate behaviour	34(14)	1(4)	6(17)	12(21)	9(21)	2(7)	1(4)	3(13)
At risk behaviour	28(12)	3(11)	2(6)	2(3)	13(31)	1(4)	2(8)	5(22)
Patient idiosyncratic response	11(5)	3(11)	2(6)	0(0)	(1)2	8(18)	0(0)	0(0)
No error detected	1(1)	0(0)	2(3)	0(0)	0(0)	0(0)	0(0)	0(0)

CHAPTER 5
DISCUSSIONS

In this chapter, the findings of the reviewed literature are integrated with the results obtained from the analysis of the data to address the aim and objectives. This type of study had never been conducted at the level of a specialized mental health establishment in the Free State Province. In this final section of my report, I wish first to summarize the findings from my work, secondly to consider some of the possible limitations to the investigation and finally, to outline the implications of this research.

5.1. Description of adverse events

This study was able to reveal a distinct pattern of Serious Adverse Events in terms of type, number reported, the occurrence and safety assessment code in a mental health environment. There were 419 Serious Adverse Events reported during the study period. In this study 5% of admitted patients suffered Serious Adverse Events and the adverse events rate increased with 3.3%. These findings were in line with previous studies similar to this one wherein it was found that 3%- 16% of hospitalized patients suffer harm from adverse events (Braithwaite, et al. 2011). It is also support the perception of Free State Psychiatry Complex Management that adverse events are on the increase. There was a significant increase in SAE's from 2008/2009 to 2009/2010 (Chi-square test, p=0.04).

Behaviour/human performance, Aggression-aggressor, Aggression–victim, Accident/occupational health and safety, falls and Pressure ulcer were the most commonly reported serious adverse event types. These findings linked to Serious Adverse Events categories highlighted by the Free State Department of Health AIMS Report July 2011. The Clinical Indemnity Schemes- and Mental Health Services Reports (2008) suggests Aggression related adverse event type as the most common serious adverse followed by the Behaviour Human Performance adverse event type. These results also revealed that Aggression adverse event type as one of the most common types of Serious Adverse Events constituting 40% of the patient safety reports. The Behaviour Human Performance adverse event type was second in fre-

quency (28%) in contributing to safety related reports. Other serious adverse event type included Accident/occupational health and safety and falls which concur with the adverse event classification of the Free State Province July AIMS Report (2011). Disability was moderate for the majority of patients, followed by a smaller proportion (15%) for minor adverse events, however 4% of the patients suffered permanent disability or died.Considering patient impact, an important conclusion that is consistent with international finding, is that only a small proportion of adverse events result in permanent disability or death. This finding is consistent with the views of the Free State Province July AIMS Report (2011) in terms of moderate and minor disability ratings but differs greatly in regarding the permanent and death rates. More than 80% of serious adverse were reported during the day and a smaller proportion of 18% at night. These results concur with the research findings of Carmel and Hunter (1993) and Vanderslott (1998) who argue that the majority of Serious Adverse Events happened during the day because of the organizational routines such as medication rounds, handover periods or mealtimes which might be generally the result thereof. In my opinion this might also be due to the fact that during the day patients are more energetic, they are more in interaction with each other and other stakeholders, anxiety levels build up, they get agitated, conflict arise and patients became aggressive. No association was found in shifts between the period 2008/2009 and 2009/2010 (Chi-square test, p-value=0.0668).

The majority of Serious Adverse Events occurred in the Acute Psychiatry speciality area, followed by Forensic Psychiatry. There was a significant increase in SAE's in all the specialities from 2008/09 to 2009/2010 except in Long term psychiatry (Chi-square test, p=0.0001). Patients in the Block A which is an Acute Psychiatry male admission ward suffered the most adverse events followed by patients in Block B which is a high risk male Forensic ward. These findings are consistent with the previous mentioned findings regarding Acute Psychiatry service that is leading in terms of Serious Adverse Events and the Forensic service was second. The reason might be ascribed to the fact that patients admitted in these wards are suffering from acute mental illnesses, are confined to the wards and are presenting with high tendencies of aggression, agitation, and actively threatening self-harm. They are also characterized by habitual absconding. There was a significant increase in SAE's from 2008/09 to 2009/2010 in Block B and in Ward 1e.

The highest rate of Serious Adverse Events was observed in the months of March October, November and December. The rate of Serious Adverse Events increased due to an increase in mental illness contributed by seasonal changes especially when the flowers blossom. The results are supported by the opinion of the researcher due to years of work experience in the mental health services as well as previous research done (Regional Health Forum report, 2008). The difference in the distribution of adverse events for months for period 2008/2009 and 2009/2010 is statistically significant (Chi-square test, 0.0006).

5.2 Patient related factors

Socio-demographic profile

The ages of the patients affected by Serious Adverse Events ranged from 9 years to 91 years, with the median age of 37.5 years. A statistical significant association was found for age for the period 2008/2009 and 2009/2010 (Chi-square test, p=0.0327). No significant differences could be found for age groups between the period 2008/2009 and 2009/2010 (Chi-square test, p=0.2861).

The age group 49-91 years accounted for the majority of adverse events and were mostly affected by permanent disability and death. These findings were consistent with international evidence that the older patient are more at risk for Serious Adverse Events compared to younger age groups (Matsaseng & Moodley, 2005; Davis, et al. 2001; Vincent, et al. 2001). It is safe to say that the frequency of Serious Adverse Events increased with age. Younger patients are more associated with Behaviour/human performance and Aggression related adverse event types and the older patients with Occupational Health and Safety and fall related Serious Adverse Events. Falls rates and fall related injuries were found to be generally higher amongst psycho-geriatric populations; hence accidental falls are a serious safety concern for mental health services (Gillespie, et al. 2008).Younger male patients are more associated with Aggression related and Behaviour/human performance adverse event types (James, et al 1990).

More males compared to females were affected by Serious Adverse Events which are in line with previous studies done in New Zealand Public Hospitals (New Zealand Public Hospitals Report, 2001; Davis et al, 2001). It might also be due to the unique situation of the 'predominance of males' amongst the inpatient population as evident in the demographical data of the Free State Psychiatry Complex. Adverse events related to aggression and behaviour human performance were rated the highest in younger male patients and were more associated with Substance Induced psychosis (James, et al 1990). Males were more associated with moderate and minor adverse events compared to female patients who suffered more permanent disability or died however, it is clear from the analysis that female patients are more associated with increased risk for serious events compared to their male counterpart. Female patients were more associated with Accident/occupational health & safety and fall related adverse events.

Almost ¾ of adverse events occurred amongst Black patients. It might be ascribed to the unique situation of the 'predominance of Blacks' amongst the inpatients population as evident in the demographical data of the Free State Psychiatry Complex. No significant differences

Clinical profile

A notable result from the study which is consistent with international findings, is that all patients affected by adverse events were mostly involuntary admitted to the hospital either through court order or by consent of relatives (Benvesniste, et al. 2005). Patients diagnosed with Schizophrenia suffered the most Serious Adverse Events followed by those diagnosed with Mental Retardation and Substance Induced Psychosis. The findings concur with previous studies concluding that adverse events were found more in inpatients diagnosed with Schizophrenia (Davis, et al. 2001). In the analysis a statistical significant difference was found for diagnosis for period 2008/2009 compared to 2009/2010 (Chi-Square test, p=0.0006).

Aggression related adverse events were more prevalent amongst patients with Schizophrenia, those with Substance induced Psychosis, Psychosis due to medical

condition as well as Mental Retardation with medical conditions. Numerous studies have explored an association between aggression and illness (Linaker and Busch-Iversen, 1995 and Link & Stueve, 1995). Previous research supports the finding that young men with psychiatric illness and a history of substance abuse are most likely to be violent James, et al. 1990). Accident/occupational health and safety and falls adverse event types were also mostly associated with patients diagnosed with Mental Retardation and Mental Retardation with medical condition. It must also be noted that Clinical Management adverse event type occurred more in patients diagnosed with Mental Retardation with medical condition (4%) and Psychosis with medical condition (4%). Organisation management/services adverse event type counted for 14% of adverse events in patients diagnosed with Schizophrenia with medical condition. Moderate disability also accounted for the majority of these patients with dual diagnosis. These results are similar with findings of other studies that have proved that the presence of co-existing illness and complexity of the disease or treatment are risk factors associated with increased risk for adverse events (Vincent, et al. 2001).

5.3 Individual factors

Human adverse event error type accounted for almost half of all adverse event error types followed by System adverse event error type. Braithwaite, et al. 2011 maintains that structural, process and the profile of patients are contributing to adverse events. Human adverse event error type was more prevalent in patients with Mental Retardation related disorders and Psychosis with medical condition. These results are in line with previous studies done by Matsaseng & Moodley (2005) stating that the presence of co-existing illnesses increases the frequency of adverse events. System adverse event error types were found more in patients diagnosed with Schizophrenia related Disorders followed by Substance Induced Psychosis. Inappropriate adverse event errors were more also associated with patients diagnosed with Mental Retardation and Schizophrenia with medical condition. These results concur with previous studies done by Gail, et al. 2006 who reflect the known burden of co-morbid medical in persons with Schizophrenia as well as Davis, et al 2001 who reported that adverse events are more found amongst patients diagnosed with Schizophrenia.

Human adverse event error type is leading in terms of adverse errors in the Persons with Intellectual disability speciality and the At risk adverse event error type in the Psycho-geriatric wards. The results in the researchers opinion might be ascribed to the profiles of the patients receiving treatment in the speciality areas for instance patients in the Persons with Intellectual disabilities have mental or physical impairments or a combination of mental and physical impairments which results in substantial functional limitations in three or more areas of life activities and made them therefore more dependent on nursing care. Patients cared for in the Psycho geriatric speciality are more at risk because of the age and mental illness factors. Previous studies have explored an association between the profile of the patient and increased adverse events (Braithwaite, et al 2011). The findings showed that human errors were more associated with Serious Adverse Events in wards where Persons with Intellectual Disorders and aged patients are cared for. These findings concur with the finding with various researchers who argued that the profile, the structure and process factors contribute to adverse events (Braithwaite, et al. 2011 and Linacker and Busch-Iversen, 1995).

CHAPTER 6
CONCLUSIONS AND RECOMMENDATIONS

In this chapter, the results obtained from this study are assessed in relation to the aims and objectives of the study, so that appropriate conclusions can be drawn. The limitations of the study are also articulated. Based on the findings of the study, appropriate recommendations and suggestions for future research are included. These recommendations focus on the improvement of safety for patients in the mental health establishments in the Free State Province.

6.1 Conclusions related to the aims of the study

Although many of the patient safety risk factors that exist in medical settings also apply to mental health settings, there are unique patient safety issues in mental health that are different to those in medical care. Aggressor-aggression, Aggressor-victim, Behavior Performance (absconding, self-harm, suicide) and Occupational health and safety, falls and other injuries are particularly prominent to mental health patients. Both the patient population and the environment make patient safety in mental health unique. In some circumstances, the uniqueness is associated more with the diagnosis, the patient population and with the mental health setting.

It is only recently that patient safety in mental health was considered a field of importance but there is there is a lack of awareness of the issues as well as a shortage of research and readily available information to guide patient safety systems, practices, policies, and care delivery in mental health. Work is required to establish a clear definition, set priorities, and develop strategies for responding to patient safety concerns. Models of quality improvement are being utilized in psychiatry hospitals but the need for evidenced-based quality improvement models for inpatient psychiatric care still exist. Findings from my study show Serious Adverse Events to be prevalent in Free State Psychiatry Complex and factors significantly associates with the frequency of aggression related, behavior/occupational health and safety and falls adverse event types. Advancing a quality and safety research agenda for inpatient psychiatric care will guide practice, improve care, and help ensure efficient and eve-

fective care. Complicated problems such as the provision of acute psychiatric hospital services require solutions that incorporate depth and breadth of understanding the complexities of acute mental illness as well as changes in prevailing attitudes and systems.

This study has also highlighted that understanding patient safety is not one dimensional, but rather a complex interaction between a varied set of contributing and interacting elements, including patient factors, human factors, system factors, and environmental factors. While some patient safety factors are common across health care settings, others are unique to mental health. What differentiates patient safety from other health sectors is a complex interaction between the mental health environment and the diagnosis/patient population. Understanding this interaction and its relationship to patient safety is very important.

In considering the socio-demographic and clinical profile attributed of patients, the factors that emerge relatively consistently was that of age, sex, co-morbidity and diagnosis, admission type, speciality area, time of occurrence of Serious Adverse Events that include the shift and seasons. The presence of co-existing illness, complexity of disease or treatment, and age are being identified as risk factors.

6.2 Limitations of the study

Since this was a retrospective study the quality of data recorded might have been affected by the following:

1. The information bias due to the recording of data by a range of different people at different times.
2. Detailed information bias due to the fact that the information that might have been available for long periods, although the format, completeness and accuracy may be compromised.
3. Data were collected routinely for clinical purposes and not for research purposes.
4. Missing records, incomplete information in the register and saved documents, and double entry of data. However an attempt was made to address this by collecting data from multiple sources**.**

6.3 Recommendations

The recommendations made below were based on the findings from this study. Possible new topics of research have been suggested. The findings that the researcher felt would be beneficial and relevant both to health professionals and to the subjects are presented below.

6.3.1 Use of findings of this study

It is hoped that the Department of Health in the Free State Province would utilise the findings of this study to improve the care, treatment, management and rehabilitation of the mental health care users. The results of the study will be disseminated to the Clinical Cluster of the Province, the Chief Director of Hospital Services, the Chief Executive Officer, the Executive Management and personnel of the Free State psychiatry Complex.

6.3.2 Expansion of the programme to the other health districts

Based on the findings of the study, the Department of Health should expand this programme to the other health districts in the Free State Province as well as other provinces.

6.3.3 Further research

The following areas of research that the researcher believes are important, as the findings would enlighten the Department of Health for better management of health care practitioners/providers and improvement in the provision of mental health care services.

1. Research reflecting the effect of seasonal changes on mental health.
2. Empirically validating risk assessment tools, training programs, and interventions for preventing and reducing patient safety incidents in mental health.
3. Research in specific causes, scientific advances, systems analysis, education and development, dissemination of guidelines and improved standard of practice is required for the reduction of Serious Adverse Events.

4. A review is needed for the range of adverse effects associated with antipsychotics and their clinical impact and an overview of the various sources of data on adverse effects and their relative strengths and weaknesses.
5. More targeted studies on special populations in the mental health field e.g. Psycho geriatric, Forensic and patients with Mental Retardation and psychosis.

6.3.4 Other recommendations for safer practices:

1. All staff in contact with patients at risk of adverse events should receive training recognition, assessment and management of risks at intervals of no more than two years.
2. The content of training should reflect many of the points highlighted by indicators of risks.
3. All patients with a history of violence in the context of mental illness should receive the highest level of care
4. Family and psychological interventions should be available to all high risk patients with severe mental illness,
5. A culture of safety needs to be embedded within all levels of an organization. It would include the adoption of a systems level approach and inclusion of staff and patients in the examination of patient safety incidents. It would allow patients and their family/caregivers to play a more active role in decision making, patient care, risk assessment and safety
6. Research funds need to be made available to attract high quality researchers who can develop and implement rigorous research methodologies.

6.4 Conclusion

The research found important associations on the adverse event types and factors contributing to their occurrence in this study setting**.**

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ETHICS CLEARANCE CERTIFICATE

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG
Division of the Deputy Registrar (Research)

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)
R14/49 Ms Jacoline M Qhali

CLEARANCE CERTIFICATE	M111156
PROJECT	Assessment of Reported In-Patient Adverse Events: Retrospective Study of Reported Adverse Events at the free State Psychiatry Complex from 200-2010
INVESTIGATORS	Ms Jacoline M Qhali.
DEPARTMENT	School of Public Health
DATE CONSIDERED	25/11/2011
M1111560DECISION OF THE COMMITTEE*	Approved unconditionally

Unless otherwise specified this ethical clearance is valid for 5 years and may be renewed upon application.

DATE 25/11/2011 **CHAIRPERSON** .....
(Professor PE Cleaton-Jones)

*Guidelines for written 'informed consent' attached where applicable
cc: Supervisor : Dr M Govender

DECLARATION OF INVESTIGATOR(S)

To be completed in duplicate and **ONE COPY** returned to the Secretary at Room 10004, 10th Floor, Senate House, University.
I/We fully understand the conditions under which I am/we are authorized to carry out the abovementioned research and I/we guarantee to ensure compliance with these conditions. Should any departure to be contemplated from the research procedure as approved I/we undertake to resubmit the protocol to the Committee. **I agree to a completion of a yearly progress report.**
PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES...