

**PATIENT-RELATED ADVERSE EVENTS IN THE
MATERNITY UNITS AT TOKOLLO/MAFUBE
DISTRICT HOSPITAL COMPLEX**

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DECLARATION

I, SESI ROSLINA NOGE, declare that this research report is my own work. It is being submitted for the degree of Masters of Public Health (Hospital management) at the University of Witwatersrand, Johannesburg. It has not been submitted before for any degree or for any examination at this or any other University.

.....

March 2011

DEDICATION

I dedicate this work to the following:

Our All Mighty God who gave me the strength and made it possible for me to complete this study.

My husband, Liphapang, for the support he always gave me through out this study.

My children, Dimakatso and Itumeleng, who understood and encouraged me to work hard despite all the challenges I came across.

ABSTRACT

BACKGROUND: The Tokollo/Mafube District (TMD) Hospital Complex located in the rural area of Fezile Dabi District within the Free State Province has reported a high number of adverse events (AE) from the maternity units. Although the information linked to AE occurring in the hospitals is routinely collected and reported to the hospital management in accordance with the Provincial policy, no study has been done to systematically analyse the available information and to explore the current situation.

AIM: To describe the patient-related AE in the maternity units of TMD Hospital Complex, related individual and health system factors, and the functioning of the reporting system used for these AE during the two year study period.

METHODOLOGY: A descriptive cross-sectional study design was used, based on a retrospective review of routinely collected hospital data from the health records of patients, the AE Committee meeting minutes, and other relevant hospital documents. The study was conducted at the maternity units of TMD Hospital Complex which consists of two hospitals in the Fezile Dabi District within the Free State Province. Data was collected in the following categories of variables: the types of AE (in terms of levels of seriousness), the profiles of patients who experienced such AE (e.g. age, gravidity, marital status, residence, and socio-economic status), the related health system factors identified during the adverse events committees meetings (such as personnel, transport, equipment, environment and management) and reporting of these AE.

RESULTS: This study revealed that a total of 88 patients, comprising 0.8% of the total number of admissions to the maternity units, experienced AE. Maternal AE occurred more commonly than perinatal AE. The majority of women experiencing AE were unemployed (93%), between the ages of 19-34 (81%), unmarried (79%) and resided in towns (88.6%). In addition, most of these women belonged to the groups of primigravida and multigravida (85%), attended between one and three antenatal visits (42%), and

delivered via normal vaginal deliveries (76%) with a high number of stillborns (77.2%). Overall, the majority of maternal AE occurred during the intrapartum stage. Another significant finding was that majority of AE reported were classified as the most serious being SAC 1, which accounted for 93% of the maternal AE and 84% of perinatal AE. The early perinatal AE accounted for 100% of the reported perinatal AE.

Although majority of AE reported at the institution were within the prescribed period, reporting time to the Complex AE Committee (CAEC) and District AE Committee (DAEC) was exceeded in the majority of cases. In addition, all AE that required investigation complied with the provincial policy but exceeded the required investigation period.

The findings regarding health systems related factors as determined by root cause analysis performed by the AE committee revealed that clinical governance issues accounted for 43% of both maternal and perinatal AE, followed by patient transport issues as provided by the Emergency Medical Services (EMS) which also accounted for a significant percentage (33%).

CONCLUSION: This study has demonstrated that specific health system related factors played a significant role on the occurrence of AE at the maternity units of TMD Hospital Complex and that the majority of the reported AE were very serious (SAC 1). It is important that these preventable, contributory factors are addressed by management at both the complex and district levels. Furthermore the results suggest that patients' profiles, to a certain extent, do have an influence on the occurrence of AE in maternity units of TMD hospital Complex and it is important that patients' profiles be taken into consideration when adverse incidents are analysed.

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LIST OF ABBREVIATIONS

AE	Adverse Events
AE Ix	Adverse Event Investigated
AIDS	Acquired Immunodeficiency Syndrome
AIMS	Advanced Incident Management System
ANC	Antenatal Care
APH	Antepartum Haemorrhage
BBA	Born Before Admission
CAEC	Complex Adverse Event Committee
CEO	Chief Executive Officer
CMO	Chief Medical Officer
COHSASA	Council for Health Service Accreditation of South Africa
CPD	Cephalo-pelvic Disproportion
C/S	CAEarean Section
CTG	Cardiotochograph
DAEC	District Adverse Event Committee
DHIS	District Health Information System
DHS	District Health System
DVT	Deep Venous Thrombosis
EMS	Emergency Medical Service
FSB	Fresh Stillborn
GRAV	Gravidity
HIV	Human Immunodeficiency Virus
HOI	Head of Institution
IQR	Interquartile range
MCHC	Mother and Child Health Care
MDG	Millennium Development Goal
PAEC	Provincial Adverse Event Committee.
PHC	Primary Health Care
PET	Pre-eclampsia

PMTCT	Prevention of Mother to Child Transmission
SAC	Safety Assessment Code
SB	Stillborn
SEO	Senior Executive Officer
STI	Sexually Transmitted Infections
TB	Tuberculosis
TMD	Tokollo/Mafube District
WHO	World Health Organization

GLOSSARY OF TERMS

Adverse Event (unusual incident) is a medico legal incident which falls outside the normal course of rendering of Health Services and results in adverse physical, mental or emotional sequelae to a person in relation to any activities in the health department (Free State Department of Health 1998) .

Adverse events reporting system refers to the processes and technology, which involve communication, response time, type of response, standardization and format of the reporting system, learning, analysis and distribution of lessons learned. Types of reporting systems, process of reporting, analysis of reporting, response and dissemination and application of results are components of an adverse event reporting system (WHO 2005) .

Clinical Governance is the system used to improve the standards of clinical practice in the health care facilities. It is also define as the framework through which National Health Service health organisations are accountable for continuously improving the quality of their services and safeguarding high standards of care by creating an environment in which clinical excellence will flourish. In practice it means doing the right thing at the right time in the right way as guided by available described sets of standards (Taylor and Jones 2006).

Early perinatal period is defined as the period from birth until 7 days after birth (Tellmann 2005).

Error is the failure of planned action to be completed as intended or the use of an incorrect plan to achieve an aim and may lead to adverse events. Errors may be of commission or omission, and usually reflect deficiencies in the health care system (Matsaseng and Moodley 2005).

Fresh stillborn is defined as a baby born dead without signs of skin or maceration and

the death is assumed to have occurred within twelve hours prior to delivery (Pattinson 2007).

Gravidity is defined as the number of pregnancies including stillbirths and abortions experienced by women (Joubert and Ehrlich 2007).

Health system factors are factors reported in the adverse events report after the incident is investigated and a root cause analysis is performed by the AE committees, prior to decisions being made about the reported incidents. The following factors are usually cited in these reports: personnel (such as unavailability of appropriately skilled personnel), transport such as unavailability of appropriate transport when needed), equipment (such as lack of appropriate medical equipments when needed), environment (such as loose electrical wiring), management (such as lack of communication between hospital management and wards)

Intrapartum period is defined as period from the onset of labour to the end of the third stage of labour (Tellmann 2005).

Late perinatal period is defined as the period between seven and twenty eight days after birth (Tellmann 2005).

Near miss is a mishap or an error which is intercepted prior to completion of an event, intentionally or by chance, resulting in no harm (WHO 2005) .

Negligence is failure to meet the standard of practice of an average qualified officer practicing in the specialty in question. It occurs when the degree of error exceeds an acceptable norm (Matsaseng and Moodley 2005) .

Perinatal period is defined as the time period before delivery from the 28th week of gestation through the first 7 days after birth (Tellmann 2005).

Postpartum period is the period after delivery (Tellmann 2005).

Referral system is the agreed upon or formalized system used to refer patients to the next level of care.

Safety Assessment Code (SAC) is the method of assessing the seriousness and the likelihood of recurrence, of any adverse event in the hospitals or other health care facilities. The SAC method is used to assess and classify or grade all reported adverse events according to their severity or seriousness which is from 1(most serious) to 4 (least serious) (South Australia Department of Health 2005).

Stillbirth is defined as the birth of a foetus at twenty eight weeks or more gestational period, which shows no signs of life during or before birth with the mass of one kilogram or more (Pattinson 2007).

CHAPTER 1

INTRODUCTION

The purpose of this study was to describe the patient-related adverse events (AE) in the maternity units of Tokollo/Mafube District (TMD) Hospital Complex in terms of individual and health system factors and related compliance to the AE reporting system during a two year study period. This introductory chapter provides an overview of the study relating to the background of the study, the problem statement, aims and objectives, and an outline of the subsequent chapters.

1.1 BACKGROUND

The TMD Hospital Complex is situated in the Fezile Dabi District (previously known as the Northern Free State District) in the Free State Province.

This district has a population of 518,024 of which 441,680 (85%) do not have medical aid cover (Free State Department of Health 2008) . It is divided into four sub-districts namely Moqhaka, Metsimaholo, Ngwathe and Mafube (Figure 1 and 2). There are four district hospitals, one regional hospital, thirty three fixed clinics, seventeen mobile clinics and five community health centres in the District (Free State Department of Health 2008) . Maternity services are provided at all hospitals as well as at the Community Health Centres.

The TMD Hospital Complex is situated in a rural area without any community health centres and a population of 198,683. Unemployment combined with low socioeconomic status are challenges facing this community. The Complex receives patients from thirteen referring primary health care (PHC) clinics which render only antenatal services, whilst all deliveries take place at the hospitals.

Adverse events (AE) occurring in the maternity units are regularly reported at the institutional, district and provincial level according to the Provincial Department of Health policy.

Fezile Dabi District Map (Free State Province) is shown by Figure 1.1.

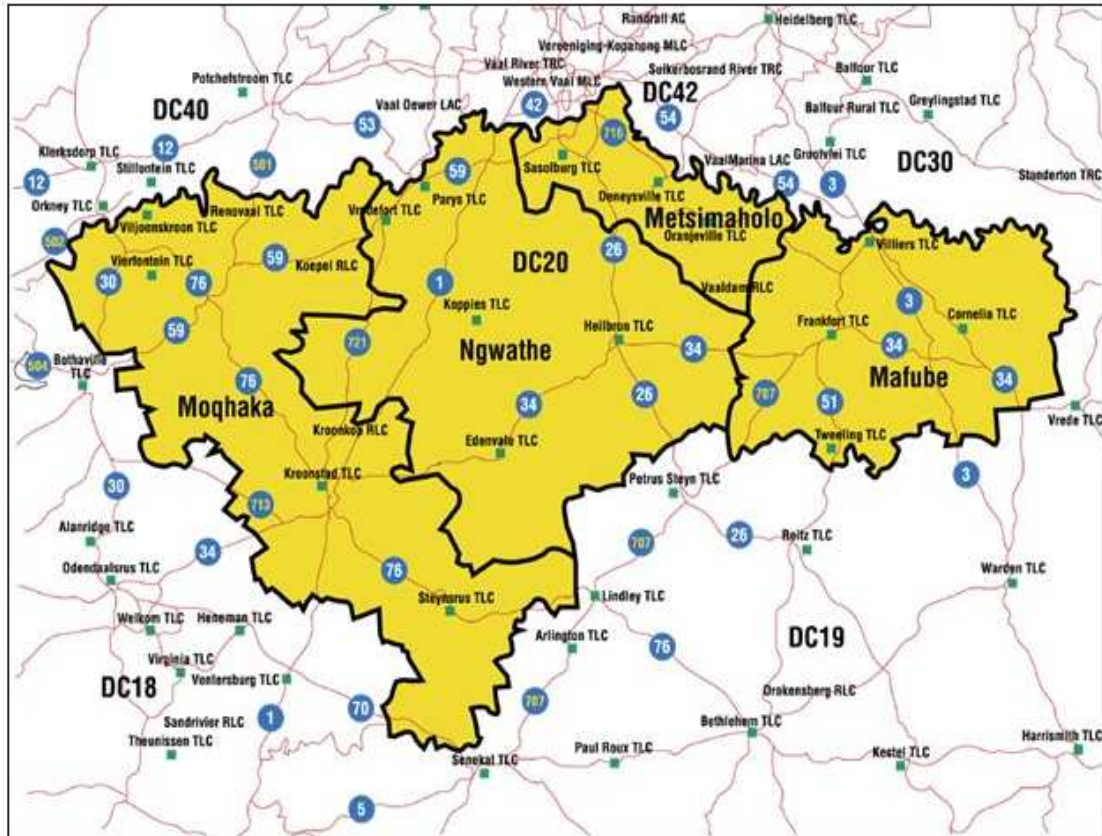


Figure 1.1 Fezile Dabi District Map in the Free State Province
(Free State Department of Health 2008) .

Fezile Dabi District population mid –year estimations are shown by Figure 1.2 below.

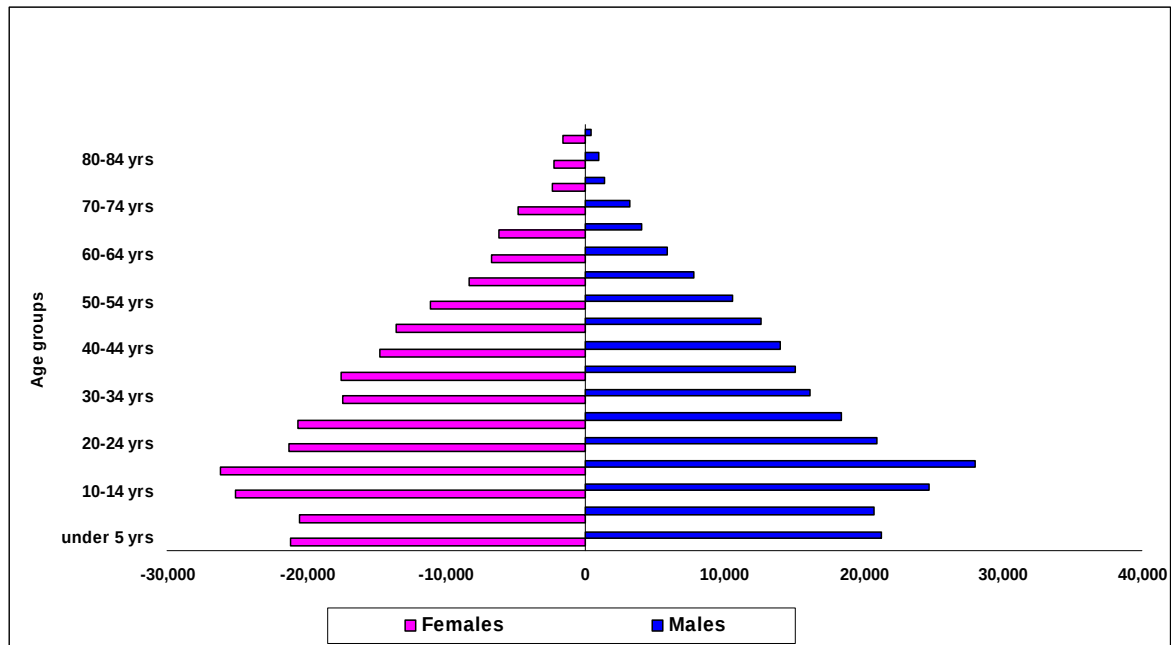


Figure 1.2 Fezile Dabi District Population Mid-year estimations 200
(Free State Department of Health 2008) .

1.2 STATEMENT OF THE PROBLEM

The Fezile Dabi District in the Province has been identified as the District with poor performance on the achievement of maternal and child health targets and Millennium Development Goals 4 and 5 (UNO 2008). Although the Maternal and Child Health Program is recognised as one of the priority programs within the Free State Province and the Fezile Dabi District, many challenges affect service delivery which includes a shortage of health professionals, under-resourced emergency medical services and being geographically distanced from the regional hospital.

The Complex's maternity units like any other maternity units within the Province have a high number of patients who experience AE incidents. According to the Complex's AE's register for 2007/2008, 56% of reported incidents were associated with patients utilizing

the maternity unit services. Of the maternity patients, 75% delivered stillborn infants while 8% were recorded as maternal deaths, and all were related to preventable factors. Due to the high number of patients experiencing AE in maternity units, professional nurses do not want to work in maternity units as they regard it as a high risk area and do not want to be implicated in the occurrence of these AE.

To address some of the above-mentioned challenges in the health system, the Free State Department of Health has put some systems in place e.g. policy on management of AE, referral system policy and other guidelines. Maternity patients are referred between the facilities according to the Free State Province policy on referral and maternal health guidelines. To facilitate the effectiveness of the referral system, the Department of Health is responsible for the provision of a commuter transport system for non emergency patients and ambulance services for emergency patients.

1.3 JUSTIFICATION FOR THE STUDY

Although the TMD Hospital Complex is faced with a high number of AE's in the Maternity units, no formal research has been conducted to systematically study this routinely collected information. The Free State Department of Health identified maternal and child health as one of the priority areas and would like to improve the maternal and child health in the District. The researcher believes this study will assist the Department with valuable information and the outcome of the study will be used by the Hospital and District management to improve maternal health services by appropriate planning and development of Complex specific preventive strategies within the maternity units.

1.4 RESEARCH QUESTION

What are the patient-related AE occurring within the maternity units of the TMD Hospital Complex? What are the individual and health system factors related to these events? And, how did the reporting system for AE function during the study period in terms of adherence to the related reporting policy)?

1.5 STUDY OBJECTIVES

1.5.1 BROAD OBJECTIVE

To describe the patient-related AE occurring in the maternity units of TMD Hospital Complex, the individual and health system factors related to these events and the functioning of the reporting system used during the 2 year study period, being 1 January 2008 to 31 December 2009.

1.5.2 SPECIFIC OBJECTIVES

1. To describe the AE (maternal and perinatal) reported with respect to the categories of AE in the maternity units during the study period.
2. To describe the factors related to the occurrence of such AE in the maternity units during the study period.
 - 2.1 To describe individual related factors in terms of the profiles of the patients who experienced AE in the maternity units during the study period with respect to socio-economic status, demographic and clinical information.
 - 2.2 To describe the health system-related factors as determined by the outcome of root cause analyses conducted by the AE committee with respect to AE reported in maternity units during the study period.
 - 2.3 To describe the functioning of the reporting system used in maternity units with respect to adherence to AE policy during the study period.

1.6 SUBSEQUENT CHAPTERS OF THIS REPORT

In the 1st chapter, the background to the research has been discussed and the objectives defined.

The following provides an overview of subsequent chapters:

Chapter Two: The literature review will discuss and explain the research related concepts with respect to the patient-related AE occurring within the maternity units of TMD Hospital Complex, the factors related to these events and functioning of the reporting system used to report such events. The chapter will also cover the solution to the identified problems.

Chapter Three: The research method and techniques used to conduct the study will be explained in chapter three.

Chapter Four: This chapter will cover the analysis of the results obtained in the study in relation to the research question, its aims and objectives.

Chapter Five: The chapter will integrate the findings from both the literature review and the research results in order to address the study's aims and objectives.

Chapter Six: This is the final chapter of the study. In addition to providing conclusions and recommendations, the chapter will provide suggestions for future interventions or improvements to address the identified problems.

1.7 SUMMARY

This introductory chapter provided a background to the study, statement of the problem, justification for the research, the research question and objectives for the study. It also provided a summary of the subsequent chapters that make up the research report.

CHAPTER 2

LITERATURE REVIEW

This chapter describes an overview of relevant report, classification of AE, AE reporting system and factors related to the reported AE in hospitals with particular reference to their maternity units are covered.

2.1 ADVERSE EVENTS IN MATERNITY UNIT

According to the Free State Department of Health, an AE is defined as an occurrence falling outside normal course of events in the rendering of a service. It is acts of omission that can result in injury, death of personnel or patients, which can lead to the ethical, financial, professional and criminal implications for the department (Free State Department of Health 1998). The term 'adverse event' may be used interchangeably with 'Medico legal incident'

Muller et al. defined an AE as an incident that leads to unintended or unexpected physical or psychological harm, loss, damage, injury and diseases not related to the patient's illness, underlying condition or treatment during the patient's stay in the health facility (Muller et al. 2006).

An AE is an unintended injury caused by medical management rather than the disease process and it can lead to prolonged hospitalization or temporary, permanent or disability to the patient (Vincen 2006) and (McFadden 2006).

.
These incidents can be classified according to levels of seriousness as indicated in Table 2.1 (Bateman 2008) .

Table 2.1 Classification of adverse events

Safety Assessment Codes	Description
Safety Assessment Code 1 (SAC1)	It is an incident leading to permanent disability or death
Safety Assessment Code 2 (SAC2)	It is a fairly severe incident which results in temporary disability.
Safety Assessment Code 3 (SAC3):	These are incidents without disabilities
Safety Assessment Code 4 (SAC4)	These incidents are considered as 'near misses'.

Examples of adverse events which may occur in a maternity unit include the following:

- Maternal mortality and morbidity
- Still birth,
- Prenatal death,
- Perinatal asphyxia,
- Intrapartum injuries,
- Failure to interpret Provincial and Hospital policy and guidelines
- Equipment failure

According to the study conducted at King Edward VIII Hospital maternity unit in Durban , the majority of AE (17.7% of the total reported AE) were classified as temporary disability (SAC2) and death (SAC1) (Matsaseng and Moodley 2005) . The results of a pilot study on the seriousness of AE conducted by COHSASA in the Free State Province hospitals revealed that 8.5% of reported incidents were serious (defined as SAC1): which is high when compared to 4% for Australia and USA (Bateman 2008) . Further study results indicated that the overall SAC2 (fairly severe) incidents at Free State Province hospitals are significantly higher (21%) than 5% for Australia and USA (Bateman 2008). The COHSASA study also found that the reporting system used in the Free State hospitals notify more SAC 1 & 2 events which are more serious than SAC 3 & 4 events (Bateman 2008).

The World Health Organization recommends that the following requirements be met for a successful AE reporting system (WHO 2005) :

- clear objectives for the system,

- designated persons to report,
- standardized report format,
- mechanism to receive report and data management,
- method to classify and make sense of reported events,
- capacity to disseminate findings,
- technical infrastructure and
- data security.

The Free State Department of Health and Fezile Dabi District faces challenges in many of these areas and the AE reporting systems as stipulated by the WHO and Free State provincial policy. Table 2.2 listed perinatal and maternal AE reported during the study period:-

Table 2.2 List of maternal and perinatal adverse events reported

Maternal AE	Perinatal AE
Ruptured uterus	Fresh stillborn
Maternal deaths	Stillborn
Bleeding caesarean section (C/S) wound	Low apgar score
Septic C/S wound	Fractured humerus
Unattended delivery	Baby's eyes to phototherapy lamp
Elective C/S performed prematurely	

An Example of an AE reporting system as described by the WHO is shown in Figure 2.1 (WHO 2005)

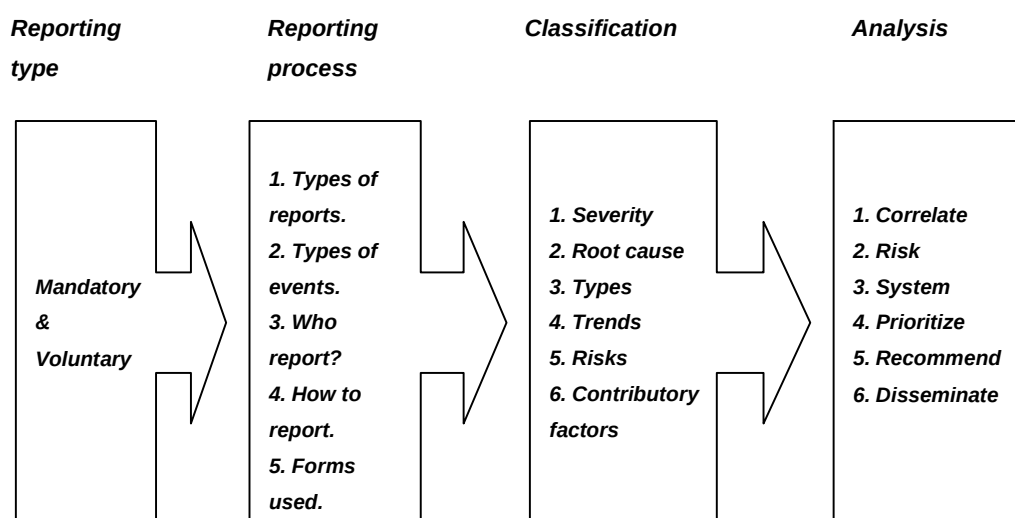


Figure 2.1 Example of an AE reporting system as described by the WHO.
(WHO 2005)

2.1.1. SYSTEMS USED IN MATERNITY UNITS TO REPORT AE.

The fundamental role of the AE reporting system in the hospital is to enhance patient safety by learning from failures of health care systems. The implementation of an effective AE reporting system by doctors, nurses and all relevant stakeholders, seeks to improve quality of care which will ensure patient safety in health facilities (WHO 2005) . It is therefore important for hospital managers to ensure responsible detection and open reporting of AE in their hospital in order to reduce the occurrence of AE.

The WHO (2005) recommends the following characteristics for successful AE reporting system:

- Non-punitive,
- Confidentiality of all involved is maintained,
- People with expert knowledge do analysis and recommendations,

- An independent body for reporting is used,
- System orientated and not individual orientated and
- Timely dissemination of recommendations to relevant stakeholders.

2.2 FACTORS RELATED TO AE IN MATERNITY UNITS

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

2.2.1 HEALTH SYSTEM FACTORS

In an emergency situation, AE can occur very quickly and may result in serious complications which may even be fatal. When patients need to be referred, the response time, availability of transport (ambulance on site) and the presence of a skilled, registered midwife, often determines the outcome for the patient. Challenges in this respect include the poor response to emergency situations, attendance to patients by unskilled birth attendants and doctors as well as long distances to the referral hospital via rural roads which are often in a state of disrepair. A study by Meda and colleagues revealed that the skilled attendance at delivery and effective referral system, in rural Burkina Faso and elsewhere in Africa, are regarded as the most important intervention strategies for safe motherhood and for decreasing maternal mortality, And were thus identified as policy priority initiatives (Meda, Houton, De Bouwer, Sombie, and Byass 2008).

Adequate training of health professionals also plays an integral role in the reduction of AE in maternity units as documented in a study conducted in the King Edward VIII Hospital in Durban (Matsaseng and Moodley 2005), in the Gugu District in Zimbabwe (Majoko, Nystrom, Munjanja, and Lindmark 2005). and in Australia (Beaves, Jenkis, and Wallace 2007)

Intrapartum maternal and perinatal surveillance practices also play a significant role in the avoidance of AE as reported in smaller rural district hospitals in the Victoria Province in Australia as well as in the UK (Beaves et al. 2007) .

. In the resource poor settings of the peripheral centres in Nigeria, effective and optimal utilisation of available resources and use of simple tools (such as the partogram) has been found to be effective in reducing prolonged and obstructed labours (Oladapo et al. 2006) .

Suboptimal administrative factors (such as timely availability of emergency transport) also plays a contributory role in the increase in reported AE as found in the Gugu Mission hospital in Zimbabwe (Majoko et al. 2005) .

2.2.2 PATIENT RELATED FACTORS

The health and well-being of mothers and their children can be negatively influenced by their socio-economic status and their family situations. When strategies are developed to reduce AE in maternity units, socio-demographic profiles of patients should be taken into consideration, especially in rural areas (Couillet, Serhier, Tachfouti, Elrhazi, Nejjari, and Perez 2007) . Although antenatal services are freely available in Morocco, it is not utilized by the patients due to poor socio-economic status and cultural norms. Multi-gravidity was cited as one of the reasons for non-utilization, which might be linked to an increased domestic work-load (Couillet et al. 2007) , which is also supported by a study conducted in Burkina Faso (Meda et al. 2008). Findings thus suggest that patient related factors might play an important role in either avoidance of, or may contribute to AE in the maternity units and they should therefore be studied simultaneously with health system factors.

2.3 ADVERSE EVENT REPORTING SYSTEM

The Free State Department of health's policy stipulates that all AE reports should be

finalized and be sent to the chief executive officer (CEO) of a hospital within seven days of its occurrence. The CEO will then send it to the District AE Committee (DAEC) within fourteen days after the event. The policy further stipulates that all meetings should be held monthly by the relevant committees (Free State Department of Health 1998) .

The establishment and constitution of institutional, district and provincial AE committees are guided by the provincial policy document. Responsibilities, authority and functions of the AE committees, in terms of classifications and analysis of reported AE, are important outcomes of the reporting system. The process will include classification of AE into types or severity, identification of related factors, interventions /recommendations, recognition of the risks and dissemination of the results to relevant stakeholders (Free State Department of Health 1998) (Figure 2.2).

Medico legal incidents (AE) reporting system steps in Fezile Dabi District in the Free State Province are shown by Figure 2.2 below.

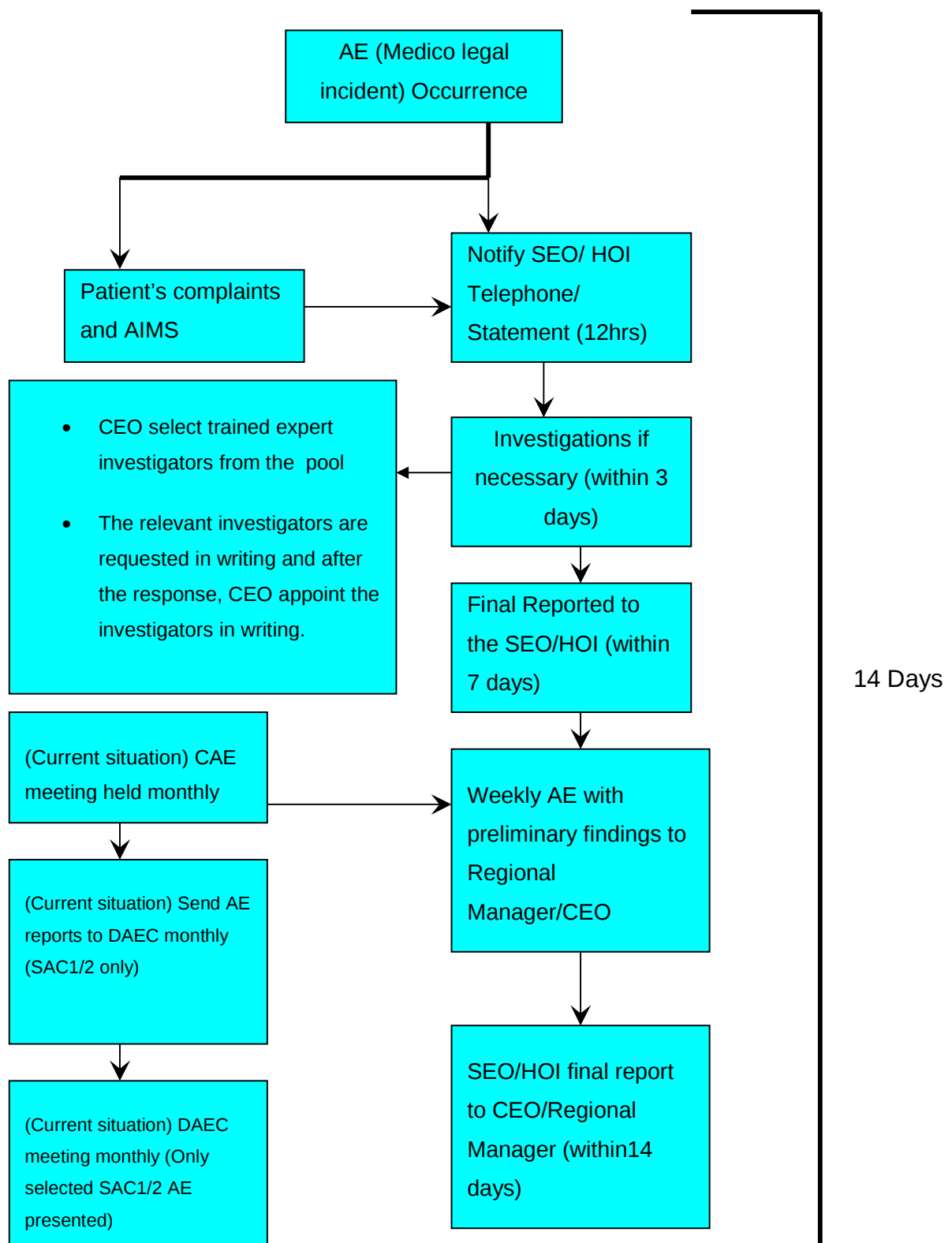


Figure 2.2 Medico legal incidents (AE) reporting system in the Fezile Dabi District
(Free State Department of Health 1998).

2.4 SUMMARY OF THE CHAPTER

The literature review chapter covered the definitions of AE reported in maternity units and it discussed the AE reporting systems used in the maternity units, the classifications of AE and health system- and patient related factors.

CHAPTER 3

METHODOLOGY

The methodology used for the study was determined by the study aims and objectives. In this chapter, the following are discussed: setting, scope, study design and data management.

Permission was granted by the Free State Department of Health to conduct the study and ethical clearance was granted by Wits University Ethics Committee through the submission of the protocol.

3.1 STUDY SETTING AND STUDY SCOPE

The study was conducted at the maternity units of TMD Hospital Complex in Fezile Dabi District, in the Free State Province.

The study was a retrospective analysis of routinely collected hospital data. No primary data was collected or intervention done as part of this study.

3.2 STUDY DESIGN

A descriptive, cross-sectional study design was used, involving a retrospective review of existing Hospital information. The information was collected from the health records of patients who experienced AE during the study period, AE Committee meeting minutes, AE registers and AE reporting forms.

3.3 STUDY PERIOD

The study was conducted over a two year period dating from 1 January 2008 to 31 December 2009.

3.4 STUDY POPULATION

Study population includes records from all AE registers, all completed AE reporting forms, statements of all personnel involved, minutes of all AE meetings and records of all patients who presented themselves in maternity units of the designated hospitals during the study period.

3.5 SAMPLING

All records linked to AE reported in the Complex's maternity units during the study period were reviewed and no sampling was done.

3.6 MEASUREMENT

The source of data was the files of patients who experienced AE, the AE register, AE meeting minutes, AE reporting forms and statements of personnel involved. A multi-disciplinary hospital committee decides on the level of seriousness and conducts the root cause analyses of the AE reported. All the information discussed by the AE disciplinary committee was available and documented in the minutes of each meeting.

3.6.1 STUDY INSTRUMENT

The measurement tools for collection of data were the MS Excel based tools (Appendix D). These tools were validated by the researcher in the Pilot Study conducted at Metsimaholo District Hospital in the Fezile Dabi District.

3.6.2 VARIABLES

The variables and indicators used for this study are listed in Table 3.1. The details of the health system related factors' has been described in the Glossary of terms.

Table 3.1 Variables

Objectives	Variables
1	Number of AE (maternal and perinatal) per category, seriousness of AE as described in Table 3 and time of AE
2.1	<u>Individual factors:</u> Demographic profile: age, marital status, place of residence Socio-economic status: employment status (employed/ not employed) Clinical profile: gravidity, antenatal visits, diagnosis, mode of delivery
2.2	<u>Health system factors with respect to AE committees' decisions:</u> personnel, transport, equipment, environment, management
3	<u>Reporting system with respect to adherence to Provincial AE Policy:</u> <u>Meetings</u> (frequency, types, attendances), <u>Reporting of AE</u> .(dates, times)

Table 3.2 shows the classifications of the different diagnoses, on admission, of all women who experienced AE during the study period. The diagnoses on admission were classified as shown in Table 3.2.

Table 3.2 Classification of diagnoses of all women that experienced AE

Classification of diagnoses	Diagnoses of all women with AE
Labour	All women admitted in labour.
Preterm labour	All women admitted with premature labour
HIV and Aids related diseases	All women admitted with pneumonia, TB, STI and PMTCT
BBA	All women who delivered before admission
Pregnancy related illnesses	All women admitted with PE, pregnancy induced hypertension, APH, anaemia, renal failure, diabetes and DVT.
Other pregnancy related risk factors	All women admitted with multiple pregnancy, post maturity, cord prolapse, malposition, poor progress, CPD, previous C/S and elective C/S

Description of Health systems related factors of all AE are listed in Table 3.3.

Table 3.3 Description of Health systems related factors of all AE reported

Factors	Descriptions
Clinical Governance	Non-adherence to clinical guidelines and protocols
	Poor monitoring and record keeping
	Poor clinical skills
Patient transport (EMS)	Delayed response
	Non-response
	Inadequate equipment in ambulance
Human Resource	Shortage of doctors and nurses
	Competency of nursing staff recruited through private agencies.
Referral between TMD Hospital and clinic	Failure to refer high-risk patients from PHC clinic to TMD Hospital in terms of the Free State Provincial protocol
Referral between TMD Hospital and Regional Hospital	Lack of critical care beds in the regional hospital
	Failure of the regional hospital to adhere to the Free State Provincial protocol

For the purpose of this study AE were classified into two broad categories, maternal AE and perinatal AE. The AE that occurred to the mother during the antepartum, Intrapartum and postpartum periods were classified as maternal AE.

3.6.3. DATA COLLECTION

The researcher extracted data from the available sources (such as patients' files, AE register, minutes of meetings, AE report forms, statements written by personnel) and captured it into a MS Excel spreadsheet. To ensure a high quality of the data, a double capture was done by the researcher when extracting data from the sources.

3.6.4. DATA MANAGEMENT

Epi-Info was used to analyse the data.

The following statistics were used:

- Descriptive statistics:-
 - Nominal and Ordinal variables (such as race): Proportions and percentages.
 - Continuous variables with normal distribution (such as age): mean and standard deviation
 - Continuous variables without normal distribution: median and inter-quartile

range (IQR).

- Inferential statistics:-
 - Continuous variables plus a bit of Mann-Whitney
 - Categorical variables – Chi-square test

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

3.7. PILOT STUDY

The pilot study was done in the maternity ward of Metsimaholo District Hospital in the Fezile Dabi District to ensure the validity of the data tools and to familiarize the researcher with the use of the tools. The data collection tool was slightly modified based on the findings of the pilot study.

3.8. ETHICAL CONSIDERATION

The researcher requested written permission and consent to conduct the study from Head of Department of Health Services in the Free State Province. The research was conducted after the approval of the research protocol by the University of the Witwatersrand Post Graduate Committee for research was granted.

The confidentiality of the patients, employee and institution information was ensured in that the hospital data was collected and captured within the hospital premises. All files or records that were collected from the different sections were registered and signed for by the researcher and the relevant officers. The same procedure was followed when the records were returned to ensure protection of the data. The anonymity of all the patients and employees was maintained by not attaching names to any data that was collected. Data collected was linked to individual patients or staff through the use of coding.

CHAPTER 4

RESULTS

The results obtained from the analysis of the data are described below.

4.1 ADVERSE EVENTS

The number of admissions, deliveries as well as the AE that occurred during the study period is listed in the Table 4.1.

Table 4.1 Total number of patients (n=88)

	Total (N, %)	Maternal (N, %)	Perinatal (N, %)
Number of admissions	10 371	5866	4505
Number of deliveries	4505	4505	N/A
No of AE	88	73	15
AE delivery	(1.9)	(1.6%)	N/A
AE admission	(0.8 %)	(1.2%)	(0.3%)

The number of maternal and perinatal AE during this period was 73 (0.8%) and 15 (0.3%) of the total admissions respectively.

4.2 ADVERSE EVENT LEVELS

The distribution of AE, as categorised in terms of the SAC is shown in Table 4.2.

Table 4.2 Total number of AE as per SAC type (n=88)

Level of seriousness	Total (N, %)	Maternal (N, %)	Perinatal (N, %)
SAC 1	81 (92)	68 (93.2)	13 (86,6)
SAC 2	0 (0)	0 (0)	0(0)
SAC 3	4 (4.6)	3 (4.1)	1 (6.7)
SAC 4	3 (3.4)	2 (2.7)	1(6.7)
Total	88 (100)	73 (100)	15 (100)

The majority of the AE were at the SAC 1 level which is the most serious. The SAC 1 level AE accounted for 93% of maternal and 87 % of perinatal AE. The SAC 3 level AE accounted for 5%, while SAC 4 level AE accounted for 3% of the total number of reported AE. There was no SAC 2 level AE reported.

4.3 ADVERSE EVENTS- STAGES OF OCCURRENCE

The stages of occurrence for the maternal AE were subdivided into ante-partum, intrapartum and post-natal stages, while the stages of occurrence of perinatal AE were subdivided into pre-natal, early perinatal and late perinatal stages.

4.3.1 MATERNAL ADVERSE EVENTS

Table 4.3 and Table 4.4 shows the different stages at which the reported maternal and perinatal AE occurred.

Table 4 .3 Total number of maternal AE per stage of occurrence (n=74)

Stages of occurrence	Maternal
Postpartum	5 (6.8%)
Ante partum	13 (17.5%)
Intrapartum	56 (75.7%)
Total	74 (100%)

Most reported maternal AE (n=56) occurred during the Intrapartum stage followed by ante partum stage (n=13) and postpartum stage (n=5.)

Table 4.4 Stages of occurrence of AE

Stages of occurrence	Perinatal
Pre-natal	0(0%)
Perinatal Late	0(0%)
Perinatal Early	15(100%)
Total	15(100%)

All reported perinatal AE (n=15) occurred during the early perinatal stage.

4.4 ADVERSE EVENT REPORTING

Maternal and perinatal AE reported and investigated are listed in Table 4.5.

Table 4.5 Maternal and perinatal AE reported and investigated

Adverse event reporting	Total	Maternal	Perinatal
Forms completed (AE Reported)	88	73	15
AE not requiring investigation	82	67	15
AE needed investigation	6	6	0
AE investigated	6 (100%)	6	0
Investigation completed	6 (100%)	6	0

The total number of maternal and perinatal AE reported were 88 (maternal 73, perinatal 15) and the total number of AE investigated were 6 (n=6 maternal 6, perinatal 0) There was no significant difference between the number of investigations for maternal and perinatal AE (Chi-square test, $p = 0.58$)

The number of days taken to report, investigate and present AE to relevant levels are listed in Table 4.6.

Table 4.6 Number of days taken to report and investigate AE

	Total	Maternal (n=73)	Perinatal (n=15)
Days taken to report AE to hospital CEO	3 (1-6); n=88	3 (1-5.7)	4 (1-11.5)
Days taken to investigate AE(Median)	38 (9-64); n=6	38 (9-64); n=6	0
Days taken to present to CAEC(Median)	36 (22-64); n=86	36 (23-53)	28 (18-61)
Days taken to present to DAEC(Median)	93 (78-181); n=26	86 (78-187); n=18	104 (55-157); n=8

For 72 AE cases (82%), the reporting was within the prescribed period (7 days from the event) to the hospital CEO. The median of number of days for reporting an AE to the hospital CEO was three days (IQR 1-6). In 16 cases (18%), the time taken to report an

AE to the hospital CEO exceeded the stipulated 7 days and in two cases of maternal AE the time taken to present these AE to the DAEC was 202 and 312 days. There was no significant difference between the times taken to report maternal and perinatal AE (Mann Whitney Test, $p=0.58$). Six maternal AE cases required investigation of which all were investigated. All exceeded the stipulated 3 days for investigation (median 38; IQR 9-64). Seventy four cases (84%) exceeded the prescribed 14 days for presenting the AE to the CAEC. There was no significant difference between the number of days taken to present maternal and perinatal AE to the CAEC (Mann Whitney Test, $p=0.50$).

Twenty six AE cases were presented to the DAEC. All of them (100%) exceeded the stipulated 14 days for the presentation of AE to the DAEC. There was no significant difference between the number of days taken to present maternal and perinatal AE to the DAEC (Mann Whitney Test, $p=0.59$).

The number of days taken to present AE cases which were reported and investigated to the CAEC and DAEC were not significantly different to the number of days taken to present the AE which were not investigated (Time taken to present to CAEC: Mann Whitney Test, $p=0.11$, and time taken to present to DAEC: Mann Whitney Test, $p=0.11$).

Figure 4.1 indicates in a chronological way the number of days taken to report, investigate and present AE at CAEC & DAEC meetings.

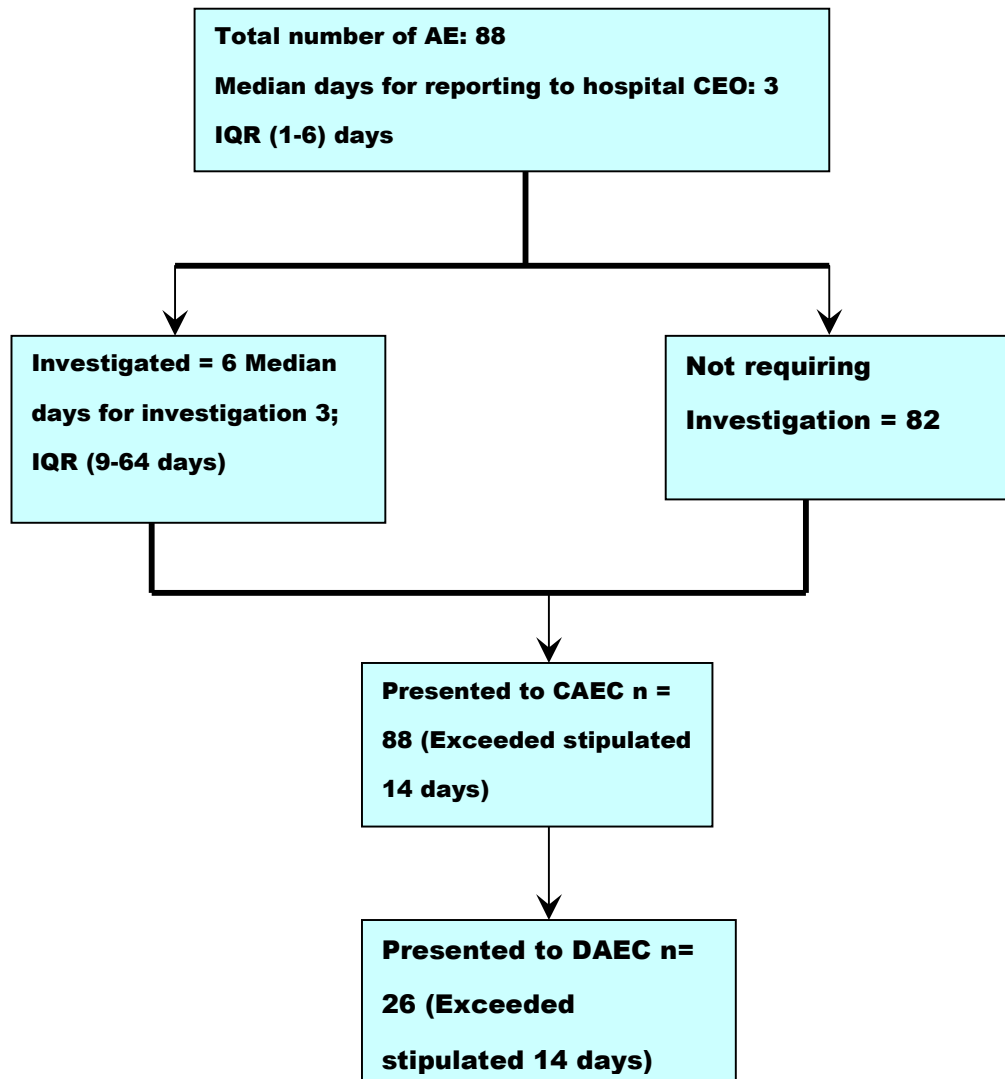


Figure 4.1 AE reported and investigated and number of days taken to present to CAEC & DAEC meetings

4.5 ADVERSE EVENT MEETINGS

Table 4.7 shows the total number of expected AE meetings and attendances as well as the actual number of meeting held and number of members that attended at each committee level (n= 24 expected meetings for each committee), (n=20 actual meetings held at CAEC) and (n=23 actual meetings held at the DAEC).

Table 4.7 AE meetings and attendances at the Complex and the District.

AE Meetings	Complex	District
Number of meetings expected	24	24
Number of meetings held	20 (83%)	23 (96%)
Attendance expected per meeting	11	19
Actual Attendance per meeting	7 (5-8)	13 (12-15)
% Attendance median (IQR)	36 (26-43)	68 (63-80)

Both the complex and the district AE committees held more than 80% of the required number of meetings. However, the attendance was inadequate. The attendances at the CAEC meetings was significantly lower than the attendances at the DAEC meetings (Mann Whitney Test $p < 0.001$).

4.6 PROFILE OF PATIENTS INVOLVED WITH AE

4.6.1 AGE

Age of the maternal patients is described in Table 4.8.

Table 4.8 Ages

Age-group	Total number of patients n (%)
<19 years	12 (14)
19-34	71 (81)
35-39	3 (3)
>40 years	2 (2)
Total	88 (100)

Figure 4.2 below shows the age distribution of all women that experienced AE during the study period.

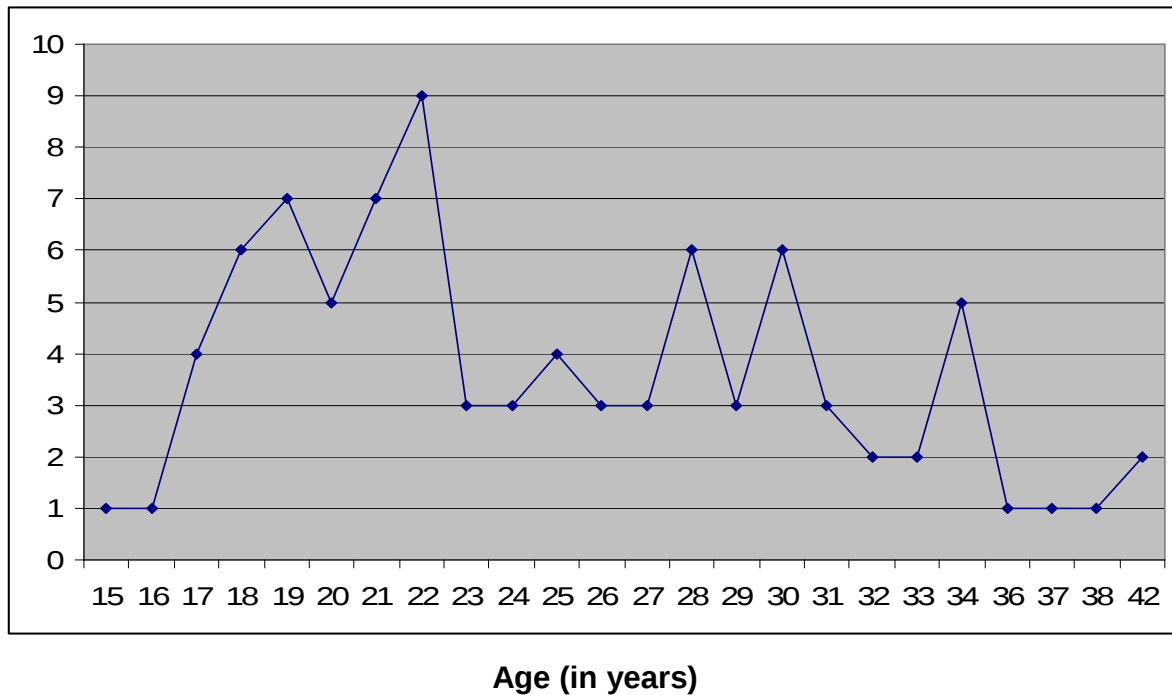


Figure 4.2 Age distribution of all woman that experienced AE

Twelve (14%) subjects that experienced AE were teenagers (younger than 19 years of age). Three were between the age of 35 to 39 (3%) and two were above the age of 40 (2%).

4.6.2 MARITAL STATUS

Table 4.9 shows the marital statuses of the patients that experienced.

Table 4.9 Marital status

Marital status	Total	n (%)
Married	18	(21)
Unmarried	69	(79)
Total	87*	(100)

* missing value

Unmarried women experienced more AE (n=69, 79%) than married women (n=18, 21%).

4.6.3 PLACE OF RESIDENCE

Table 4.10 indicates the total number of patients, that experienced AE, that resided in towns and on farms, (n=78) and (n= 10) respectively

Table 4.10 Residence

Residence	Total n (%)
Town	78 (89)
Farm	10 (11)
Total	88 (100)

More of the women residing in towns (n= 78, 89%) experienced AE than those who resided on farms (n=10, 11%).

4.6.4 EMPLOYMENT

Table 4.11 below shows employment statuses of women that experienced AE

Table 4.11 Employment status

Employment	Total n(%)
Employed	6 (7)
Unemployed	80 (93)
Total	86* (100)

* missing value

More unemployed women n= 80(93%) experienced AE than women that were employed n=6(7%).

4.6.5 GRAVIDITY

Table 4.12 below indicates gravidity of women that experienced AE.

Table 4.12 Gravidity

Gravidity	Total n (%)
1	37 (42.5)
2-3	37 (42.5)
4 and above	13 (15)
Total	87* (100)

The majority of women that experienced AE were primigravida and multigravida.

4.6.6 TOTAL NUMBER OF ANTENATAL VISITS

Total number of antenatal visits is described in Table 4.13.

Table 4.13 Antenatal visits.

Number of Antenatal visits	Total n (%)
0	12 (15)
1-3	35 (42)
4 and above	36 (43)
Total	83* (100)

The distribution of the number of antenatal visits attended by the women who experienced the reported AE is as follows: - Women who never attended an antenatal visit and experienced an AE were n= 12 (15%), those who attended one to three visits were n=35 (42%) and those who attended four or more visits were n= 36(43%).

4.6.7 DIAGNOSIS ON ADMISSIONS

The diagnoses on admission were classified as follows: - Those admitted in labour as labour, those admitted in premature labour as preterm labour, those with pneumonia, TB, STI and PMTCT as HIV and Aids related diseases, those who delivered before admission as BBA, those with PET, pregnancy induced hypertension, APH, anaemia,

renal failure, diabetes and DVT as pregnancy related illnesses while those with multiple pregnancy, post maturity, cord prolapsed, malposition, poor progress, CPD, previous C/S and elective C/S were classified as other pregnancy related risk factors

Table 4.14 indicates the different diagnoses on admission of all women who experienced AE during the study period.

Table 4.14 Diagnoses on admission.

Diagnosis on admissions	Total n (%)
Labour	51 (33.3)
Pregnancy related illnesses	33 (21.6)
HIV and Aids related diseases	21 (13.7)
Other pregnancy related risks factors	18 (11.8)
BBA	17 (11.1)
Pre-term labour	13 (8.5)
Total	153 (100)

The primary diagnoses on admission were classified as follows: - Those admitted with anaemia, PET, diabetes, HIV and Aids and APH were classified as disease related, those who were in labour, signs of poor progress, CPD and ruptured uterus were classified as labour related, those with multiple pregnancy and breech presentation were put together as perinatal presentation related while those who were admitted with preterm labour and post maturity were classified as gestational period related.

Table 4.15 indicates the different primary diagnoses on admission of all women who experienced AE during the study period.

Table 4.15 Diagnoses on admission

Diagnosis on admissions	Total n (%)
Disease related	37 (47.4)
Labour related	21 (26.9)
Gestation Period related	15 (19.2)
Perinatal Presentation related	5 (6.4)
Total	78 (100)

The diagnoses on admission of women involved in the reported AE in % were as follows: - Those admitted in labour 33.3%, those with pregnancy related illnesses 21.6%, those with HIV and Aids related diseases 13.7%, those with other pregnancy related risk factors 11.8%, those with BBA 11.1% and those admitted with preterm labour 8.5%.

The primary diagnoses on admission of all patients involved in AE were (47.4 %) for disease related diagnoses, (26.6% labour related diagnoses, while gestational period related diagnoses and perinatal presentation related diagnoses accounted for 19.2% and 6.4% respectively.

4.6.8 MODE OF DELIVERY

Modes of delivery for women that experienced AE are listed in Table 4.16.

Table 4.16 Modes of delivery

Mode of delivery	Total n (%)
C/S	14 (15)
NVD	77 (85)
Assisted vaginal delivery	0 (0)
Total	91 * (100)

* Twin pregnancies resulting in multiple mode of delivery

Table 4.16 shows that modes of delivery: normal vaginal delivery (77, 85%), C/S (14, 15%) and none of the women that experienced AE during the study period had an assisted delivery.

Table 4.17 Foetal presentation

Foetal Presentation	Total n (%)
Twin	4 (5)
Breech	3 (3)
Vertex	81 (92)
Total	88 * (100)

* Twin pregnancies resulting in multiple foetal presentations

Table 4.17 shows that foetal presentation for women that delivered per vagina and experienced AE: Twins (4, 5%), Breech (3, 3%) and Vertex (81, 92%).

4.6.9 DELIVERY OUTCOME

Maternal and perinatal delivery adverse outcomes are described in Table 4.18.

Table 4.18 Maternal and perinatal delivery adverse outcomes

Delivery outcomes	Total n (%)	Maternal n (%)	Perinatal n (%)
SB	67(77.2)	67(91.7)	N/A
Birth Asphyxia	13 (15)	N/A	13(92.9)
Fracture Humorous	1 (1.1)	N/A	1(7.1)
Maternal death	3 (3.4)	3 (4.1)	N/A
Puerperal Sepsis	1 (1.1)	1(1.4)	N/A
Postpartum Haemorrhage	1(1.1)	1(1.4)	N/A
Ruptured uterus	1(1.1)	1(1.4)	N/A
Total	87 (100)	73(100)	14 (100)

The following are total percentages of all maternal and perinatal delivery outcomes for all AE reported during the study period: SB 77.2%, birth asphyxia 15%, maternal death 3.4% while Humerus fractures, Puerperal Sepsis, Postpartum Haemorrhage and Ruptured uterus are all 1.1%.

4.6.10 OTHER ADVERSE EVENTS

Other AE are listed in Table 4.19.

Table 4.19 Other maternal and perinatal AE not related to delivery outcomes

Adverse Events	Total n (%)	Maternal n (%)	Perinatal n (%)
Eyes exposed during phototherapy	1 (33.3)	N/A	1 (100)
Unattended delivery	1 (33.3)	1 (50)	N/A
Pre term elective C/S	1 (33.3)	1 (50)	N/A
Total	3 (100)	2 (100)	1 (100)

Other maternal and perinatal AE not related to delivery outcomes such as eye exposure during phototherapy, pre-term elective c/s and unattended delivery were also recorded and they were all at 33.3%

4.7 HEALTH SYSTEM RELATED FACTORS

Table 4.20 shows the descriptions of maternal and perinatal health systems related factors FOR all AE reported. (n=72 maternal AE and n= 16 perinatal AE). Health systems related factors had a more significant effect on maternal AE than perinatal AE.

Table 4.20 Health systems related factors of all AE reported

Factors	Total n (%)	Maternal n (%)	Perinatal n (%)
Clinical Governance	38 (43)	29 (40)	9 (56)
Human Resource	7 (8)	6 (8)	1 (6)
Patient transport (EMS)	29 (33)	26 (36)	3 (19)
Referral between TMD Hospital and clinic	11 (13)	11 (16)	0 (0)
Referral between TMD Hospital and Regional Hospital	3 (3)	0 (0)	3 (19)
Total	88 (100)	72 (100)	16 (100)

Clinical governance was the greatest contributing health system related factor for both maternal and perinatal AE. The patient transport related issues such as delays also played a significant role in both AE categories. The referral between TMD Hospital Complex and the regional hospital contributed 19% towards the perinatal AE. A significant difference existed (Fisher's Exact test, $p < 0.01$) between the health systems

related factors that had an effect on maternal AE and those which had an effect on perinatal AE.

Table 4.21 indicates association between health systems related factors and SAC levels of reported AE.

Table 4.21 Association between health system related factors and SAC levels of AE

Factors	Total	SAC 1	SAC 2	SAC 3	SAC 4
Clinical Governance	38 (100%)	32 (84%)	0	4(10%)	2 (6%)
Human Resource	7 (100%)	6 (86%)	0	0	1(14%)
Patient transport (EMS)	29 (100%)	29(100%)	0	0	0
Referral between TMD Hospital and clinic	11(100%)	11(100%)	0	0	0
Referral between TMD Hospital and Regional Hospital	3(100%)	3 (100%)	0	0	0
Total	88 (100%)	81	0	4	3

The majority of the AE were at the SAC 1 level AE. There was no significant association between the various health systems related factors and the SAC levels of AE (Fisher's Exact test, $p < 0.27$). However, this might be due to low reporting incidences of less serious AE (SAC 2 to SAC 4).

CHAPTER 5

DISCUSSION

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

5.1 INTRODUCTION

The aim of the study was to describe the patient - related AE in the maternity units of the TMD Hospital Complex, the related individual and health system used factors and the reporting system for these AE during the two year study period.

The records of 88 patients who were involved in AE were reviewed.

5.2 ADVERSE EVENTS

The number of maternal AE (1.2%), reported in relation to the total number of admissions, was more than the number of perinatal AE (0.3%). Of the total number of maternity admissions recorded, these findings indicate that 0.8 % experienced AE. The above-mentioned results suggest that the number of reported AE in relation to the total number of admissions in the maternity units, is far lower than the expected 10% (Muller et al. 2006) , (WHO 2005), (Milch,Salem, Pauker, Lundquist,Kumar, and Chen J 2005).

The study conducted in the Netherlands, by the Dutch Organization of Health Research and Development, also confirms that the median overall incidence of in hospital AE was 9.2% of total admissions, implying that AE affected nearly one out of every ten patients admitted in the hospital (de Vries, Ramrattan, Smorenburg, Gouma, and Boermeester 2007). The low percentage of reported AE in the maternity units of TMD Hospital Complex may be due to the under reporting of less serious AE (such as SAC 2 – 4) by personnel. Furthermore, the research evidence suggests that, in hospitals of more

developed countries, the expected AE incidence rate of 10% was significantly high (Muller et al. 2006).

The results of a study, conducted at Chulalongkorn University in Thailand, on identifying AE, with the use of the Global Trigger Tool, revealed that AE in hospitals are under reported due to limitations in the incident detecting and reporting systems (Asavaroengchai, Sriratanaban, Hiransuthikul, and Supachutikul 2009).

5.3 ADVERSE EVENTS LEVELS

The majority of AE reported were SAC 1 level AE which accounted for 93.2% of the maternal AE and 83.6% of perinatal AE. This study suggests that the TMD Hospital Complex reported more serious AE (SAC 1) than any other level or category of AE. The study findings thus confirm the findings reported in a pilot study, conducted in twenty four hospitals in the Free State Province by Bateman, wherein, out of four hundred reported incidents, most were SAC1 and 2 level AE. The results of the pilot study further demonstrated that in the Free State hospitals, staffs was more likely to report more serious incidents than those considered less serious (Bateman 2008).

Although the AE policy stipulates that all categories of AE should be reported to all committees, the current prevailing culture in Free State Department of Health is that only SAC1 and 2 AE are reported to the DAECs and Provincial AE Committee (PAEC.) This practise also encourages personnel at the institutions to report the more serious rather than the less serious AE. The study results indicated that the Free State Department has a deficiency in the monitoring of the implementation of the AE policy, and as a result, not all categories of AE are reported as outlined within the policy.

The department needs to address this deficiency, as a matter of urgency as near misses and other less serious adverse incidents reporting is vital because such incidents give warning and enable preventative and proactive approaches to safety (Vincen 2006).

In another study conducted in New York State hospitals, where the focus was on the incidents that may eventually lead to legal action, less serious AE or those causing discomfort were also not reported (Vincen 2006).

Similar studies conducted on the incidence of near-miss (SAC 4) events in maternity wards in African hospitals, found that the occurrence of near-miss incidents varied from 1% to almost a quarter of the total deliveries (Filippi, Ronsmans, Gohou, Goufodji, Lardi, Sahel, Saizonou, and Brouwere 2005). This wide variability can be explained by the safety culture and the nature of the reporting systems used in these hospitals, which could be influencing the reporting practice.

This study was conducted at the maternity units of the two district hospitals which tend to receive high risk referrals. This may explain the higher percentage of more serious AE than percentage of less serious events. It may also be due to staff being obliged to report on these more serious events, as the culture in the department is that all very serious AE (SAC1 and 2 level AE) must be reported to the DAEC and PAEC on the monthly basis, resulting in serious consequences for the individuals as well as for the institutions concerned, where there is a failure to report such events.

5.4 ADVERSE EVENTS: STAGES OF OCCURRENCE

More maternal AE happened during the intrapartum stage of delivery that accounted for 75.7% of all reported maternal AE, followed by the ante partum (17.5%) and postpartum (6.8%) stages. The maternal intrapartum period is the period when the woman is in labour. Usually, during this period, most women are already in the maternity units which provide an opportunity for improved patient outcomes. This short period is extremely influential and is critical in determining the outcome for both mother and baby.

A study conducted at Frontier Hospital in Queenstown (South Africa), on perinatal mortality, revealed that the majority (70%) of deaths in the year 2000 were due to

personnel avoidable factors. Further analysis indicated that intrapartum care mismanagement such as failure to use and incorrect use of the partogram accounted for majority of adverse incidents reported (Patrick and Pead 2007).

This study has demonstrated that the TMD Hospital Complex maternity units have a deficiency in their capacity to manage patients who are in the intrapartum period, which is a great concern that needs to be addressed urgently. Quality of care issues, for addressing system failures during this period should be targeted. According to the study conducted in South Africa at Zithulele rural district hospital in the Easter Cape Province on improving perinatal outcomes, quality improvement measures put in place reduced incidents, related to avoidable factors associated with perinatal deaths, over the five year period by over 50% (Gaunt 2010). The Gaunt study revealed that the implementation of Problems Identification Programmes, development of protocols for safe augmentation and induction of labour, regular perinatal meetings, auditing of records and training of health personnel on partogram use, cardiotachograph in the maternity units, were all strategies that can be used to reduce perinatal deaths related to avoidable factors in the maternity unit of Zithulele district hospital (Gaunt 2010).

Another study conducted in Zambia revealed that training on the (WHO) Essential Newborn Care course improved midwives' skills and knowledge which led to the reduction of early neonatal death related to avoidable factors and significantly decreased the rate of stillbirths ($P=0.003$) (Waldemar, Carlo, Shivaprasad, Gouder, Imtiaz Jehan, Chomba, et al. 2010).

The early perinatal AE within the TMD Hospital Complex accounted for 100% of the reported perinatal AE. A study, conducted in the Victorian hospitals in Australia, made similar findings and, reported that a significantly high number of AE occurred during the intrapartum and early perinatal period due to peripartum hypoxia and deficient intrapartum care (Beaves et al. 2007).

5.5 ADVERSE EVENT REPORTING

Of the total number of reported AE, only 6 needed investigation. Although all events requiring investigation were investigated as per policy, the stipulated investigation period was exceeded in all cases. This can be explained by the bureaucratic processes taking place, which may have contributed to the delays in investigation. Other factors which have contributed to the long investigation period are unavailability of the investigating officers and all involved personnel during the time of investigation. The poor quality of the final report produced by the appointed investigating officers, in terms of its comprehensiveness, which should assist the CAEC to take an informed decision about the AE at their disposal, also contributed to the long investigating period.

With respect to reporting of AE, 82% was noted to be within the prescribed period. The remainder exceeded the reporting period and in the two cases of maternal AE, the time taken for investigation was abnormally long, 202 and 312 days respectively. In both cases the delays were due to the poor progress on the investigation report by the investigating officers, who were appointed by the Chief Executive Officer (CEO) of the TMD Hospital Complex from the pool of experts who are officials outside the institution.

In the first case, the incident took place on the 29th August 2009. The investigating officer only managed to produce and send the final report to the CEO of the hospital on the 21st April 2010, eight months after the incident. The second incident took place on the 9th May 2008 and the investigating officer only produced and sent the report to the CEO on the 21st May 2009, eleven months after the occurrence of the incident.

The above-mentioned situation is due to the fact that all AE, which need investigations, are to be investigated by officials who are not employees of the hospital Complex where the incident took place. Most of the time, these appointed investigators take very long to come and investigate incidents due to other activities that they are involved in at their respective institutions. This is one of the challenges which the TMD hospital Complex experienced as it does not have total control over the appointed investigating officers.

Seventy four cases were presented to the CAEC, and twenty six were presented to the DAEC. All of them exceeded the stipulated 14 day of presentation period as stipulated in the AE policy. Therefore, while the research results suggest that the days taken to report AE (complete the form) was within the stipulated time period, the time taken to investigate the AE was excessive. The study further indicated that the time taken to present the reported AE to the CAEC and DAEC also exceeded the stipulated number of days.

The study results did not show any significant difference in the time taken to present AE which required further investigation and those which did not, implying that the delays in the presentation of AE to the CAEC and DAEC was not related to complicated incidents which may have needed more time to be investigated. No comparison is available in the literature, as this is the first study following this systematic process.

With respect to AE meetings, the DAEC managed to hold 96% of scheduled meetings and the CAEC 83%, which is more than 80% of the required number of meetings. The attendance at the DAEC was 68%, and at the CAEC 36%. The findings from this study indicated that although the meetings occurred according to the protocol, the attendance at the CAEC meeting was inadequate. The reason for the low attendance at the CAEC meetings may be due to some of the committee members not reporting to the management of the Complex (managers from surrounding clinics and from EMS), although they are members of the CAEC in terms of the policy guideline.

According to the Council for Health Service Accreditation of South Africa research findings, there has been no reliable AE reporting and monitoring system in place in South African hospitals. As a result, COHSASA introduced the Australian- based electronic AE reporting and monitoring system called Advanced Incidents Management system (AIMS) (Bateman 2008). The system takes only 7 to 10 minutes to capture information, thus reducing the need for staff to supply time-consuming written reports and to complete complicated forms. The system also ensures that all reported AE are

analysed weekly in order for management to take decisions (Bateman 2008) .To adopt the AIMS, the Free State department institutions will have to use a centralized computerized system to report all AE s. The call centre will need to be operated by well trained health professionals for capturing and analyzing the data. All health institutions should have telephone linked to the call centre where all primary reporters will report incidents.

To ensure the success of this system, the Free State department need to change, and establish a non-punitive culture as well as anonymous, voluntary reporting which will encourage all reporters to report AE (Bateman 2008).

According to the study conducted on the monitoring of voluntary electronic reporting systems, under reporting of medical errors and adverse events was associated with different definitions or perceptions of what constitutes an error or adverse events by personnel. There was a demonstrable need for training of all categories of personnel (Milch et al. 2005).

The results of the project on patient safety monitoring and reporting systems which was under taken as part of the Organization for Economic Cooperation and Development Patient Safety, Quality Indicators showed that some countries which introduced national incident monitoring, as well as mandatory and confidential reporting of adverse events indicated a significant under reporting of near miss incidents (Mcloughlin, Millar, Mattke, Franca, Jonsson, Somekh, et al. 2006). The result of the project further indicated that patient safety indicators has some conceptual limitations which restrict reporting of AE by leaving out some indicators for near misses, thus contributing to the under reporting of AE (Mcloughlin et al. 2006).

According to the results of the study conducted on an open-source application system for reporting adverse events and near misses, hospitals which used mandatory and non-anonymous reporting systems showed grave under reporting when compared with

voluntary and anonymous open-source application systems which showed significant increase in reporting within the first year of its implementation (Pietrobon, Lima, Shah, Jacobs, Harker, McCready, et al. 2007). The study further suggested that the difficulties with the under reporting of AE stems from the fact that many reporting systems focus blame on individuals rather than on the prevention of similar events (Pietrobon et al. 2007).

Another study conducted, in hospitals in Scotland on the detection of AE, suggested that the current voluntary reporting system does not provide a complete measurement of AE as it managed to report only 10% of the AE, while the old, traditional, retrospective record review managed to identify 90% of the AE (Williams, Olsen, Crichton, Witte, Flin, Ingram, et al. 2008). The study further suggested that in order to ensure an effective voluntary reporting system, there is a need to complement this with the retrospective record review system (Williams et al. 2008).

5.6 ADVERSE EVENTS: PATIENT RELATED FACTORS

The majority of women who experienced AE were between the ages of 19-34 years (81%), were unmarried (79.3%), resided in towns (88.6%) and were unemployed (93%). According to the study conducted at three hospitals in Uganda, poverty and lack of awareness were identified as factors contributing to the delays in seeking care which indirectly led to the near-miss type of AE reported (Okong, Byamugisha, Mirembe, Byaruhanga, and Bergstrom 2006).

The unmarried and unemployed statuses probably signify an association between low socio-economic status and occurrences of AE. According to the study conducted in Canada on effect of income on birth outcomes, maternal socioeconomic status was identified as an important determinant of maternal and perinatal outcomes during birth. (Luo, Wilkins, and Michael 2006).

Furthermore the study revealed that unemployment and low level of income contribute to elevated risks of preterm deliveries, stillbirths and neonatal deaths (Luo et al. 2006). The Luo et al. study also revealed that women of poor socioeconomic status were vulnerable to the occurrence of AE. Further studies are needed to elaborate more on this and to establish any causal links.

Most of the women who experienced AE were in the primigravida and multigravida (42.5%) . The study showed that there was no relation between the employment status and gravidity of the women involved in the reported AE.

More than two thirds of the women who experienced AE did not attend the stipulated number of antenatal visits. Since the majority of the women who experienced AE resided in towns, the study findings contradicts the popular knowledge where the Urban population is said to have better opportunity to access more and better health facilities than those who reside on the farms or in Rural areas.

This may be related to the quality of antenatal services, which needs further research to understand the complexities of the situation. According to Fezile Dabi District Health Plan data for 2008/2009, the vacancy rate for professional nurses in the clinics in Ngwathe and Mafube municipalities were 34% and 37% respectively which indicates a gross shortage of professional nurses (Free State Department of Health 2008).

This shortage of professional nurses may have contributed to the provision of poor quality antenatal care at these surrounding clinics, as well as the long waiting periods which could have led to poor antenatal clinic attendance by these women. Another reason may be that the majority of these women who experienced AE were unmarried and they would normally avoid antenatal care visits as a means of hiding the pregnancy, as single parenthood is still culturally unacceptable in rural parts of the Free State Province.

The poor attendance at antenatal clinics is further supported by a study conducted

in Nigerian hospitals on maternal AE. This study revealed that the majority of near-miss and SAC 1 AE were among mothers who did not attend antenatal clinics, but delivered in the hospitals (Oladapo, Sule-Odu, Olatunji, and Daniel 2005).

One third of women who experienced AE were in labour on admission. Of these women, 21.6% were admitted with pregnancy related illnesses. Furthermore, in terms of primary diagnoses on admission of these women, most were disease related (47.4%) followed by labour related and gestational period respectively.

According to Filippi et al. and Oladapo et al., women who were admitted with ante partum haemorrhage and hypertension were those who experienced near – miss incidents. Similar to the above-mentioned findings, the study conducted by the Research Triangle Institute International in USA on systematic reviews to meet critical priorities in maternal health in the intrapartum period, suggests that pregnancy related illnesses, such as hypertension, bleeding and others, lead to AE in the preventability range of 30% to 40 % (Viswanathan 2008). The fourth report on Confidential Enquiries into Maternal Deaths in South Africa also indicated that hypertension and haemorrhage were identified as the major primary cause of deaths under avoidable deaths per categories of diseases (National Department of Health 2007).

Similar to this study, the Okong et al. study also suggest that the primary diagnoses, such as disease related and gestational period, had an effect on the occurrence of near-miss AE.

Of the women who delivered in the TMD Hospital Complex and experienced AE, 85% had normal vaginal deliveries followed by caesarean sections 15% and none of the women that experienced AE during the study period had an assisted delivery. The Viswanathan study findings also indicated that the mode of deliveries such as normal vaginal deliveries, assisted and caesarean sections, for women who are at risk, like preterm labour, multiple pregnancies and others, are associated with the occurrence of AE.

Delivery outcomes of the reported AE were stillborns (77.2%) followed by birth asphyxia and maternal death respectively. According to the study conducted at the Gambian hospital in the UK on foetal outcome in severe maternal morbidity, 67% were potentially preventable fresh stillborns which occurred during the intrapartum period. The study results further suggest that better intrapartum monitoring, with the use of partographs, will provide opportunity for early identification of complications which will ensure prompt action (Cham, Sundby, and Vangen 2009).

The Cham et al. study also indicated that skilled attendance at the deliveries should be advocated for reducing the number of stillbirths in maternity units.

The study results suggest that the TMD Hospital Complex has a serious challenge with the management of patients who are in labour and this is confirmed by the delivery outcomes which demonstrated a high number of fresh stillborns reported, as well as a majority of normal vaginal deliveries with high number of AE.

The study findings also suggest that there is a deficiency in the capacity of health personnel to manage pregnancy related illnesses in the TMD Hospital Complex. This may be due to the fact that, on a continuous basis, the TMD Hospital Complex experiences a high turn over rate of health professionals. As a result the maternity units are staffed with agency nurses and foreign doctors who are less experienced and knowledgeable.

5.7 HEALTH SYSTEM RELATED FACTORS

In terms of the health system related factors, the maternal AE accounted for (n=72) of all reported AE. Of the above-mentioned health system related factors, high numbers of the AE reported were related to clinical governance issues for both maternal and perinatal (43%) aspects followed by patient transport factors (33%) which also played a significant role, and referral system factors and human resource factors respectively. The study

also indicates that there was no significant association between various health systems related factors and the level of seriousness of the reported AE (SAC). However this might be due to under reporting of the less serious AE (SAC 2 to SAC 4).

Similar findings were reflected in a study conducted in England. Root cause analyses of maternity AE showed that these AE were mostly related to failure of staff to diagnose or refer to the next level of care. Human error was linked to clinically inexperienced health personnel and staff shortages, failure to consult and failure to manage eclampsia and APH (Smith and Dixon 2007).

According to Filippi et al. 2005, the high incidence of AE in the maternity wards took place upon arrival which was the indication of failure of the system to ensure prompt access to care for women in need of such maternity care.

Filipp's study further indicated that transport and the referral chain had a huge impact on the occurrence of the AE in the maternity wards, as almost two thirds of women arrived at the facilities within less than one hour of delivery. It was evident from the statistics, of that women who experienced AE at TMD Hospital Complex upon arrival, can not always assess the quality care of the maternity units of this Hospital Complex.

Furthermore results of the study, conducted by the Postgraduate Institute of Medical Education and Research in North India on factors related to postpartum haemorrhage in hospital maternity units, showed that most near-miss AE were due to delayed referral and a failure to manage the third stage of labour by clinical personnel (Kaul, Bagga, Jain, and Gopalan 2006).

In another study conducted in the maternity units of different hospitals in the Volta and Central region of Ghana on the confidential enquiry based on the causes of AE leading to maternal deaths, the following health system related factors were identified as the root causes: - delays in response to complications by medical officers, poor management at all stages of labour, failure to manage APH, unavailability of health

professionals to escort patients during referral, unavailability of doctors at some stage and poor record keeping especially by means of partograms (Ansong-Tornui, Armar-Klemesu, Arhinkul, Penfold, and Hussein 2007). In the study which took place in four maternity units of Europe more AE were clinical governance issues such as late diagnosis, inadequate treatment and non-compliance with available protocols (Dupont, Touzet, Rudigoz, Audra, Gaucherand, and Colin 2006).

According to the findings of a study conducted on AE reported in the maternity units of some public hospitals in the Free State Province by COHSASA, patient transport factors, and delays in taking decisions or providing treatment were major health system related factors. Clinical governance issues were identified as the major contributing factors in this study (National Department of Health: Fourth Report on Confidential Enquiries into Maternal Deaths in South Africa 2007) and (Bateman 2008). In addition, Bateman further revealed that in the Free State pilot study, 80% of SAC1 incidents were related to the clinical governance.

In another study conducted in South African hospitals on avoidable factors and causes of perinatal deaths due to asphyxia-hypoxia, inadequate perinatal monitoring and mismanagement of second stage of labour by health professionals were identified as most common factors related to perinatal deaths in hospitals (Velaphi and Pattinson 2006).

Similar to the findings of this study, the results of the Fourth Report on Confidential Enquiries into Maternal Deaths in the Free State Province indicated that avoidable health systems related factors such as transport delays and health workers related issues, which are mostly clinical governance, contribute into the high incidents of maternal mortality in the Province (National Department of Health 2007).

The results of this study revealed that the TMD Hospital Complex faces very serious challenges around the issues of clinical governance followed by transport, and to a lesser extent human resource issues. Failure to manage women in the intrapartum

period, by health professionals which was revealed by the high number of fresh stillborns is a serious issue which needs urgent attention by the management of the TMD Hospital Complex. The findings also revealed that the current Centralized EMS transport management system needs to be revised, as a matter of urgency, to address delays which contribute to the high number of reported AE at TMD Hospital Complex. According to the accepted standard in the Free State, the target for EMS response time is 30 minutes in the Urban Areas and 45 minutes for the Rural Areas(Free State Department of Health 2008) . Currently this set standard is not even monitored.

CHAPTER 6

CONCLUSIONS AND RECOMMENDATIONS

In this chapter the results are assessed in relation to the aims of the study, so that appropriate conclusions can be drawn. The limitations of the study are also articulated. Appropriate recommendations are made within the context of study findings. Finally, further research proposals are presented.

The study results indicated that health systems related factors have a great impact on the occurrence of AE in maternity units of TMD Hospital Complex. The importance of the user friendliness of the available policy to manage and report AE in the institutions can not be overemphasised. The reporting of less serious AE can provide valuable information to prevent more serious AE and therefore monitoring of the AE reporting system to report all categories of AE will assist in reducing the high number of serious AE reported.

6.1 CONCLUSIONS RELATED TO THE AIMS OF THE STUDY

The study managed to reach its intended aim in that the description of patient-related AE in the maternity units of Tokollo/Mafube District Hospital Complex, factors related to those events and the reporting system used during the 2 year study period being 1 January 2008 to 31 December 2009, was outlined

6.1.1. DESCRIPTION OF THE AE REPORTED WITH RESPECT TO CATEGORIES OF AE IN THE MATERNITY UNITS DURING THE STUDY PERIOD

The majority of AE reported are SAC 1 (serious) probably due to under reporting of less serious AE. However maternity is a high risk area and it is possible that this might be a true reflection. Although the policy states that all AE should be reported to all committees, the culture in the Free State is that only SAC 1 and 2 AE are reported to the

DAEC and PAEC monthly, this practise may have contributed to the under reporting of less serious AE by the TMD Hospital Complex.

6.1.2 DESCRIPTION OF THE FACTORS RELATED TO THE OCCURRENCE OF AE IN THE MATERNITY UNITS DURING THE STUDY PERIOD

According to the individual patients' profiles, the majority of women with AE were between the ages of 19-34, unmarried, resided in towns and unemployed. Furthermore, the majority of these women were among groups of primigravida and multigravida, attended 4 and more antenatal visits, admitted in labour with pregnancy related illnesses, had normal vaginal deliveries with the delivery outcomes of fresh stillborn followed by birth asphyxia. The maternal health systems related factors accounted for more reported AE than perinatal health systems related factors. The majority of AE related to health system factors were about clinical governance issues for both maternal and perinatal AE followed by patient transport, referral issues and human resource issues.

6.1.3 DESCRIPTION OF THE REPORTING SYSTEM USED IN MATERNITY UNITS WITH RESPECT TO ADHERENCE TO AE POLICY TO REPORT AE DURING THE STUDY PERIOD

The majority of the AE reported were maternal AE and very few needed investigation. The time taken to report AE (complete the form) was within the stipulated time period while the time taken to investigate the AE was excessive. The time taken to present reported AE to the CAEC and DAEC was well beyond the stipulated number of days.

Both CAEC and DAEC held more than 80% of the required number of meetings. The attendance at the DAEC was satisfactory, while the attendance at the CAEC was very poor. The investigations conducted did not have any significant influence on AE which required further exploration.

6.2 LIMITATIONS OF THE STUDY

The following were the limitations of the study:

- Quality of the source data was poor at times because of illegibility of handwriting and entries being made by different personnel with different experience and skills thus affecting data collection.
- The sample size (n=88) was small and therefore no associations were assessed. This was a purely descriptive study.
- The finding of this study is limited to the TMD Hospital Complex and can not be generalized to other district hospital complexes as the situation at the other hospital may not be the same as at TMD Hospital Complex.
- It was a retrospective study design with inference limitations.

6.3 RECOMMENDATIONS

Based on the study findings, the researcher produced the following recommendations:-

According to the results of the study, 92% of the reported AE were SAC 1 which showed under reporting of other less serious categories of AE. It is recommended that training be conducted to empower personnel about the importance of reporting less serious AE. Furthermore the Free State Province and Fezile Dabi District should put in place strategies to ensure monitoring of the implementation of the AE policy in terms of reporting of all categories of AE.

To address the challenge of under reporting of AE, it is further recommended that all AE related data which is identified during records reviews, be linked with the AE reporting system to avoid loss of data, on occurrence of AE in TMD Hospital Complex. The Free State Province should establish a non-punitive culture which will address the reluctance to report AE, meaning that hospitals or health facilities staff will not be afraid to report incidents. The department of health and the District should channel their resources to

investigate and analyse reports and disseminate information which will promote learning and contribute to system redesigning so that health care organizations can perceive reporting of AE as opportunity for learning and improving health systems not as time wasting. The department of health and the District should review the current process of reporting AE and make it user friendly in terms of types of reports to be written, types of events to be reported, investigated and analysed, who should report and how they should report as well as the structures of the forms used.

The study results indicated a high number of reported maternal AE (75.7%) which occurred during the intrapartum stage followed by ante partum stage at 17.5%.

Based on the above-mentioned findings it is recommended that the hospital and the district management monitor and strengthen the provision of antenatal services at all the surrounding clinics. It is also recommended that the hospital management identify and address all factors related to the occurrence of AE during intrapartum stage as well as causes of early perinatal AE.

The majority of AE related to health system factors were due to clinical governance issues for both maternal and perinatal AE followed by patient transport, referral system issues and human resource issues.

To address the clinical governance issues, the clinical audits should be made compulsory or mandatory to all health professionals providing clinical care in maternity units, where structured peer reviews by a clinician examines their practices against acceptable standards and they are able to learn from the range of audit topics such as, quality of patient care, development of staff and improved management. It is also recommended that mortality and morbidity meetings, as well as perinatal meetings relating to maternity cases, be held weekly and records of the meetings be kept.

Based on these findings it is recommended that agency nurses not be allocated in the maternity units. It is also recommended that all foreign medical officers be placed at the

maternity units of regional hospitals for at least six months for orientation and proper supervision before they can be deployed to the district hospitals.

It is further recommended that the Emergency Medical Services be decentralized in the district and its personnel, who are stationed at the hospitals and clinics, report to the manager in charge of the institutions concerned.

The outcome of the study showed that there is a need for the District and the Complex to prioritize the filling of vacant posts at the hospitals.

According to the findings of the descriptions of the AE reported by the AE committees, there is a need to review the current policy on referral of patient to high risk clinics. There is also an urgent need to train professional nurses and doctors on proper record keeping, the monitoring of maternity patients, interpretation of sonograph, signs of perinatal distress, management of all high risk patients and plotting of partogram.

It is also recommended that the district strengthen the functionality and realization of clinical meetings to address all issues affecting the district, like the referral system and orientation of foreign medical officers.

It is further recommended that the district strengthen a district specific forum which will discuss all maternal and neonatal related issues affecting the district (maternal and child health care program meetings).

According to the study findings, it was clear that patient related factors like marital status, employment, antenatal visits, diagnosis on admission and mode of delivery had an impact on the occurrence of maternity AE during the study period. It is therefore recommended that when maternal AE are reported or discussed, the above-mentioned individual patient related factors be taken into consideration.

It is recommended that the current Free State Department of Health policy on the management and reporting of AE be reviewed as it is not user friendly or realistic and is outdated and therefore needs to be reviewed. The researcher would like to encourage

the Fezile Dabi District to compile district specific AE policy in line with the Free State Department of Health to give direction to institutions.

It is also recommended that, in reviewing the current policy, the department should look at the issues of adopting the Australian model in term of the reporting system, which is user-friendly and most importantly analysing and providing feedback about all reported AE to institutions weekly.

6.4 USE OF FINDINGS OF THIS STUDY

The outcome of the study will assist the District Manager to address all gaps or challenges in the implementation of the maternal health program within the Complex. The results will also assist the Complex and the District to review or develop some systems which will enhance patient safety and promote continuous implementation of the quality assurance program.

6.5 FURTHER RESEARCH

It is recommended that further study be conducted to investigate the quality of intrapartum health care as well as accessibility to this care, as provided at the maternity units of TMD Hospital Complex. It is further recommended that another study be conducted on the attitudes influencing health seeking behaviour of pregnant women and the use of antenatal care services within the Ngwathe and Mafube municipal areas.

An evaluation should also be conducted on the impact of the AE committees (CAEC and DAEC), that act upon information as provided in the meetings, on the prevention of the recurrence of similar AE.

6.6 CONCLUSIONS

The outcome of the study will assist the District Manager and the Complex Management to address gaps or challenges in patient safety and the reporting of AE as related to maternity units within the Complex. The results will also assist the Complex and the

District to review or develop some systems which will enhance and promote continuous implementation of the quality assurance program.

Most importantly the results of the study will also be used to improve the performance indicators of the District in terms of maternal and child health care program as well as the Millennium Development Goals 4 and 5.

Although there is a functional referral system in the district, its efficiency is reduced by the failure of health personnel to comply with the referral criteria and the inability of EMS to provide adequate patient transport services when the need arises.

Most importantly the study findings showed that the health system related factors played a significant role on the occurrence of AE in the Complex and that the majority of the reported AE were very serious (SAC 1). It is therefore critical that the District Manager and the Complex Management urgently intervene and address all health system related factors which are outlined by this study and known to be preventable.

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APPENDICES

APPENDIX A: PERMISSION LETTER FROM FREE STATE TO CONDUCT STUDY

APPENDIX B: POSTGRADUATE COMMITTEE CLEARANCE CERTIFICATE

APPENDIX C: ETHICS CLEARANCE CERTIFICATE FROM ETHICS COMMITTEE

APPENDIX D: DATA COLLECTION TOOLS