

# A critical evaluation of health care reform in maternity services in the Western Cape Province of South Africa, 2007-2012.

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## Declaration

By submitting this thesis electronically, I declare that the entirety of the work contained therein is my own original work, that I am the authorship owner thereof (unless to the extent explicitly otherwise stated) and that I have not previously in its entirety or in part submitted it for obtaining any qualification.

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## Abstract

This thesis is a critical evaluation of the impact of service delivery shifts within maternity care on the clinical governance of a well-defined geographical service delivery area (Metro East section of the Cape Town health district) during 2007 to 2012. This period saw the implementation of a comprehensive health plan that envisaged the provision of safe maternity care at a non-specialist hospital within the metropolitan area. The data presented in the first part of the thesis shows that well defined levels of maternity care can provide safe management of pregnancies in a large, well-functioning district hospital. A central event in this time period was the opening of a newly-built district hospital in Khayelitsha and the major change in the drainage boundaries of Tygerberg hospital to include referrals from this new hospital. The thesis presents all the clinical governance aspects that went into the planning and eventual execution of a maternity service and the impact it had on the base hospital.

The second part investigates the role of the regional maternity service in Tygerberg hospital as it relates to the clinical governance of the regional and district service in the Metro East sub-district. To this extent a few chapters place quality of care aspects such as structural audits, caesarean section rates, maternal and perinatal mortality data, medico-legal liability, patient and provider satisfaction and protocol compliance within this context. An in-depth root-cause analysis was made of all the obstetrics and gynaecology medico-legal cases within the Western Cape which showed that poor clinical note keeping was a major factor hampering defence of cases.

The information obtained from this thesis builds on the Western Cape healthcare plan for 2030 aimed at improving quality of care and wellness with an outcomes-based approach and the prioritisation of evidence-based interventions. It concludes with the description of a maternity dashboard for the Tygerberg labour ward and the Metro East maternity service

based on the information obtained from this thesis. The tool can inform the hospital management on progress, successes and challenges within the system on a regular basis.

## Opsomming

Hierdie tesis is 'n kritiese evaluasie van die impak van 'n verandering in die dienslewingsplatform binne die konteks van verloskundige sorg in 'n goed-omskrewe geografiese gebied (die Metro Oos deel van Kaapstad se gesondheidsdistrik) tussen 2007 en 2012. Tydens hierdie tydperk het die provinsiale gesondheidsdepartement 'n omvattende gesondheidsplan geïmplementeer. Hierdie plan het voorsiening gemaak vir die lewering van veilige sorg vir swanger vrouens in 'n groot distrikshospitaal binne 'n stedelike gebied. Die data wat in die eerste deel van die tesis weergegee word bewys dat hierdie sorg veilig kan geskied met die gebruik van goed gedefinieerde vlakke van sorg. 'n Omvangryke verandering het in dieselfde tyd plaasgevind deurdat 'n nuwe hospitaal in Khayelitsha gebou is en die dreinasie grense van Tygerberg hospitaal is verander om hierby aan te pas. Die beplanning rondom kliniese bestuur van hierdie nuwe diens en die impak wat dit op Tygerberg se verloskunde diens gehad het word ook hierin bespreek.

Die tweede deel van die werkstuk het die verwantskap tussen die spesialisdiens by Tygerberg hospitaal en die streeks- en distrikdiens in Metro Oos ondersoek. 'n Paar hoofstukke oor strukturele audits, keisersnitkoerse, moederlike en perinatale mortaliteitsdata, medies-geregtelike risikos, die tevredenheid van pasiënte en gesondheidswerkers asook die nakoming van protokolle bespreek hierdie verwantskap en plaas dit binne die konteks van sorg en kliniese bestuur in Metro Oos. 'n Omvattende ontleding is ook gedoen van al die medies-geregtelike gevalle wat deur die provinsiale gesondheidsdepartement hanteer is. Dit het onder andere gewys dat kliniese notas in baie gevalle benede standaard was.

Die tesis eindig deur voort te bou op die Wes Kaap regering se 2030 gesondheidsplan wat die kwaliteit van pasiëntsorg hoog op die hart dra. Dit beskryf die ontwikkeling van 'n meetinstrument spesifiek vir die Tygerberg kraamsaal wat op 'n gereelde basis inligting

rondom pasiëntsorg weergee. Dis veral belangrik vir die bestuurders in die diens en die suksesse en uitdagings binne die diens kan hiermee aangespreek word.

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## List of Abbreviations

ACOG American College of Obstetricians and Gynecologists

AFI Amniotic fluid index

AIDS Acquired Immunodeficiency Syndrome

APH Antepartum Haemorrhage

BANC Basic antenatal care

BoD Burden of disease

BMI Body Mass Index

CPAP Continuous positive airway pressure

CS Caesarean section

CSIR Council for Scientific and Industrial Research

CSP Comprehensive services plan

CT SCAN Computerised Tomography

CTG Cardiotocograph

DBSA Development Bank of Southern Africa

DCDA Dichorionic, diamniotic

DCST District Clinical Specialist Team

DDI Decision to delivery interval

DHS District health system

DM Diabetes mellitus

DRANZCOG Diploma in Obstetrics from the RANZCOG

DRCOG Diploma in Obstetrics from the RCOG

EFW Estimated fetal weight

FP Family physician

FRCOG Fellow of the Royal College of Obstetricians and Gynaecologists

GDM Gestational diabetes mellitus

GHT Gestational hypertension

GSA Geographical service delivery area

HST Health Systems Trust

ICD International classification of disease

iMMR Institutional Maternal mortality ratio

IOL Induction of labour

IUD Intra-uterine death

IUGR Intra-uterine growth restriction

IUSS Infrastructure Unit Support System

KMC Kangaroo mother care

MDG Millennium development goals

MMR Maternal Mortality Ratio

MOU Midwife Obstetric Unit

MR Mortality Rates

MRC Medical Research Council

NCCEMD National Confidential Committee for Enquiry into Maternal Deaths

NCS National Core Standards

NHI National Health Insurance

NHS National Health Service

NICE National Institute for Health Care and Evidence

NTSV Nulliparous term singleton vertex

O&G Obstetrics and Gynaecology

PGDipOMG Postgraduate Diploma in Obstetrics and Medical Gynaecology

PNM Perinatal mortality

PPH Post-partum haemorrhage

PIIP Perinatal Problem Identification Program

PPROM Preterm premature rupture of membranes

PTL Preterm labour

RANZCOG Royal Australian and New Zealand College of Obstetricians and Gynaecologists

RCOG Royal College of Obstetricians and Gynaecologists

ROM Rupture of membranes

SF Symphysis fundal

TB Tuberculosis

UK United Kingdom

US United States

VBAC Vaginal birth after a previous caesarean section

WC Western Cape

WHO World Health Organisation

## Glossary

Book- attend an antenatal clinic for the first time

Cardiotocography – the electronic monitoring and recording of the fetal heart rate and uterine activity.

Early neonatal death- any live born baby that dies within the first 7 days of life.

Khayelitsha- means "new home" in Xhosa. It is the largest and fastest growing township in South Africa.

Late neonatal death- any live born baby that dies after the first 7 days of life but within 28 days.

Live birth- WHO definition used (the complete expulsion or extraction from its mother of a product of conception, irrespective of the duration of the pregnancy, which, after such separation, breathes or shows any other evidence of life).

Neonatal death- any live born baby that dies within the first 28 days of life.

Neonatal death rate- the number of neonates dying before reaching 28 days of age, per 1,000 live births in a given year.

Neonatal encephalopathy- a disturbance of neurological function in the earliest days of life in the term infant manifested by difficulty initiating and maintaining respiration, depression of tone and reflexes, abnormal level of consciousness and often by seizures.

Perinatal mortality rate- number of stillbirths and deaths in the first week of life per 1000 live births, expressed as either all babies  $\geq 500\text{g}$  or  $\geq 1000\text{g}$ .

Perinatally-related wastage (or loss)- all deaths (stillbirths and neonatal deaths)  $\geq 500\text{g}$  within the first year after birth.

Stillbirth- a baby born with no signs of life at or after 22 weeks gestation (or 500g if no gestation available).

# Chapter 1

## Problem statement and overview of chapters.

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## Chapter 1. Problem statement and overview of chapters.

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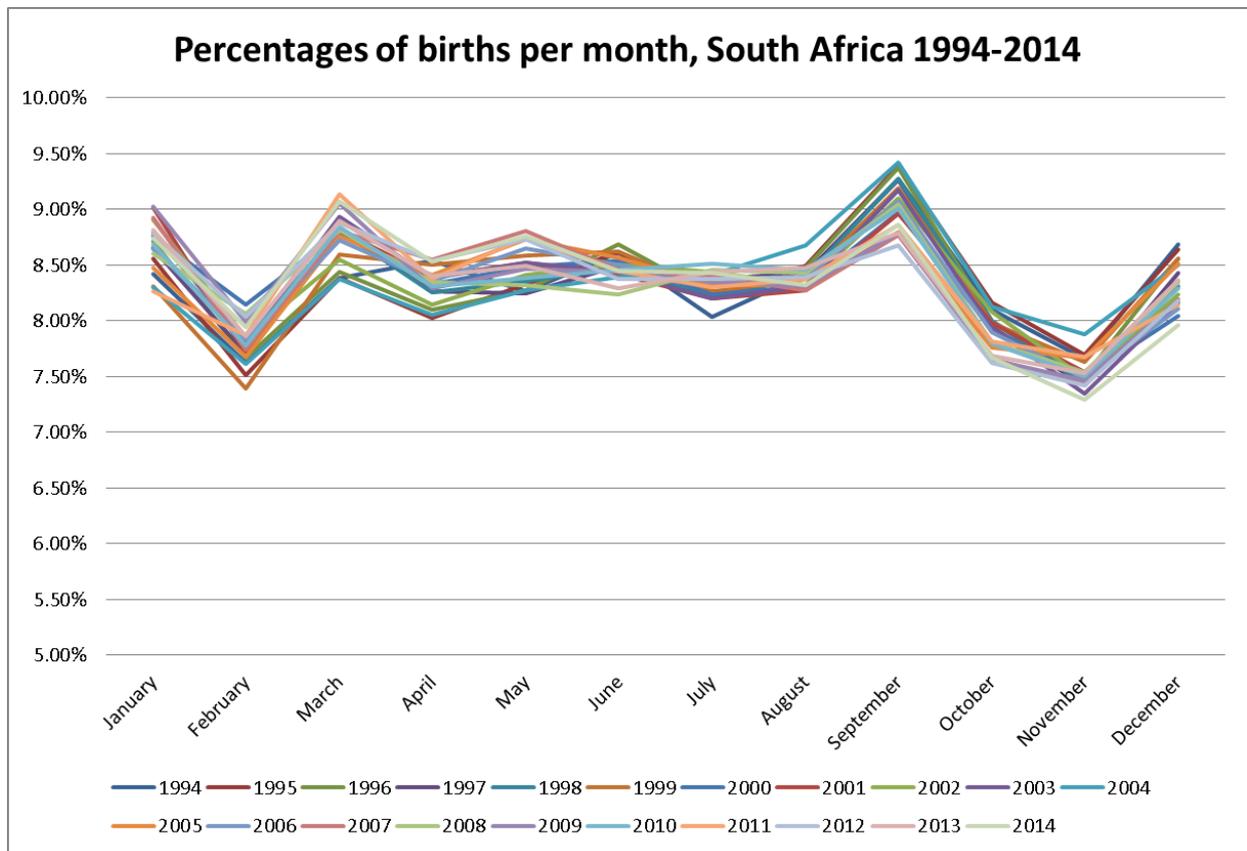
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## 1.1 Introduction

South Africa has an estimated population of 53 701 000, of which 6 131 000 people (11.4% of the total population) resides in the Western Cape province (1). The only provinces with more people are the Eastern Cape (6 656 000), Gauteng (12 996 000) and KwaZulu Natal (10 571 000). There were only two provinces (Western Cape and Gauteng) that had an increase in population over the past 10 years. This growth is mostly due to migration and according to the 2011 census, 71% of people living in the Western Cape was born there (2). The Western Cape encompasses a surface area of 10.6% of the total South African landmass.

There are just more than a million births per year in South Africa, with peaks of deliveries occurring in December, March and September of each year. This is most likely due to more pregnancies conceived during the school holidays in December (births in September), March (births in December) and June (births in March). The birth data from 1994-2014 was obtained from Statistics South Africa (3) and plotted over time as shown in Figure 1.1.1. This shows the higher percentages of births in the months mentioned.

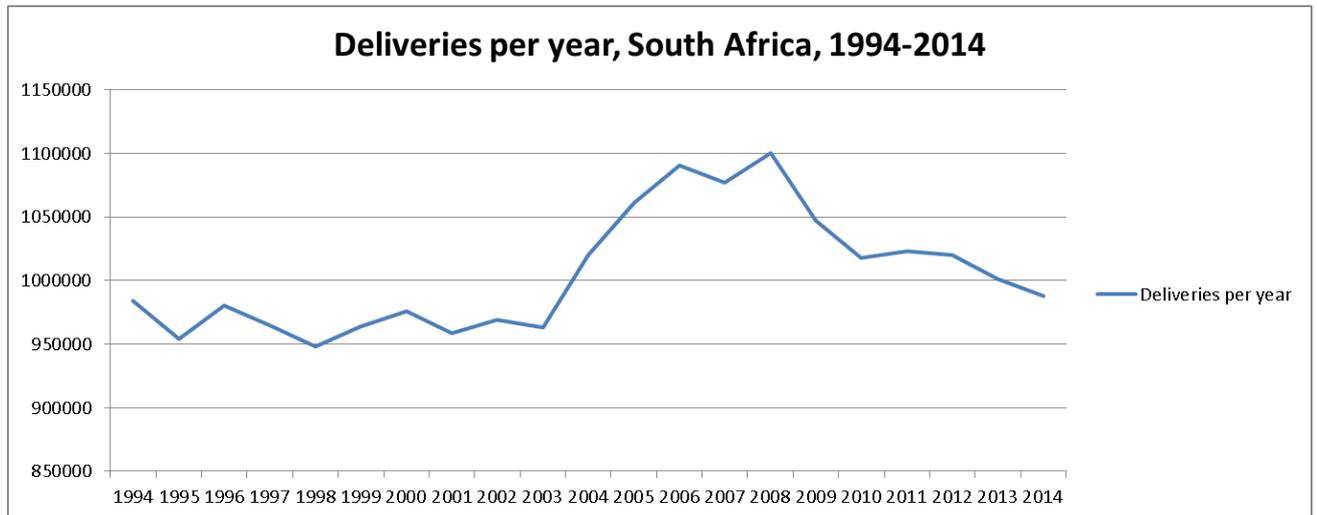
Figure 1.1.1. Percentages of births in South Africa, 1994-2014.



*Adapted from Recorded Live Births 2014 (Statistics South Africa)(3)*

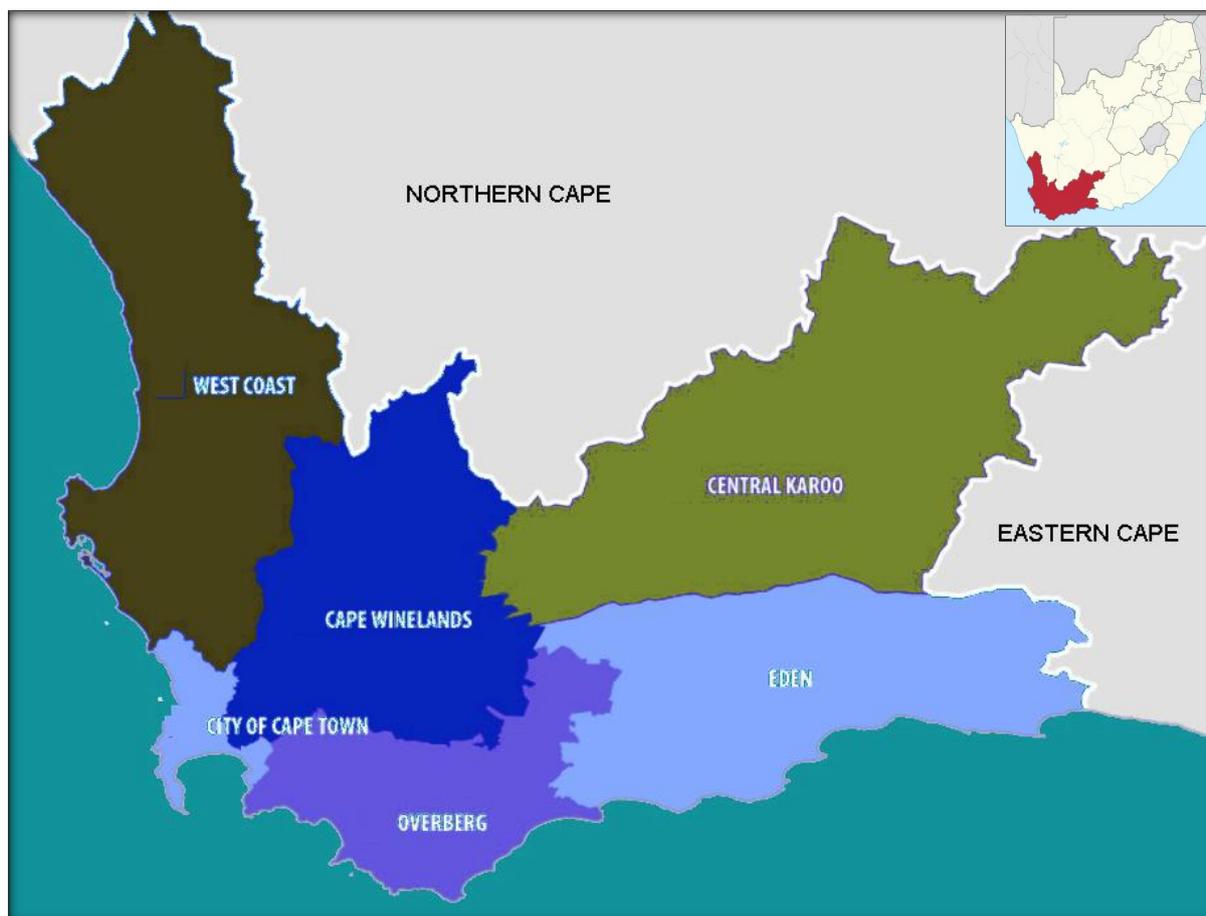
The total number of deliveries per year, in South Africa in the corresponding time is shown in Figure 1.1.2. For the past five years the number of deliveries remained at an average of one million per year.

Figure 1.1.2. Deliveries in South Africa since 1994.



The Western Cape is divided into six districts with health care services aligned to these (Cape Town Metro, West Coast, Cape Winelands, Overberg, Eden and Central Karoo). There are three rural regional hospitals that offer general specialist services in the major clinical disciplines, including obstetrics. There is a small district hospital in most major towns and about one third of all deliveries occur in the rural districts. The 6 health districts are shown in Figure 1.1.3.

Figure 1.1.3. Health districts within the Western Cape.

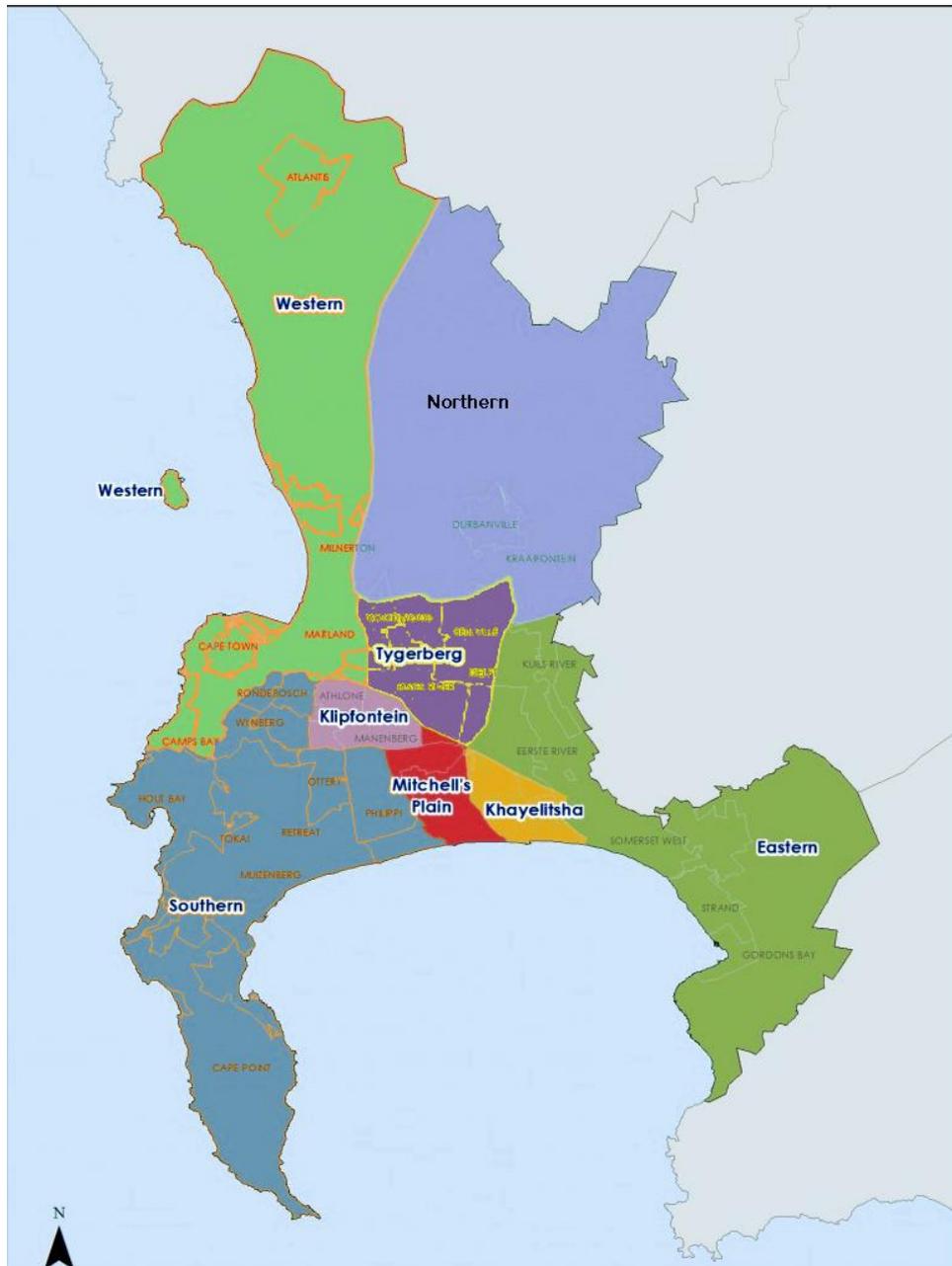


For clinical governance purposes the province is divided into five geographical service delivery areas (or GSAs) whose boundaries corresponds somehow to the districts. The responsibility for clinical governance of discipline-specific health services are entrusted to a dedicated general specialist in each of the major clinical disciplines (obstetrics, paediatrics, internal medicine, general surgery, anaesthetics, orthopaedics and mental health). These specialists are the head of the clinical discipline at the regional hospital in each of the GSAs (namely George, Paarl, Worcester, Metro East and Metro West), but oversee the clinical governance within the GSA with outreach to the district hospitals and community clinics within its catchment area.

The Cape Town metropolitan district is divided in two GSAs (Metro West and Metro East) due to its size. The rural regional hospitals are Paarl, George and Worcester hospitals and in Cape Town the regional hospitals are Somerset and Mowbray (within Metro West) and Tygerberg hospital (within Metro East). Paarl hospital serves the part of the Winelands district to the west of the Limiet mountain range and the West Coast district. Worcester hospital manages the part of the Winelands district on the eastern side of the Limiet mountain range as well as the Overberg district. George hospital serves Central Karoo and Eden districts.

The metro also has four large district hospitals (Karl Bremer, Helderberg, Khayelitsha and Mitchell's Plain) that provide maternity care for complicated pregnancies that do not require specialist care. They receive referrals from the midwife obstetric units (MOUs) in their catchment area and these are mainly referrals for poor progress in labour or suspected fetal distress in low risk, term women. There are three regional hospitals with a general specialist service (Mowbray, Somerset and Tygerberg hospitals) and severe complications are referred to the tertiary/highly specialised units within the two central hospitals, Groote Schuur and Tygerberg. These hospitals are each linked to an academic institution (the Universities of Cape Town and Stellenbosch medical schools respectively). Tygerberg hospital therefore serves as a tertiary and regional hospital within one infrastructure. The Cape Town metropolitan health sub districts are shown in Figure 1.1.4, with acknowledgment to the Western Cape Department of Health (4).

Figure 1.1.4. Cape Town metropolitan sub-districts.



The journey described in this thesis involves the maternity services in Metro East (consisting of the Northern, Tygerberg, Khayelitsha and Eastern sub districts) with Tygerberg hospital as its central and regional referral hospital. It started in 2007 with restructuring of the health services in Metro East, which is described in more detail in chapter 3. It involves Tygerberg, Karl Bremer and Khayelitsha hospitals as well as the MOUs surrounding them (Kraaifontein,

Michael Mapongwana, Site B, Bishop Lavis, Elsies Rivier and Delft). Their geographic locations are shown in Figure 1.1.5.

Figure 1.1.5. Health institutions in Metro East.



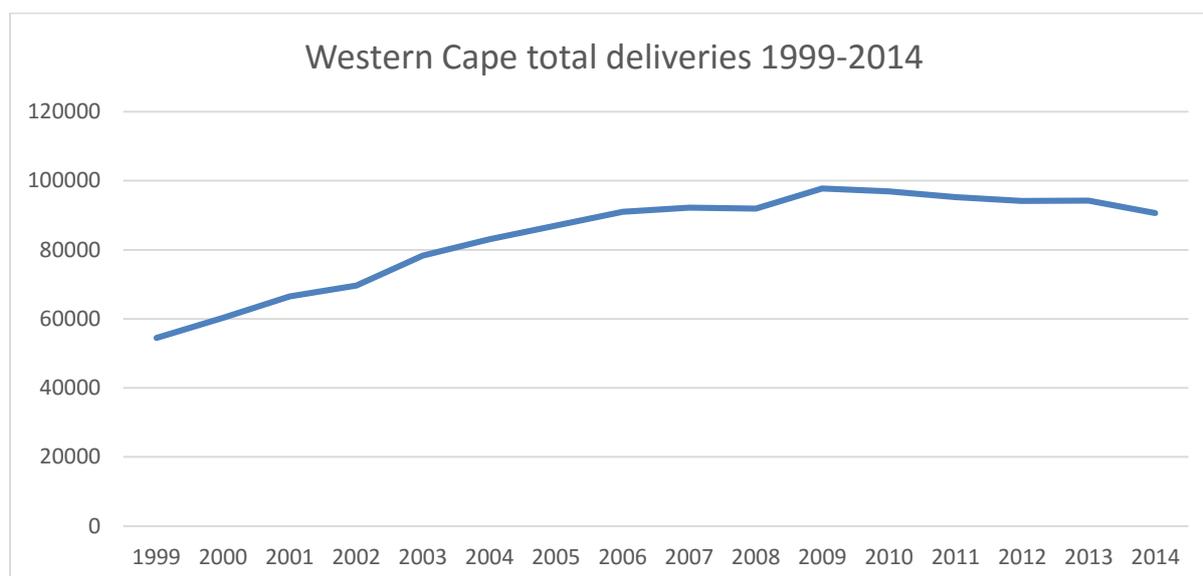
- 1= Karl Bremer hospital
- 2= Tygerberg hospital
- 3= Elsies Rivier MOU
- 4= Bishop Lavis MOU
- 5= Kraaifontein MOU
- 6= Delft MOU
- 8= Site B MOU
- 9= Khayelitsha hospital
- 10= Michael Mapongwana MOU

The Western Cape strategic plan for health (also called the Comprehensive Service Plan or CSP), published in its final form in 2007 (5) provided a framework for re-shaping the health service in line with its Healthcare 2010 vision of *Equal Access to Quality Health Care*. The emphasis was on strengthening the district health system to allow easy access for all to the full package of care according to their needs that can be rendered at a district level. The plan also had a strong financial aspect as it aimed to bring expenditure to within affordable and sustainable limits. To this end, a big cost driver was identified as patients that are treated at a level of care that is more specialised than what they really need. To render a service that is

affordable, a quantum of admissions had to be diverted to a less specialised and more appropriate level of care.

The maternity service in the metropolitan Cape Town was always subjected to service pressures, but underwent a major increase in delivery numbers after 1999. This growth was more marked in the Tygerberg and Northern substructure of the metropolitan Cape Town municipality. The increase in deliveries is shown in Figure 1.1.6.

Figure 1.1.6. Deliveries in the Western Cape since 1999.



The CSP direction was towards a strong, district-based service with management at the appropriate level of care and had the potential to address the challenge of overcrowded obstetric service, as it would remove relatively uncomplicated patients from the congested central hospitals. To cater for the less-specialised cases, this model included the planning, building and commissioning of large district hospitals within the metro, each with 60 dedicated maternity beds.

Due to the inherent urgency, a task team was established to oversee application of this model to obstetrics, starting with the Tygerberg hospital drainage, and the author was tasked with the clinical leadership for this team. The author (in his capacity as clinician and later as the provincial coordinating clinician for obstetrics and gynaecology) was already involved in the Metro East maternity service since the re-opening of Karl Bremer hospital for public sector obstetrics (July 1996) and the establishment of the new Michael Mapongwana MOU in Khayelitsha (built in 1987/88 but opened for obstetrics in July 1996), where he was tasked with the clinical management of that new maternity service.

This thesis is written from the perspective of an obstetric clinician working within the maternity service, and not from that of a public health specialist or health systems expert. The emphasis is on the impact of health system interventions and service shifts on clinical services and the clinical governance of maternity services, and how this impacts on the broader aspects of clinical governance within Metro East and the rest of the province.

## 1.2 Problem Statement and presentation of information

This thesis has two main objectives. The **first** is a critical evaluation of several aspects of the CSP model for service delivery within an urban maternity service. It will attempt to answer the following question: In a large, metropolitan population of obstetric patients, does a three-tiered approach to management of pregnant women at an appropriate level of care, that includes a large, well-functioning district hospital, provide safe management of pregnancies? The rationale for this specific model is the large number of women falling between the low risk (midwife obstetric unit model) and high risk (academic hospital) cadre of patients that can safely be managed in a less technologically advanced and less expensive environment, provided there is 24-hour access to skilled general doctors and operating theatres. This should theoretically decrease the cost of obstetric care and the burden on the central hospitals without compromising safety.

The **second** part investigates the role of the regional maternity service in Tygerberg hospital as it relates to the clinical governance of the regional and district service in the Metro East sub-district. To this extent a few chapters place quality of care aspects such as structural audits, caesarean section rate, maternal and perinatal mortality data, medico-legal liability, patients and provider satisfaction and protocol compliance within this context.

The emphasis of the new Western Cape healthcare plan is *patient centred care* and the plan is appropriately called *The Road to Wellness* (6). A major part of its philosophy is a move towards an outcomes-based approach and to prioritise evidence-based interventions that have the largest impact on specific outcomes. The thesis concludes with a proposed maternity dashboard (7) for the Tygerberg hospital labour ward and the Metro East service based on the information obtained from this thesis. The aim is to produce a tool that can inform the hospital management on progress, successes and challenges within the system.

## 1.3 Brief Chapter overview

### **Part 1 (Chapters 1-6): Regionalisation in Metro East**

#### **Chapter 1: Problem statement and overview of chapters.**

#### **Chapter 2: Literature review.**

The literature review presented in chapter 2 focus on different funding models for health systems and international models for the delivery of maternity care, to set the scene for the modelling described in chapter 3. The literature overview of chapter-specific issues (e.g. regionalised care, caesarean section rates, perinatal mortality, maternal mortality and medico-legal aspects of maternity care) is presented within those relevant chapters.

#### **Chapter 3: Regionalised maternal care in the Western Cape, South Africa-implementation; and evaluation of the impact of, levels of maternity care within a specific geographical service delivery area: 2007-2012.**

Chapter 3 presents the research, modelling and description of the eventual establishment of two district maternity systems and the subsequent service shifts and will start with an overview of the services prior to the shifts. It includes a description and evaluation of the detailed planning that involved mapping of the existing services, modelling to predict bed numbers, bed occupancy rates, length of stay and patient flow and referral routes for the newly planned district hospital-based obstetrics service. Chapter 3 also includes a description of the point prevalence surveys of maternity services performed on delivery data during July 2007 and the

subsequent annual July folder reviews up to July 2012, to map the movement of patients across the service during those intervening years.

#### **Chapter 4: Clinical governance in a changing obstetric service: evaluation of a district hospital maternity service- Karl Bremer hospital.**

Chapter 4 follows on the implementation of the model in chapter 3, with an evaluation (point prevalence survey) of the service at Karl Bremer hospital, evaluating access to care, level of care, access to theatre, complexity of the case mix and adherence to ultrasound guidelines.

#### **Chapter 5: Clinical governance in a changing obstetric service: Caesarean section rates at Tygerberg hospital.**

This chapter expands the discussion on caesarean section rates from chapter 3 (during 2007-2012) by placing it in context with all caesarean sections done at Tygerberg hospital since the opening of the hospital as well as within Metro East and the wider provincial service.

#### **Chapter 6: Clinical governance in a changing obstetric service- trends in the measurement of perinatally-related losses at Tygerberg hospital 2003-2014.**

Changes in maternity services also impacts on perinatal outcomes. Although this thesis did not include a description of the parallel shifts taking place in neonatal services in the metro, this chapter discusses the trends in provincial perinatal indicators as it relates to Tygerberg hospital.

#### **Part 2 (Chapters 7-12): Clinical governance in a regionalised obstetric service**

## **Chapter 7: Audits of Tygerberg hospital maternity services, 2009 and 2012 in terms of aspects relating to quality of care.**

Chapter 7 will present two similar structural audits of the state of the maternity service during 2009 and 2012; the 2009 audit was in preparation for the Khayelitsha drainage shift and the 2012 audit was to document the state of the service after the shift. The audit also examined quality of care and the improvement measures taken after the findings.

## **Chapter 8: Clinical governance in a changing obstetric service: in-hospital mortality of women in their reproductive age- determining the burden of disease in women at Tygerberg hospital 2011-2014.**

Obstetricians tend to focus on reducing maternal deaths, but there are a large number of women in their reproductive years dying from conditions unrelated to pregnancy. This chapter is a retrospective case note audit of all women discharged from the Tygerberg hospital information system with the international classification of disease (ICD-10) diagnostic code of “death”. This study will place the maternal death data within the bigger frame of deaths (from any cause) in all women of reproductive and post-menopausal age and also examine the deaths occurring more than 6 weeks after a pregnancy (outside of the accepted definition of a *maternal death*). It includes the approach identified to ensure all maternal deaths within the system are reported.

## **Chapter 9: Clinical governance in the Western Cape: maternal mortality in Metro East and trends in maternal mortality in the Western Cape over the past two decades.**

The author was the chapter head for the Western Cape chapter in the last two national Saving Mother’s reports (fifth report, 2008-2010 (8) and sixth report, 2011-2013 (9) of the NCCEMD). This chapter uses the public domain data from these reports as well as the Western Cape provincial death database to give a short

overview of the last 15 years of confidential enquiries into maternal deaths in the Western Cape. Permission to use this data was obtained from chairperson of the National Committee for Confidential Enquiries into maternal deaths. This chapter do not repeat the data from the published chapters, but rather re-align it to get a GSA specific demographic view and combine triennial data for a more comprehensive overview of maternal mortality ratios.

**Chapter 10: Clinical governance in a changing obstetric service: assessing patient safety by monitoring adherence to a new protocol for induction of labour.**

This chapter analyses the adherence to a new protocol on induction of labour introduced at Tygerberg hospital at the start of the re-arranged obstetric platform. It measured compliance to a safety check list with the aim of introducing and measuring this type of criterion-based audit into routine clinical practice.

**Chapter 11: Risk management in obstetrics: analysis of outcomes in obstetric litigation at Tygerberg hospital and the Western Cape.**

This chapter is a critical analysis of retrospective, anonymous data from the medico-legal office to investigate obstetric litigation and to search for ways to avoid risk. It was a review of legal documentation and case notes of all cases reported to the provincial legal department since 1997. The Department of Obstetrics and Gynaecology at Tygerberg hospital was involved in several medico-legal cases (either as defendants or expert witnesses) and this chapter place this responsibility within the larger provincial liability framework. The main aim of this chapter was to identify aspects of clinical governance that can be improved to reduce the risk of medico-legal action.

## **Chapter 12: Discussion**

The thesis ends with a proposed set of clinical indicators arranged in a maternity dashboard specific for Tygerberg hospital. This is based on a minimum number of indicators that are feasible to collect on a monthly basis, but that are powerful enough to ensure continuous quality improvement.

## 1.4 Timeline

To facilitate understanding of the role of the author within the health system changes described in these pages, a timeline of activities and responsibilities are depicted in Table 1.4.1.

Table 1.4.1. Timeline of activities and responsibilities.

Year	Activity	Responsibility
1996	July 1996, Karl Bremer hospital opens a public sector maternity service.	Training of midwives, co-ordinating the service, establishes a new antenatal high risk clinic.
1996	July 1996, Michael Mapongwana midwife obstetric unit opens in the Khayelitsha informal settlement.	Training of midwives at the MOU, co-ordinating the service, establishes drainage routes for medium risk cases to Karl Bremer hospital and high risk pregnancies to Tygerberg hospital.
2003-2006	Head of department of obstetrics at Paarl regional hospital.	Establishes outreach to district hospitals, decentralise the obstetric service by establishing basic antenatal care packages in municipal clinics, introduced levels of care and protocols for use at regional and district hospitals within the Paarl GSA.
2006-2009	Co-ordinating clinician for Obstetrics, Gynaecology and Neonatology.	Develops the clinical governance framework for perinatal and women's health service within the province. Oversee the development of provincial guidelines, protocols and policies to guide the service.
2007-2009	Service shifts in Metro East.	Clinical lead for the task team that managed these shifts.
2009 to present	Head of general specialist services within Metro East, based at Tygerberg hospital	Help to develop the clinical governance framework within Metro East. Clinical lead for the establishment of an obstetric service within the new Khayelitsha hospital. Prepare the Tygerberg maternity service for the addition of Site B geographic catchment area to Tygerberg hospital. Introduce various aspects of clinical governance on the Tygerberg hospital platform (structured mortality reviews, protocols and standard operating procedures, audit cycles) to develop a maternity dashboard.

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## Part I (chapters 2-6)

Health system changes and the impact on maternity services, metro east 2007-2012.

## Chapter 2

### Literature Review- health financing, models and levels of maternity care.

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## Chapter 2. Literature Review- health financing, models and levels of maternity care.

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## 2.1 Introduction and historical background.

This chapter investigates the different models for delivering maternity care in other countries across the world against the background of health financing for that specific system. The model investigated in this thesis was the incorporation of a district (generalist doctor-led) service into a metropolitan service that (up to then) has consisted of midwife obstetric units referring directly to specialist hospitals in case of emergency. The aim was to find similar models of non-specialist obstetric care (family physician maternity services without the backing of universal health coverage by way of a national health insurance system).

The first civilian hospital in Cape Town (Somerset hospital) was built in 1818; and rebuilt on its current site in 1859 (1). It served as the academic hospital for the University of Cape Town medical school and the first medical students were admitted in 1918. On the eastern side of Cape Town, Karl Bremer hospital opened in 1956 and served as the teaching hospital for the University of Stellenbosch medical faculty. When Tygerberg hospital (and with it a concurrent move of academic teaching) opened, Karl Bremer subsequently served as a mainly private hospital. It was re-opened as a regional public sector hospital in 1996 and reclassified a district hospital in 2009.

The future Tygerberg service moved from the Karl Bremer hospital to the newly built Tygerberg hospital Complex on 6 March 1972. Maternity services in the Western Cape were under pressure since the late 1960s. Pioneering work was done in the 1970s and early 1980s to develop a model of community maternity services within in the metro leading to the establishment of stand-alone midwife-led models of antenatal, intra-partum and postpartum services, governed by outreach specialists from the referring hospitals (2)(3). In the 1972 annual report of Tygerberg hospital it was observed that the “impossible issue of accommodating patients on trolleys in the corridors” was satisfactorily eliminated in the new

premises (4). That year there were 4109 deliveries recorded at Tygerberg hospital. In 1973, the need for an alternative district-based delivery outside of the hospitals led to the establishment of the community based, midwife-led obstetrical services in the peninsula and northern suburbs of Cape Town that helped address the issue of overcrowding in the teaching hospitals while achieving an acceptable perinatal mortality rate (5).

## 2.2 Health systems funding models.

Before comparing different models of maternity care in various countries, it is important to examine the funding of the health system in which they take place as the availability (or not) of resources may have a major impact on the care delivered. Universal health coverage aims to develop health financing systems so that all people can have access to health services without suffering financial hardship in the process. The barriers to universal coverage is the availability of resources, the inefficient and inequitable use of available resources and the over-reliance on direct payment in times of need (6). The WHO global overview on spending on health lists the United States (US) as the country with the highest total spending per person per year on health (\$8362 in 2012) (7). Luxembourg is the country with the highest government spending per person per year on health and Myanmar the lowest (\$2). The WHO estimates a \$44 minimum spending per person per year to provide basic life-saving services.

Universal health coverage can be financed through different channels and there is variation in the systems used throughout the world. Although direct (out-of-pocket) payment for health services is the most frequent way of payment for health care in developing countries, it is overshadowed (in terms of global health spending) by social and private insurance and taxation for health (8). In public insurance programs, the state accrues funding through different forms of taxation or social insurance institutions (9). Private health insurance is defined as the channelling of funds to a risk-pooling entity (insurance company) that then

enters into a private contract with the insured individual, without involvement from the state (10). Risk pooling enables the provision of health services according to need rather than the individual's ability to pay for it (11).

Many capitalist democracies have a 'socialised medicine' system, where the government both provides and pay for health care. This is also referred to as single-payer healthcare, where the government (rather than private insurers) funds all health care. They may either contract this health care to private providers (as is the case in Canada) or employ their own health care providers (as in the United Kingdom (UK)). Examples include the *National Health Service* (NHS) in the UK, *Medicare* in Australia and Canada and the *National Health Insurance* (NHI) in Taiwan.

The four major forms of international health care systems are summarised by Reid as follows (12):

The Bismarck Model (named after Otto von Bismarck, who invented the welfare state).

This is the social insurance model followed in Germany where citizens are free to buy insurance from non-profit sickness funds that are required to sign up all citizens without any conditions. The poor receive public assistance to afford the premiums. It uses private initiatives to provide the medical services. The government controls costs by playing a central role in determining payments for various health services. It is also followed in France, Belgium, the Netherlands, Switzerland and some parts of South America.

The Beveridge Model (named after William Beveridge, the designer of the NHS in Britain).

The model adopted by Britain is socialised medicine and almost all health care providers work as government employees. The government pays for all health services. The patients do not incur any costs apart from some co-pays for dental care

and eyeglasses. This system is under pressure due to rising costs. A small number of specialists see private patients outside of the NHS. Other countries using this system include Spain, most of Scandinavia, New Zealand and Cuba. Beveridge also laid the foundations of a welfare state, where the state undertakes to protect the health and well-being of its citizens.

The National Health Insurance Model (combining elements of the Bismarck and Beveridge system).

This system has a single-payer system like Britain, but the health care providers are mostly private. Payment comes from a government-run insurance program that every citizen pays into. The major drawback of this system comes from long waiting times for several procedures. The classic system is found in Canada but other countries like Taiwan and South Korea has also adopted this model.

The Out-of-Pocket Model

This is the kind of model followed in most poor countries (rural regions of Africa, India, China and South America) where there is no public or private system of health insurance. Countries with such a system have a much lower life expectancy and higher maternal and infant mortality rates.

The US model for health follows all of the above in bits and pieces as it has many separate systems for separate classes of people. The Patient Protection and Affordable Care Act of 2010 ('Obamacare') aims to reform the health care industry in the US.

It can be argued that South Africa is a welfare state as it plays a key role in the protection and promotion of the well-being of its citizens. The difference from welfare states in the rest of the world is that the emphasis is on social assistance as opposed to social insurance (13). The current health care system in South Africa is two-tiered and divided along socio-

economic lines, where a small percentage (16%) of the population has access to private health care, funded by 83 private medical schemes, whilst the bulk of its citizens receive state-funded care in public sector hospitals. Spending through the SA medical schemes is currently the highest in the world (14). Maternity and new-born care as well as all primary care services are provided free of charge to citizens with a minimum monthly income. Specialised services are charged according to income. There is no fee-for-service structure in the public sector and all doctors receive standard salaries governed by an occupation specific dispensation. All deliveries in the public sector is conducted by midwives with the exception of operative deliveries, where a midwife is still in attendance and care for the new-born directly after birth.

Universal health coverage in the form of a NHI is envisaged for SA and a White Paper outlining the key steps was published on 10 December 2015 (15). This will be a compulsory social insurance plan that centralises the health care funds with equal access to health care for all citizens. Implementation is planned in three phases over 14 years. It aims for a system similar to those in Brazil, Canada, Finland, Norway, Sweden, Thailand, Turkey and the United Kingdom. The system it describes closely resembles the NHI in Taiwan, instituted in 1995, with the exception that most providers in Taiwan are private.

### **2.3 Models of care.**

There are several models for delivering maternity care in South Africa (SA). At community level, this includes traditional birth attendants (with no training) conducting home deliveries and trained birth attendant care by midwives in either stand-alone units or linked to hospitals. At hospital level there are different models. The specialist-obstetrician model (including most of the private specialist obstetrician practices in South Africa) provides care to women with

private health insurance. At district hospital level a family physician/general practitioner provides care to women without private health insurance. At regional and tertiary hospitals there is the academic registrar training model (a specialist-obstetrician supported service providing care to women without private health insurance). The Canadian family practitioner model (also called a non-specialist doctor-led delivery model) is equivalent to the district doctor model in the Western Cape (and most of South Africa), where a midwife or generalist physician conducts a delivery within a district hospital with a doctor (general practitioner, medical officer or family physician specialist) continuously on-site and 24-hour theatre facilities are available.

The South African district model of health care provision is closely modelled on that of Brazil, who (with South Africa) is one of the five major emerging national economies in the world (also called BRICS as an acronym for Brazil, Russia, India, China and South Africa). The Brazilian Family Health Program also place the focus on primary and preventative care, with the first interaction with a health care worker shifted to local communities (16). The SA national minister of health visited Brazil in 2010 and on return established a task team to oversee the re-engineering of the primary health care system(17). This will be further discussed in chapter 4.

The World Health Organisation estimated the maternal mortality ratio (MMR) for the other BRICS countries by 2013 as: Brazil (69/100 000), China (36/100 000), Russian Federation (27/100 000) and India (270/100 000) (18). The MMR in South Africa was 154/100 000 live births in 2011-2013 (19). Only India has a higher MMR.

Maternity care in Russia was described in a recent review by Shuvalova and colleagues (20). Russian citizens have free access to medical care in the state facilities, financed

exclusively through compulsory health insurance. Almost 99% of women use antenatal services and up to 90% see a doctor in the first trimester already.

Bangladesh is the 8<sup>th</sup> most populous country in the world with a population of almost 160 million, according to the Bangladesh Bureau of Statistics. It has a both private (for profit) and public sector maternal health care services, those in the public sector governed by national policies. It has a MMR comparable to South Africa, estimated at 191/100 000 live births in 2015, but only about 52% of public sector women receive antenatal care and less than 20% of births is attended by trained health care providers (services are provided free of charge). Although general doctors provide the bulk of this service, there is not much information available on their function (21). In Western Africa, Senegal has a free delivery and caesarean section policy similar to SA, although it is mainly limited to regional hospitals. 51.9% of births are attended by skilled personnel (including doctors). An analysis of the financial expenditure shows significant problems with implementation and allocating resources according to need (22).

The Brazilian *Prenatal and Birth Humanization Programme* (PHPN is the Brazilian acronym) standardise antenatal visits to a minimum of six visits for a full term pregnancy, with the first visit aimed before 16 weeks of gestation and more than 95% of women attend antenatal clinics (23). Most deliveries are in hospitals and not in community clinics. This is very similar to the Basic Antenatal Care package (BANC) introduced in South Africa in 2005 and based on the WHO model of reduced visits for antenatal care (24)(25).

### **2.3.1 Levels of care in the South African health service.**

The different levels of care within the health service of South Africa and how they compare to international classifications and World Health organisation (WHO) definitions will be discussed.

The WHO describes a district hospital (or the first-level for referral within a health district) as having the following characteristics (26):

- Recognition by a health authority within the district as providing a 24 hour service.
- It provides a more specialised form of clinical service (higher level of competence) than the referring unit.
- It relates effectively to the entire health district in that it is concerned with the health and well-being of the entire population and shares in the gathering of health information and health statistics and in the planning, implementation and evaluation of health programmes.
- It supports the primary health care service in general administrative maintenance and procurement of equipment, and ensuring continuity of care within the platform.
- It can interact with community members and organisations through its primary clinic network.
- It has a referral function, both to more specialised levels of care and to primary clinics and home-based workers.
- It has a basic professional training, continuing education and up-skilling function, both within the community and for students from other hospitals.
- It links with other sectors of development such as education, provision of drinking water and sewerage and housing.

- It serves as a problem-solving resource within the community for specific health issues.

The Health Systems Trust of South Africa (a consortium of organisations working with the national Department of Health with the main aim of reducing infant and maternal mortality) formed an *Initiative for Sub-District Support* who added the following to the WHO definition (27):

- A district hospital has the following clinical departments: surgery, psychiatry medicine, obstetrics, paediatrics, emergency care and outpatient services.
- Provides a 24 hour service and has more than 30 beds.
- Staffed by generalist doctors who receive support from secondary and tertiary level hospitals.

The District Health System (DHS) was implemented in South Africa in 1995. The South African Department of Health released a *White Paper for the Transformation of the Health System in South Africa* in 1997, detailing plans to restructure a unified health system based on a primary care approach (28). The Norms and Standards were published in March 2002 by the National Department of Health (29). It added family medicine and primary health care, geriatrics, eye care and rehabilitation to the list of generalist services to be provided. In terms of women's health, the district hospital maternity standards include a 24-hour emergency theatre, capabilities to do a CS, vacuum and forceps delivery and ultrasound.

No published criteria are available in SA for bed and staffing norms in maternity units. The Infrastructure Unit Support System (IUSS), a structured collaboration between the National Department of Health, the Development Bank of Southern Africa (DBSA) and The Council for Scientific and Industrial Research (CSIR) published a first draft on bed norms for maternity care in March 2013) (30). According to the task team, the need for a caesarean section theatre is calculated at one dedicated obstetric theatre for every 8 birthing rooms. Maternity beds are calculated by using 20% of the total hospital beds. They did not include

staffing norms.

The *Regional Package of Care*, since 2002 only available in draft format, attempted to determine a package of care to be rendered at a regional hospital, but did not attempt to work out staffing norms or bed numbers (A Radloff, personal communication). The *Strategic Plan for Maternal, Newborn, Child and Women's Health 2012-2016* from the national Department of Health has as one of its aims the calculation of bed and staffing norms (31). There are also no norms in the National Core Standards for hospitals that initiates from the NHI documents (32).

Bed norms have been suggested for neonatology, coming from work done in the Limpopo Province in the 1990s and summarized in a document presented at the Priorities in Perinatal Care conference in 1997 (called a *Health Plan for Neonatal Care*). Although never officially adopted by the Department of Health, these norms have also been used in planning bed numbers in the Western Cape neonatology services. It was summarised in a working document by the IUSS (33) and calculated beds according to the number of deliveries in a district (0.5-1 tertiary neonatal beds; 2-3 regional beds and 3-4 district beds per 1000 deliveries).

### **2.3.2 The Western Cape package of care.**

In the Western Cape, for obstetrics, gynaecology and neonatology a Delphi-type consensus process was used to determine the packages of care at each health level within the province. The process was coordinated by the author in his capacity as provincial coordinating clinician for obstetrics, gynaecology and related neonatology. The two national draft documents, (the *District Package Of Care* (29) and the *Regional Package of Care* (A Radloff, personal communication)) as well as the established protocols from the existing

maternity services were used as a departure point for a draft document subjected to rigorous peer review and expert consultation. The discussions occurred within a coordinating clinician forum (consisting of the two academic heads of Obstetrics and Gynaecology at the Universities of Cape Town and Stellenbosch, other prominent academics and rural obstetricians and gynaecologists) and with interaction with clinicians in all the sub-specialist disciplines. The final consensus document was adopted as a provincial policy in 2007 (34).

The three levels of care were defined as those appropriate for district (level 1), specialist (level 2) and subspecialist (level 3) care. The district health service was further subdivided into those services that can be rendered by a clinical nurse practitioner only, those rendered by a midwife in a dedicated midwife obstetric unit and those that need onward referral to a district doctor service (medical officer or family physician specialist). The utilisation of this document for planning health services within metropolitan Cape Town is further discussed in Chapter 3.

Subsequently, the provincial Department of Health organised workshops with the coordinating clinicians and representatives from clinicians to establish a package for levels of care across all general specialist disciplines as well as to determine the skills and equipment needed to render this package. This resulted in a document that was published and distributed within the health service. The existing obstetrics and gynaecology package, skills and equipment was refined within this document.

### **2.3.3 Midwife-led care.**

Midwife-led care is defined by the Royal College of Obstetricians and Gynaecologists (RCOG) as a service where “the midwife is the lead professional in the planning, organisation and delivery of care given to a woman from initial booking to the postnatal

period” (35). The *International Confederation of Midwives’ Council* defined the midwife’s care as preventative measures, the promotion of normal birth, the detection of complications and carrying out emergency measures (36). It is assumed that care within the community (and outside of a hospital) will be more women-centred and holistic with better continuity of care than a doctor-driven service in a hospital (for patients at low risk). A midwife-led model of care is the dominant way in New Zealand, the Netherlands, Australia and Canada and extensively investigated and published (see 2.4).

Very few studies have investigated the economy of substituting doctor-led care for midwifery-led care, but a meta-analysis of the available studies shows that nurse health outcomes are comparable to doctors in terms of safety and quality, while methodological weakness prevents any firm conclusions to be drawn on economic aspects (37). A 2013 Cochrane review on midwifery-led care (also called the *midwife-led continuity of care* model) concludes that women receiving this model of care were less likely to undergo regional anaesthesia, instrumental delivery or episiotomy and more likely to achieve vaginal birth (but with a longer mean length of labour) (38). There was a trend towards a cost-saving effect. Eight of the trials randomised 11 195 low risk women between midwife-led and other models of care. The other five trials included women deemed to be low and high risk which may confound the findings.

The main benefit for the midwife-led model is indeed the continuity of the care giver and the special attention received during one-on-one contact with a known midwife. It is the model of choice for many women, with the caveat that they must be regarded as low risk. The success of the midwife-led model in the Midwife Obstetric Units (MOU) in Cape Town is testament to this (2)(3).

## 2.4 Maternity care models in other countries.

The WHO estimates that at least 15% of pregnant women will require specialist intervention at some stage during their pregnancy to avoid death or serious morbidity (39). Almost half of pregnancies are of low-enough risk to be managed by midwives only. The movement in developed countries since the 1970s was mostly away from community based obstetrics towards centralisation of services with even low risk pregnant women receiving care with advanced technology that may not be appropriate (e.g. too sophisticated and expensive) for their need (40). This also became an issue in the larger central hospitals in South Africa, as there was often not an intermediate-care facility available between the community MOU and the large referral hospital, with many women (without complications that require tertiary care) receiving care in a tertiary unit.

In a developed country, where the CS rate at non-specialist doctor-led delivery units was compared to midwife-led and consultant-led units, there was no difference in total operative deliveries between the three units: 16.3% in a midwife-led unit; 18.0% in the doctor-led unit; and 18.8% in the consultant-led unit (41). There were also no differences in postpartum haemorrhage, sphincter injuries or neonatal outcomes.

The focus of this thesis is more on the doctor-led model as a midpoint of care between midwife and specialist care (42); the group of relatively uncomplicated women that requires access to theatre or some other medical or surgical intervention, but with no underlying medical or fetal disorders. To put this in perspective, it is first necessary to describe the systems in use in other countries.

The models of care in summary:

- Midwife-led continuity model
- Obstetrician-provided care
- Family doctor-provided care
- Shared care, where a midwife may provide the antenatal care and a family physician or obstetrician delivers the baby or where initial care is in a midwife-led service with referral to a unit with CS capabilities (family physician or obstetrician) only when complications develop.

### 2.4.1 Australia.

The service description of the Australian maternity service (which has 6 levels) and the Western Cape model correspond to some extent. The gestational cut-off points used for onward referral correspond within one week and can be used for comparisons (43). It is summarised in more detail in Table 2.4.1.1; with the Western Cape equivalent in the last column.

Table 2.4.1.1. Comparison between Western Cape and Australian maternity services.

Service	Description	Requirements	Western Cape equivalent
Level 1 maternity service. Rendered by midwives.	Provides community antenatal and/or postnatal care for women and infants, but have no planned births or maternity inpatient services.	Hand-held pregnancy records. Home-based or community care. Basic equipment for antenatal care. Access (by referral) to ultrasound.	Basic Antenatal Care clinics (BANC)
Level 2 maternity service. Primarily delivered by midwives and local registered medical practitioners.	Have access to a functional theatre, not necessarily on-site. Only spontaneous onset of labour- no induction service, no epidural	Medical supervision. May have a visiting specialist obstetrician. Association with higher-level support. Ability to do a Caesarean	Stand-alone midwife-obstetric units. Smaller, rural district hospitals (e.g. Porterville, Piketberg, Montagu). False Bay and Wesfleur

	service.	section within 75 minutes of the decision.	metro district hospitals
<b>Level 3 maternity service.</b>	Provides community and inpatient care for antenatal and postnatal women and babies without risk factors with a pregnancy >36 weeks gestation who are not <i>expected</i> to have labour or birth complications.	Can offer induction of labour for uncomplicated cases at term.  Elective and emergency CS can be performed on-site.  Delivered by practitioners with credentials in obstetrics.	Large district hospitals within the metro and larger rural hospitals (e.g. Ceres, Stellenbosch, Mosselbay, Oudtshoorn)
<b>Level 4 maternity service</b>	Provide maternity care for low- and moderate-risk women, but cannot care for women with complex, high-risk conditions (e.g. complex multiple births; heart lesions, severe fetal anomalies etc.)	Can care for women >32 weeks or expected birth weight of >1500g.  Positive air ventilation usually available on site.  Access to multi-disciplinary care including a neonatal unit.  Capacity to ventilate a women awaiting transfer.  Clinical lead a specialist obstetrician. Emergency care with 24 hour access to an obstetrician.	Regional hospitals- Paarl, Worcester, George, Somerset and Mowbray.
<b>Level 5 maternity service</b>	Registered medical specialists in the birth suite during business hours and accessible 24 hours. 24 hour availability of practitioners enrolled in a specialist training program.	As above, with planned care for women at 29 weeks gestation (or expected birth weight of >1000. Maternal-fetal medicine service in conjunction or as outreach.	General specialist obstetrics within Tygerberg or Groote Schuur hospital.
<b>Level 6 maternity service</b>	Provide complex care for women with serious obstetric and foetal conditions that require high-level multidisciplinary care.  Access to in-utero fetal surgery.  Plays strategic role in planning.	Access on-site (24 hours) to an obstetric tertiary imaging service.  Capacity to manage all unexpected pregnancy and neonatal emergencies.	Groote Schuur and Tygerberg hospital tertiary services.

Less than 1% of women in Australia choose home birth as an option (44). The majority (>97.0%) of Australian women give birth in conventional labour wards within hospitals, with 70.2% in the public system and 29.8% delivering in the private system. In 2010, there were

299 563 babies delivered in Australia (45), 5 times less than the 1.1 million babies born in South Africa in that year. The Caesarean section rate was 31.6% and the perinatal mortality ratio 9.3 per 1,000 births. There is a well-developed post-natal system of home-based care with the majority of women receiving at least one visit (46).

#### **2.4.2 New Zealand.**

In New Zealand, 89% of women choose a midwife as a Lead Maternity Caregiver, 7% choose a specialist and only 4% a general practitioner (GP). There is a 35% referral rate for consultant opinion at some stage within the pregnancy (47). Midwives in New Zealand work fully independent and can prescribe drugs, use laboratories and hospitals and gets the same financial compensation as general practitioners (GP), which may be one of the reasons why midwife delivery is chosen over GP delivery. As in South Africa (at least in the public sector), New Zealand midwives attend every birth, not just the low-risk or uncomplicated cases in hospital.

#### **2.4.3 Scotland.**

In Scotland, there are 8 different levels of care, designated by location and clinical situation. Level 1, where care is rendered by midwives or general practitioners, has 4 subdivisions (1a home planned delivery; 1b stand-alone maternity unit, 1c MOU connected to non-obstetric hospital; and 1d MOU connected to an obstetric hospital). Level 2a is a consultant-led service but with no access to a neonatal nursery; level 2b when then there is a neonatal facility on site, and level 2c when there is access to maternal high care. Level 3 has access to intensive care unit and neonatal surgery (48). The total number of births in Scotland has declined since 1990, from 67,000 in 1991 to 55,147 in 1999. There was a slight increase in deliveries during the first decade of the 21<sup>st</sup> century and 58,590 births were registered in Scotland in 2011 (49), almost the same number of babies delivered in the Cape Town

metropolitan service during 2011.

#### **2.4.4 The Netherlands.**

In the Dutch system, health care is free and there is universal access to the national health insurance system. The levels of maternity care are determined by a *List of Obstetric Indications*. Within this system 77.3% of pregnant women start their care with an independently practicing midwife and the odds of specialist involvement in the pregnancy are 59.4% (50). The primary obstetric provider (mostly midwives, but also general practitioners) do the risk selection based on this quite extensive list. There is a four tiered system as follows: primary care/delivery at home; primary transferred care (delivery in hospital); consultation (where a specialist only becomes involved for a specific problem); and secondary (specialist) care (51). In 2002; 29.4% of deliveries were regarded as completely low risk and delivery took place at home, 11.2% of pregnant women delivered at a primary care clinic and 59.4% had specialist involvement in their antenatal care and delivery; numbers that stayed almost the same since 1995 (52). Home birth is only allowed if the woman is still regarded as low risk with the onset of labour, The health insurance does not pay for specialist services if the woman is regarded as low risk.

#### **2.4.5 The United Kingdom.**

In the UK, since 2009, maternity care is also structured in a four-tiered system, but (in a typical patient-centred approach) the woman is given the choice (“national choice guarantees”) of where to deliver (53). About 3% of deliveries end up as home births attended by midwives or general practitioners. A standardised risk- and needs assessment is made by the primary care provider, ideally before 12 weeks of gestation, to determine whether:

- 1) Midwifery care can take place at home
- 2) In a clinic linked to a hospital

- 3) In a hospital
- 4) In a hospital with maternity team care (this includes a specialist obstetrician).

General practitioners are very rarely involved in midwifery care in the UK. A study that examined a general doctor-led model in the UK reported specialist referral rates of around 35% (54).

#### **2.4.6 Canada.**

Health care in Canada, as discussed earlier is delivered through a publicly funded health care system and is available free to all permanent residents in Canada. Services are mostly provided by private practitioners and hospitals, which then bill the state. Quality of care is assured through federal laid-down standards. Non-essential care is covered by private insurance (55). In 2008, according to the Canadian Institute for Health Information, there were 101 Family Physicians and 95 Specialist Physicians per 100 000 of the population. Midwifery care is funded by the state and available to all women who are deemed to be low risk. Specialist referral rates is around 35% (56)(57).

#### **2.4.7 The United States.**

Childbirth is uniquely expensive in the US and maternity and new born care is the biggest category of pay-outs for medical aid programs. 45% of births are covered by Medicaid and “pregnancy and delivery” and ‘new born infants’ are the two most expensive conditions billed (58). Home birth is not endorsed by the American College of Obstetricians and Gynecologists (ACOG) (59). In the US doctor-led model, about 35% of women are referred for specialist care (60)(54)(61). The ACOG has published a consensus document describing the levels of maternal care (see chapter 3) (62).

#### **2.4.8 Russia.**

There are three levels of maternity care in the Russian system, all hospital based and providing different levels of specialised care according to uniform requirements described in legislative documents (20). Although some care is provided by midwives and general doctors, the bulk of hospital services are provided by specialists. The doctor-led level 1 hospitals are small (<30 beds) and restricted to rural areas, but have specialists available on call. The level 2 hospitals provide specialist care between 33-36 weeks and there are intensive care units at these hospitals. There are 5.7 obstetrician-gynaecologists per 10 000 Russian women. In the Western Cape there are approximately 0.18 obstetrician-gynaecologists for every 10 000 women.

#### **2.4.9 Concluding remarks.**

It is clear from the above that the focus in most countries with available data is on the maternity-led and specialist consultant-led service, with very little focus on general practitioner/family medicine maternity care. The next section will focus on countries that practice (and have researched) family-doctor provided care.

### **2.5 Family-doctor provided care.**

The longest experience with non-specialist obstetrician practitioners (general practitioners or family doctors) providing obstetric care comes from rural Australia, New Zealand and Canada. A general practitioner holds a degree in medicine and surgery, (e.g. MB ChB or equivalent) while the speciality of Family Medicine requires a post-graduate residency of some years (e.g. 2 years (Canada), 3 years (US), 4 years (South Africa)) including an exit examination and registration as a specialist with the relevant college and regulating body. The residency requires a certain number of months' rotation in obstetrics and gynaecology (and the other general specialties), thus a family physician should theoretically be better equipped to manage obstetrical complications than a general practitioner or medical officer without this training. In Australia, they also recognise a special category of senior doctor, the

Rural Generalist, active in either rural general practice or hospital-based practice with at least one advanced skill in a specialist discipline like obstetrics.

That said, a number of colleges offers further training in obstetrics to non-specialist general practitioners, equivalent or more advanced to the diploma in obstetrics offered by the South African College of Obstetrics and Gynaecology. Examples are the UK diploma in obstetrics (DRCOG), the Diploma in Obstetrics and Women's Health from the Royal College of Physicians in Ireland, the Postgraduate Diploma in Obstetrics and Medical Gynaecology (PGDipOMG) from New Zealand Universities, the advanced GP Diploma (DRANZCOG) from the Australia/New Zealand College and the 2-year post-graduate Diploma in Obstetrics offered in India. This becomes important when discussing non-specialist obstetric services, as within this category care can be rendered by a GP with or without further training, a medical officer with or without extensive experience and/or further training or a family physician specialist. It is clear that within these ranks there can be a wide variation in the level of skill and competence. A local overview of 27 Western Cape district hospitals indicate that (apart from dental extractions) the most frequently performed surgical procedure done by generalist doctors were female sterilisations, caesarean sections and dilation and evacuation of the uterus (63). This emphasises the fact that all doctors working in SA district hospitals should be competent in the performance of CS.

### **2.5.1 Modelling for service delivery challenges.**

Predictive modelling is used extensively in managed health care and health insurance to identify and stratify those patients who could most benefit from a specific intervention. It is defined as *the process by which a model is created or chosen to try to best predict the probability of an outcome* (64). In health care, predictive models use demographic, socio-economic and clinical data to help managers and clinicians improve efficiencies and quality

of care. This should ultimately lead to a decrease in cost and improved outcomes for patients (65).

There are a few diverse studies on the use of predictive modelling to confront service challenges, which will be highlighted in the regional descriptions that follow. Most of the models use a variety of defining factors (e.g. demographics, infrastructure or geography) as well as other characteristics (e.g. human resources or facility setup).

### **2.5.2 Canada.**

During the first decade of the twenty-first century, the rural health services in Canada were in a state of instability as many smaller units closed and women migrated to larger centres to give birth and there was also difficulty in recruiting staff to work in small rural units (66). In addition, there seemed to be very little systematic planning or even evidence-based policies for rural maternity health services available (67). The problem is particularly bad in the western provinces of British Columbia and Alberta. It is not surprising that the hospitals in British Columbia able to offer a general practitioner CS service can deliver up to 85% of the women from the local population, while those that do not have access to CS only deliver about 30% (66). These smaller units are usually the ones to close down. The same results were found in Alberta, where 80% of women in a population delivered in the GP-surgery units and only 24% in those without access to CS (68). It is evident that the availability of safe CS facilities (in this case GP surgery) is paramount to a sustainable service and that policy makers should focus on the strengthening of this specific model.

Grzybowski and co-workers describes an elaborate predictive model for British Columbia with which they aim to predict the appropriate level of sustainable maternity service for a rural community based on population need (67). They calculate a Rural Birth Index (RBI)

based on the Population Birth Score (PBS; basically the average number of births per catchment area of the hospital over a 5-year period), an adjustment for social factors (APV; adjustment for population vulnerability) and an Isolation Factor (IF; measured as the travel time to a CS facility. Travel time of more than one hour was weighted). The final formula was

$$\text{RBI} = (\text{PBS} \times \text{APV}) + \text{IF}$$

The resulting score (falling between 0-25) segregated services into 5 groups:

1. No local Intrapartum service
2. Local intra-partum service without operative delivery
3. Local GP surgical services
4. Mixed model of specialist and GP services
5. Specialist services only

The modelling could accurately predict most of the already existing service and flagged the rest as over or under serviced. The applicable factor to local SA services could be the adjustment for social factors. The method they used was based on the Regional Socio-Economic Index from the Ministry of Labour and Citizens' Services of British Columbia (a weighting system that incorporates human economic hardship, crime, health problems, education concerns, children at risk and youth at risk) (69).

The decline in family doctors providing generalist obstetric care in Canada is attributed to job satisfaction and medico-legal concerns (70). In 2010 only 10.5% of family physicians still practiced intra-partum obstetrics, with most low-risk obstetrics being managed by specialist obstetricians (71). Health planners in Canada need to ensure that solo family physician (FP) obstetrics becomes attractive again. To that extend different models are implemented with success. Some practitioners share after-hours calls, which on the downside decreases continuity and patient satisfaction, and others have tested a system where every family physician sees their own patient up to 36 weeks, after which woman are consulted by all the

FP in the hospital until term, thereby ensuring that the delivery will be done by a physician known to them. Patient satisfaction with three different models (solo GP, GP group practice and solo obstetrician) were tested in the Canadian islands of Newfoundland and Labrador (70). Low risk women were more satisfied with group GP practice and solo GP practice; preferring this continuity over a specialist that only deliver the baby and then refer back to the GP for postnatal care. Home births are at less than 2% and many pregnant women begin antenatal care with a family physician that do not offer intra-partum care, so they have to find another provider halfway through pregnancy (72).

### **2.5.3 Australia.**

Needs-based health service planning in rural and remote communities like Queensland (the second largest and third most populous state in Australia) are governed by documents such as the *National Strategic Framework for Rural and Remote Health* (73) of the State of Queensland Health Department and the national *Rural and Remote Health Service Planning Process* (74) policy documents. Most of these documents are high-level frameworks that outlines basic policies around planning but do not contain actual models, nor does it speak specifically to maternity care.

As there was a lack of evidenced-based planning for rural maternity care, the Rural Doctors Association of Australia developed a consensus document with other role players (that included the RANCZOG, the Australian College of Rural and Remote Medicine and the Australian College of Midwives) that specifically addressed rural maternal health. This document, released in 2008, sets out specific principles and the suggested strategies to achieve this (75). The document served as the basis for their National Maternity Services Plan (NMSP) which was released in November 2010 (76).

The 5-year vision of the NMSP included:

- Woman-centred care.
- Access for all to high-quality, evidence-based, culturally competent maternity care.
- Maternity care provided by appropriately trained and qualified maternity health professionals.
- The plan mostly just sets priorities for the next few years as well as indicators to measure the success thereof. For rural maternity care, provision is made for locum services to continue in the near future while the government provides training scholarships to increase the maternity workforce in rural and remote Australia. As in the United States and the United Kingdom (but unlike South Africa), the Australian Government collaborates with the relevant College of Obstetricians (RANZCOG) for the development of evidence-based consultation and referral guidelines for maternity care.

The plan is still in the development phase with a rigorous methodology to assist in woman-centred maternity service planning. The methodology includes consideration of access to a choice of birthing options, safety and quality requirements, numbers and qualifications of maternity care professionals, resources and sustainability. It is thus too preliminary to consider as a model for local planning.

#### **2.5.4 The United States.**

There is only limited data comparing the outcomes of Caesarean delivery performed by family doctors as compared with obstetricians. In a recent study from Homan and co-workers, the maternal and perinatal outcome in two New England hospitals (one with Family Physician led care and one with consultant obstetrician care) compared favourably (77). It was only a retrospective review of 125 deliveries each, so arguably the numbers are too small to make any significant conclusions.

### **2.5.5. Cuba.**

The public health system in Cuba ensures the right of all individuals to free access to health care. Health care is nationalised and based on the concept of socialised medicine. All infants have to be delivered in a hospital setting by a medical doctor (78). There are on average one family physician available for every 159 individuals in a population. Rural women with risk factors can await delivery in maternity homes close to a hospital. The maternity home concept was also introduced in the rural SA setting as part of South Africa's *National Strategic Plan for a Campaign On Accelerated Reduction of Maternal and Child Mortality in Africa* (79).

### **2.5.6 Concluding remarks.**

There is large variation in the delivery of maternity care throughout the world, but the literature search did not find a model comparable to the public-sector funded, family physician provided district hospital service within a metropolitan setting described in the Western Cape. The closest resemblance is the family physician system in Cuba, but even that is not exactly comparable as there is less focus on community midwifery.

Davis-Floyd, in the book "Birth Models That Work" uses 24 criteria to characterise the ideal model (80). The essential focus is on the woman-centred (midwifery) ideology based in the community, with physicians providing appropriate services for high risk births and seamless transfer up and down the levels of care according to need. It does not distinguish between the general doctor/family physician and specialist obstetrician categories of care. In most systems, general practitioners play the role of a midwife, rather than the next level of care in the referral chain.

Restructuring within SA maternity services has taken place in many settings (especially in the Free State, Gauteng and Kwa-Zulu Natal) but only a few publications have documented some of the effects on the service (81) while others are mere descriptive studies of practice at a district hospital service (82). The restructuring of maternity services in the Metro East GSA will be discussed in Chapters 3 and 4. The literature review for aspects relating to a specific chapter will be discussed in that chapter.

## 2.6 References.

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## Chapter 3

Regionalised maternal care in the Western Cape, South Africa. Implementation and evaluation of the impact of Levels of Maternity Care within a specific geographical service delivery area: 2007-2012.

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## **Chapter overview.**

On 1 July 2008, the maternity services within a specific geographical service delivery area in the greater Cape Town metropole was re-organised to improve capacity at primary level. This followed planning and modelling based on concepts of regionalised perinatal care and over the next following years also the opening of a new large district hospital within this district. This chapter is a narrative report and analysis of the events from the planning stages in 2007 until full implementation by the end of 2012 and will be presented in four parts, spanning the objectives of this venture:

Objective 1: To document the state of the service before the regionalisation of maternity services and to describe the policies, point prevalence surveys and modelling that guided the shifts in this specific metropolitan geographical service delivery area (GSA) governed by a single hospital (Tygerberg).

Objective 2: A short description of the actual service delivery shifts.

Objective 3: To determine the impact on the maternity care referral patterns. Annual snapshot surveys of deliveries during July over a 6-year period were done from the start of regionalisation (2008) through the opening of a new district hospital (2009) up to 2012. The results will be documented here.

Objective 4: To document the impact of regionalisation on the central (tertiary) hospital and its catchment area in terms of complexity of care, trends in deliveries, caesarean section (CS) rates and neonatal and maternal mortality.

### 3.1 Introduction.

The concept of regionalised perinatal care is well known for more than four decades. The main aim of regionalised perinatal care is to ensure timely access to the correct level of care. Low risk pregnant women should receive antenatal and delivery care within their community and high risk women must be identified and referred appropriately to a more specialised level of care. The primary aim is to reduce maternal and neonatal mortality and morbidity, by reducing pressure on the specialised services (1). The safety of delivering term and near-term infants in low-risk (level 1 care) hospitals has been confirmed and increasing the acuity of care does not improve the outcome for more than 90% of low-risk woman (2). This system was established in developed countries where there is good neonatal high care and intensive care (ICU) facilities available and a good transport system in place for in-utero transfers.

However, most perinatal mortality in the world occurs in lesser resourced countries where simple interventions for term babies at primary level or with home-based care make more impact than access to tertiary care (3). Tertiary ICU care is also unaffordable for most developing countries and even the Western Cape, where the infrastructure is relatively better developed than elsewhere in South Africa, does not have the recommended norm of one neonatal ICU bed for every 1000 deliveries (4). Therefore adaption of international regionalised policies for poorly resourced countries should place emphasis on acceptable standards of care at all levels.

The guiding role of the Comprehensive Service Plan (CSP) (5) and the development of the regionalised perinatal package of care for each health level within the province are described in Chapters 1 and 2. The resulting three-tiered healthy system is summarised in Table 3.1.1. In a metropolitan area, implementation of this model would include (for the first time) a

district-type large hospital maternity service that is not led by obstetric specialists or specialist trainees (registrars), but by generalist doctors. There would also be a redirection of low-risk women out of the central hospital to the appropriate district hospital.

In the Tygerberg hospital drainage, implementation of the CSP for perinatal care necessitated the redesign of Tygerberg as the only regional/tertiary hospital in the eastern half of greater Cape Town, with its three large drainage hospitals designated to function as district hospitals. Each district hospital would be responsible for the clinical governance of the MOUs in their respective drainage area. Although many reports have shown improvement in maternal and neonatal outcomes with regionalised care (6)(7)(8), a recent meta-analysis shows only a modest effect and thus the effect of regionalisation on maternal and neonatal outcomes remains an area where robust studies are required (9).

The implementation of the CSP in the Western Cape province occurred according to a policy that initiated a continuous process that commenced in the TBH drainage area. The other half of Cape Town was to start with a similar redesign in the following year. It was therefore not possible to evaluate the impact with a controlled trial. The main confounders in any such uncontrolled before-and-after type study is concomitant implementation of other quality improvement programs, technological advances, introduction of new drugs or policies (e.g. surfactant administration, continuous positive airway pressure ventilation (CPAP) at district level) or a shift in patient demographics, making it virtually impossible to exclude some form of bias. This is a complex intervention, built up from a number of components which may act independently and inter-dependently (10). The evaluation of complex interventions should ideally follow a sequential approach, starting with the theoretical basis for the intervention, defining the components of the intervention using modelling or similar techniques, exploratory studies to develop the intervention and then the planning of a definitive evaluation study (11).

Eccles summarises the different research designs for studies evaluating the effectiveness of change and improvement strategies (12). It should be noted that the emphasis of regionalisation in the Western Cape was in the opposite direction as usual; more on developing capacity at less specialised levels of care [district (level 1D) and community based (level 1B and C)] and confining the scarce resources of a tertiary hospital to those that really need it, than a drive towards improved ICU access. It was not designed as a quality improvement program but as a model for increasing capacity at community level. The theoretical basis, modelling and preliminary work was contained in the blueprint (the CSP).

As it was difficult to randomise or identify an appropriate control group and the researcher had no control over the delivery of the implementation, Eccles suggest that a *time series design* methodology is followed, where the intervention is compared to the underlying secular trend (12). In this specific instance, the researcher was interested in the impact of this intervention on maternity care in the central hospital itself and the methodology used was largely descriptive, using sampling of clinical data at multiple time points and comparing trends in mortality, morbidity and delivery numbers before and after the shift using baseline hospital and population data (13). The author was actively involved and supervised the complete venture from the preliminary planning in 2007 until the final phase during 2012.

Table 3.1.1 Levels of care within the Western Cape maternity services.

Service	Description	Requirements
Level 1A Home-based service provided by community volunteers or trained providers	Provides basic home-based care including wound care, information and motivation to attend appointments	Home-based or community care.
Level 1B Maternity service rendered by general nurse practitioners in a Community Health Centre or general Clinic (Basic Antenatal Care).	Provides community antenatal and/or postnatal care for women and infants, but have no planned births or maternity inpatient services.	Hand-held pregnancy records. Basic equipment for antenatal care. Access (by referral) to ultrasound
Level 1C Maternity service primarily delivered by midwives in a stand-alone midwife-obstetric unit within the community.	Only spontaneous onset of term (>36 weeks) labour- no induction or augmentation of labour, no electronic fetal monitoring.	Medical supervision (clinical governance only) by a visiting medical officer or specialist obstetrician on outreach basis.
Level 1D Maternity service- district hospital	Provides community and inpatient care for antenatal and postnatal women and babies without risk factors with a pregnancy >35 weeks gestation who are not expected to have major (specialist intervention) labour or birth complications.	Can offer induction of labour for uncomplicated cases at term. Elective and emergency CS can be performed on-site. Delivered by general practitioners with experience in obstetrics. Large services governed by an onsite specialist to ensure delivery of the district package of care (no specialist services rendered).
Level 2 (regional) maternity service	Provide maternity care for moderate-risk women, but cannot care for women with complex, high-risk conditions (e.g. placenta accreta; complex heart lesions, severe fetal anomalies etc.). No blood bank on-site.	Can care for women >32 weeks or expected birth weight of >1500g. Neonatal CPAP available on site. Multi-disciplinary care available for the major clinical disciplines Capacity for short-term ventilation for a woman awaiting transfer. Clinical leader is a specialist obstetrician. Emergency care is rendered by general doctors with 24 hour access to an obstetrician.
Level 3 (tertiary) maternity service	O&G specialists on-site in the maternity emergency centre during business hours and available after hours. 24 hour availability of registrars enrolled in a specialist training program. Provide complex care for women with serious obstetric and fetal conditions that require high-level multidisciplinary care. Ability to do in-utero transfusions.	Maternal and fetal subspecialists and general specialist with a special interest provide dedicated cardiac, recurrent fetal loss, fetal anomaly, endocrine, diabetic clinics and in-patient conservative management of severe pre-eclampsia. Dedicated obstetric high care with direct access to the tertiary hospital ICU care.

### 3.2 State of the service before regionalisation.

A situational analysis of the state of maternity services for the entire Western Cape was performed by the retired head of Tygerberg Obstetrics and Gynaecology, Professor HJ Odendaal during 2003-2004 (14). The Odendaal analysis made several important recommendations, most of them towards improving capacity at district level and this guided the maternity planning in the CSP. To document the state of the service as it was prior to July 2008, a point-prevalence survey was done of all women who delivered in a single month (July 2007) in the tertiary hospital (Tygerberg hospital) as well as in the regional/district hospital (Karl Bremer) within the same drainage. Folders of all women who delivered (obtained from the hospital delivery register) were analysed retrospectively and classified in the level of care received, using the levels of care policy.

This provided a snapshot of the then current case mix of patients. This point prevalence survey served as the basis for calculating patient numbers to be redirected during the service shifts. After the point prevalence surveys were done, a thorough analysis of existing bed numbers and numbers of beds needed to accommodate the shifts was done. This was followed by modelling, in order to predict the proposed state of the service after each part of the shift.

Folders were classified according to the highest (most specialised) level of care provided for the mother-baby dyad during the admission that led to delivery as well as their antenatal, intrapartum or direct postnatal journey until maternal discharge. For example, if a patient entered the hospital as a low risk patient, but developed eclampsia and needed admission to a high care unit, she was classified at the highest level of care she required (e.g. 'tertiary'). If a patient required tertiary input earlier in pregnancy, but by the time of delivery the problem has resolved, she was re-classified into a lower risk category (e.g. preterm labour

successfully suppressed at 28 weeks, now at 40 weeks with no risks). Classification was not restricted to the delivery process only. If there was an underlying problem requiring tertiary care throughout the pregnancy (e.g. diabetes), she was classified as tertiary, even though the actual delivery itself may have been uncomplicated. If a patient was transferred from a rural regional hospital for fetal reasons (and not maternal, e.g. preterm labour at a very early gestation), she was counted as tertiary even though the maternal problem was minimal. Admissions to obstetric high care were counted as tertiary care, according to the levels of care policy, even though high care is regarded nationally as a regional (level 2) package of care.

If a mother was discharged healthy but within 6 weeks postpartum re-admitted for a complication (e.g. wound sepsis) the level of care was not re-assigned, as she would now be a new referral to the level of care needed for that specific condition. Likewise, when an infant developed complications after maternal discharge (during the first 28 days of neonatal life) the maternal category was not re-assigned. The number of antenatal visits and pre-natal admissions as well as length of stay for all admissions was audited for all mothers who delivered in July, even if this care was during the previous months, to calculate the work force and hospital stay involved in a typical delivery at each specific level of care. Thus, a single delivery could serve as a proxy for a certain amount of antenatal and postnatal activities that can be used for determination of human resources required for that specific level of care. The aim was also to be able to predict the total care pathway of generic women booking for first antenatal visits in a community clinic. Therefore the number of deliveries at community level could inform the bed numbers needed at district or more specialised levels.

The method of delivery during 2007 (prior to any shifts) is shown in Figure 3.2.1 and the indications for Caesarean sections (using the Robson classification (15)) is shown in Figure 3.2.2. The Robson classification of indications for CS is further discussed in Chapter 7.

Figure 3.2.1 Method of delivery at Tygerberg hospital January-December 2007.

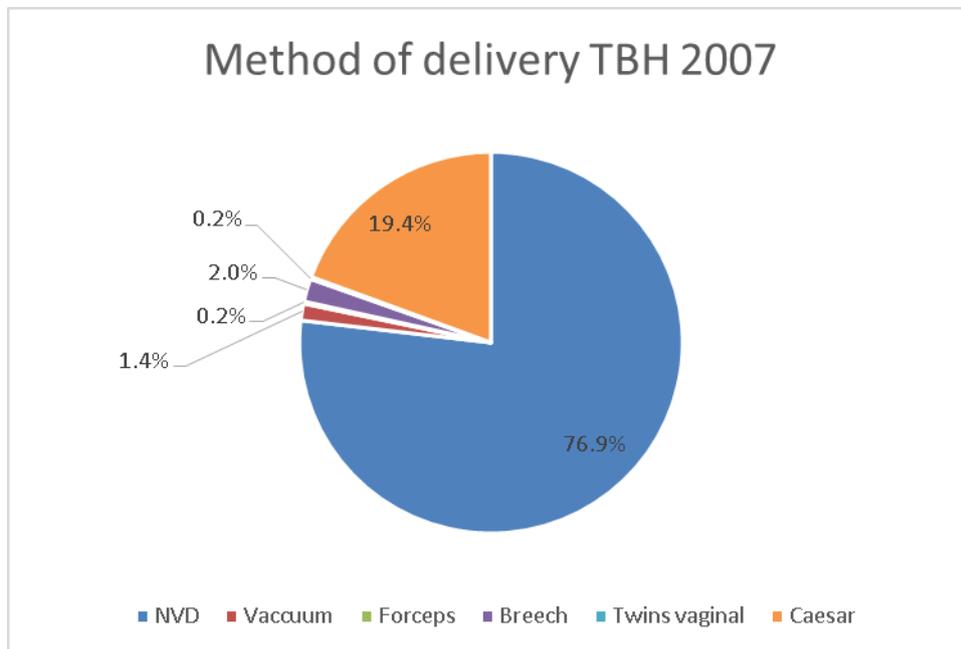
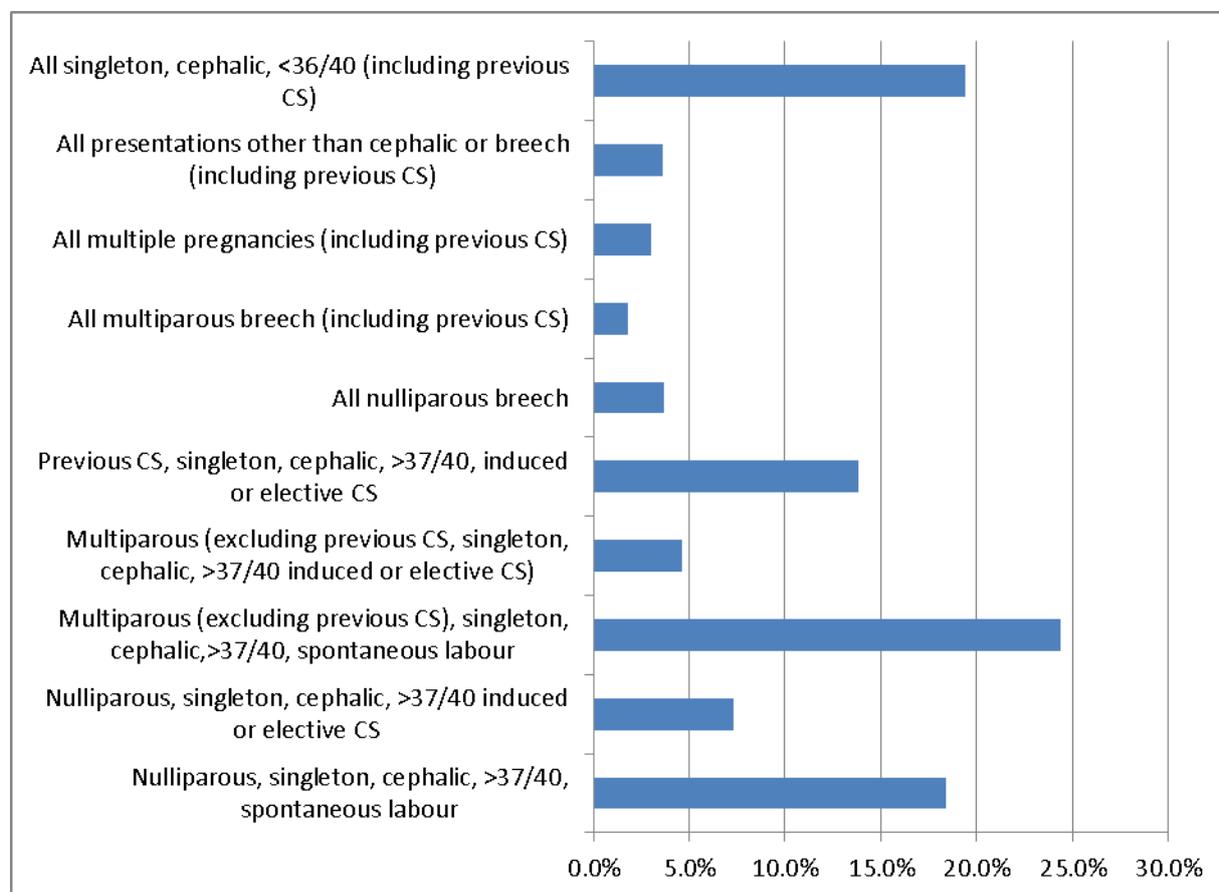


Figure 3.2.2 Robson classification for CS indications at Tygerberg hospital during July 2007.



There were 824 admissions to Tygerberg hospital labour ward in July 2007 and 661 of these delivered. Of the 824 admissions, 67 were admitted more than once in the same month. Of the actual 757 women admitted, there were sufficient notes available to analyse 658 folders (86.9%).

Of the patients that delivered in July 2007 at Tygerberg hospital, care received could be assigned as follows:

Level 1 care 322 (48.9%)

Level 2 care 252 (38.2%)

Level 3 care 84 (12.9%)

Of the 322 level 1 deliveries, 268 (40% of the total deliveries) could have been redirected (or primarily referred) to a less specialised level of care. The folders of these patients was of particular interest as it was important to identify the woman-baby dyad where there was no need for specialist involvement in their management and where development of simple evidence-based protocols could guide their management in future. The remaining women with level 1 deliveries (n=54) were also low risk, but arrived at the hospital in advance labour. Most of them never booked for antenatal care and in all probability the same health-seeking behaviour will apply for women living close to the hospital in future, whatever the referral criteria, so they were not factored into the calculations. The diagnosis identified from the folder review is listed in Table 3.2.1.

Table 3.2.1 Patients that can safely be managed at a level 1 (district) hospital.

Prelabour rupture of membranes at term, if no contractions within one hour after rupture (HIV positive)
Prelabour rupture of membranes at term, if no contractions after 24 hours observation at the MOU (HIV negative)
Poor progress in labour, gestation of 36 weeks or more
Induction for post term pregnancy
Elective (scheduled) CS at term
Removal of retained products after delivery
Trial of labour after one previous caesarean section at term (spontaneous onset of labour)
Adolescent deliveries (<16 years of age)
Moderate anaemia (haemoglobin 8g/dl or more)
Untreated syphilis (the baby may need specialised care)
Mothers with asthma and good control
Hyperemesis gravidarum

A similar snapshot survey was done at Karl Bremer hospital during July 2007; where there were 373 deliveries. Of these, 75 were identified as needing specialist input (level 2; 20.1%). There were no women needing tertiary care (level 3) amongst them, as they were already correctly referred to Tygerberg hospital. There were 60 women referred from Wesfleur hospital on the West coast, which at this time was still referring women to Karl Bremer for further care. Two of the MOUs (Elsies Rivier and Bishop Lavis) referred all their complications to Tygerberg hospital and one (Kraaifontein MOU) directly to Karl Bremer hospital. All the deliveries in the analysis, re-allocated to the level of care rendered, is summarised in Table 3.2.2. The patients referred from the MOUs are added in the level of care column of the hospitals to which they were referred.

Table 3.2.2. Attribution of levels of care in Metro East following the 2007 folder analysis.

	Deliveries analysed	Level 1 MOU	Level 1 District hospital	L2 Regional hospital	L3 Tertiary hospital
Karl Bremer hospital	373		298	75	
Tygerberg hospital	658		322	252	84
Elsies River	228	228			
Bishop Lavis	209	209			
Michael Mapongwana MOU	159	159			
Kraaifontein MOU	193	193			
Helderberg hospital	224		224		
Macassar	252	252			
Wesfleur	95	95			
<b>TOTAL numbers</b>	<b>2394</b>	<b>1136</b>	<b>844</b>	<b>327</b>	<b>84</b>
Percentage of total when re-aligned		<b>47,5%</b>	<b>35,3%</b>	<b>13,7%</b>	<b>3,5%</b>

This shows that with regionalisation, the activity at one the district hospitals (Karl Bremer) will increase, but it will be patients with a lesser risk. The activity at the central hospital should decrease somewhat, but the acuity of the patient case load will increase.

In summary: for the Metro East geographic region in 2007:

47.5% of deliveries took place at a midwife obstetric unit (MOU)

35.3% could take place at a district level hospital

13.7 % will need secondary level care

3.5 % will need tertiary level care (but this included the rural referrals as well, the actual number may be smaller)

Or, for every 100 deliveries in a MOU, provision should be made for an additional 74 district level deliveries, 28 regional deliveries and 7 tertiary deliveries somewhere in the same

drainage system. This model was then applied to the MOU in Khayelitsha (initially only Michael Mapongwana MOU, as the Site B MOU shift was planned for 2012). The 159 deliveries in July 2007 could now be assumed to represent 47.5 % of deliveries originating in that specific geographical area. A new Khayelitsha district hospital could then expect 118 deliveries per month after stabilisation of the referral pattern. It was expected that referral patterns will take about 9 months to one year to stabilise, as pregnant patients already familiar with their current provision of antenatal care and delivery plans was not expected to redirect during their pregnancy. Of these, with the CS rate expected to be similar to Karl Bremer (about 43%, see Figure 3.5.2), 50 CS will be done per month (1-2 per day). An additional number of 46 women per month  $[(159 \div 47.5) \times 13.7]$  will need to be accommodated at the regional hospital and a further 12 women per month  $[(159 \div 47.5) \times 3.5]$  will need access to tertiary care.

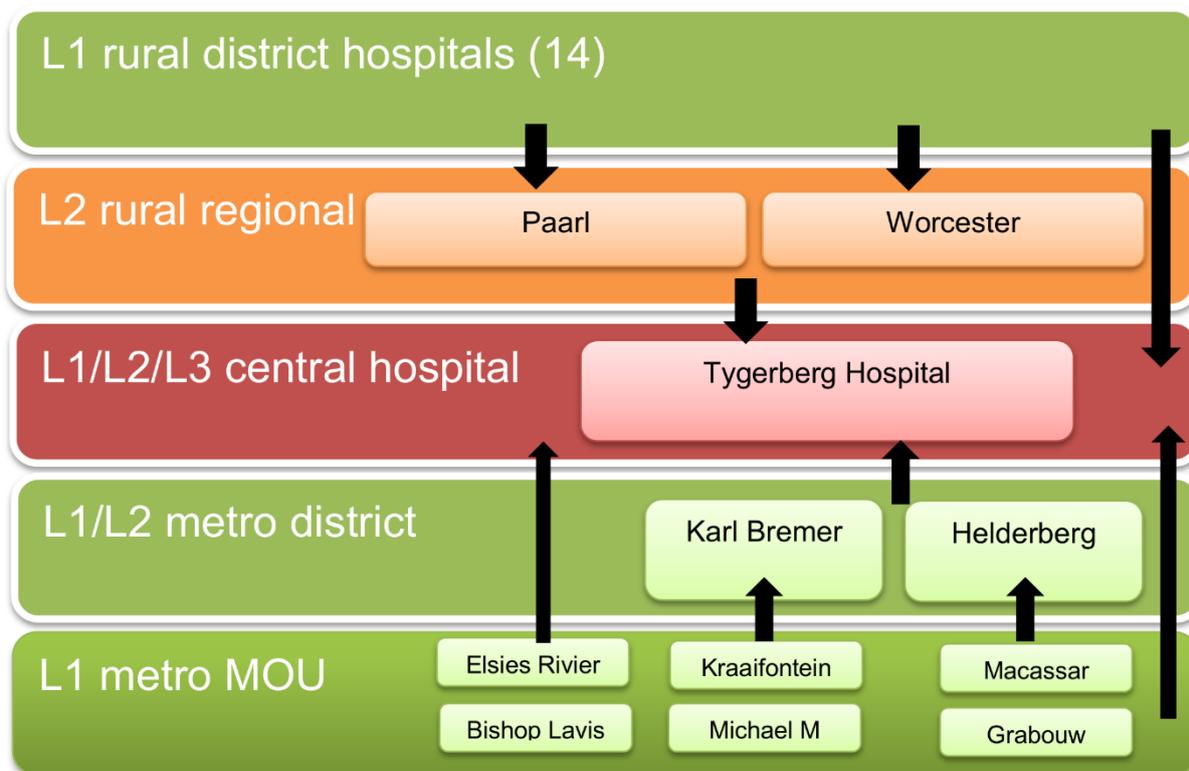
The July folder review was expanded, with the help of obstetric colleagues working in those hospitals, to include all the large hospitals within the metro (Mowbray, Somerset and Groote Schuur). The total metro picture that emerged using the same levels of care and including all MOUs and all the hospitals where deliveries take place was the same for MOU's but with a slightly higher need for regional and tertiary care. Although the same definitions was used to determine the level of care, there are only tertiary and regional hospitals in metro west and the practitioners may be more biased towards a slightly higher level of care. This is depicted in Table 3.2.3.

Table 3.2.3. Levels of care required by hospitals in Metro West.

Levels of care required by hospitals in Metro West	
MOU	47%
District hospital	30%
Secondary hospital	17%
Tertiary hospital	6%

A graphical representation of the obstetric drainage patterns of Tygerberg hospital before the implementation is shown in Figure 3.2.3.

Figure 3.2.3 Tygerberg hospital drainage pattern before the service shifts.

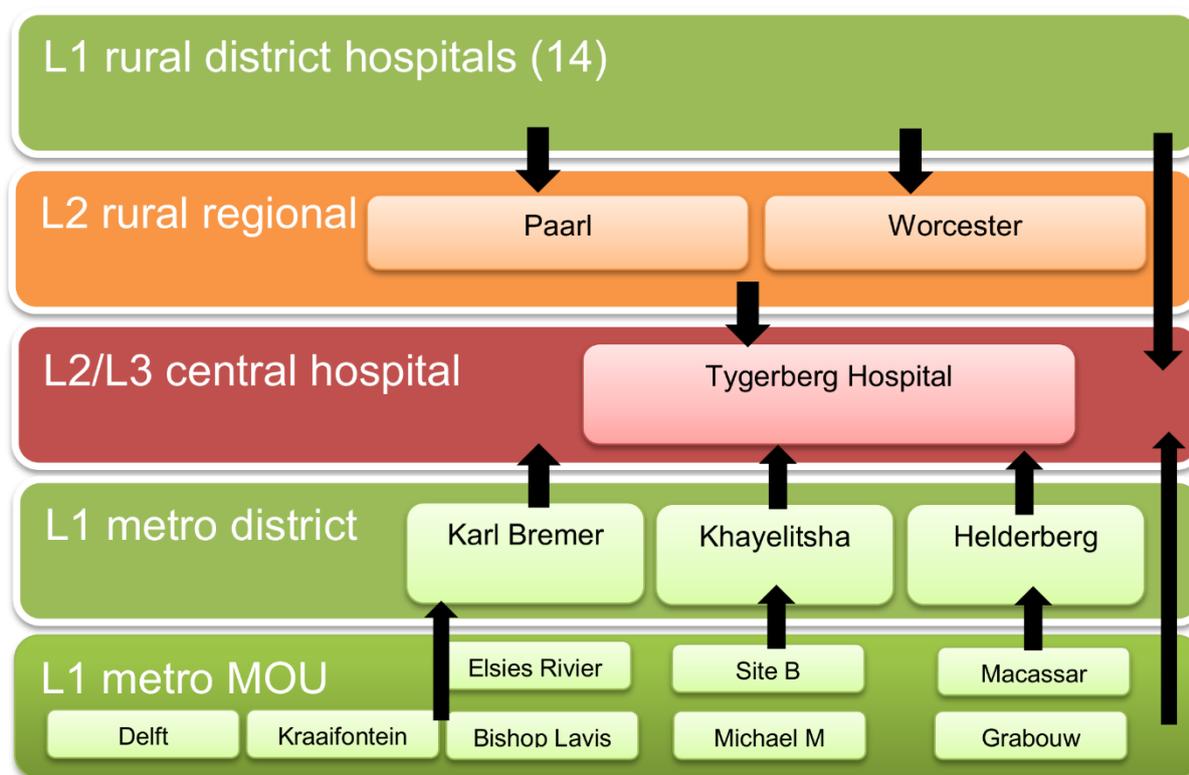


### 3.3 Service shifts.

The detailed steps involved in the execution of this specific model were:

- The establishment of a district-based maternity service at Karl Bremer hospital (KBH), to function as the primary district hospital for the Tygerberg/Northern metropolitan substructure. Karl Bremer now received all level 1 referrals from three Midwife Obstetric Units (MOUs) within its boundaries, as well as all of the level 1 referrals previously referred to Tygerberg hospital (from 1 July 2008). Karl Bremer hospital would take over the primary function as immediate custodian for three MOUs (Bishop Lavis, Elsies Rivier and Kraaifontein) and a fourth (Delft, newly built and opened in 2010). Wesfleur started to re-direct to Somerset hospital from 1 July 2008. Tygerberg hospital will be the only regional/level 2 and Tertiary/level 3 hospital in the drainage area. The two MOUs (Elsies Rivier and Bishop Lavis) that drained to Tygerberg hospital prior to the move will now send their level 1 referrals to Karl Bremer hospital, and their level 2/level 3 directly to Tygerberg hospital.
- The establishment of a third district hospital service for obstetrics, the future Khayelitsha hospital, initially within the Tygerberg hospital infrastructure (opened on 1 July 2008 next to the Tygerberg hospital labour ward) and later (15 February 2012) at the newly built hospital complex within the Khayelitsha sub-district, when it also took over the complete Khayelitsha Site B drainage area (including Site B MOU).
- The establishment (by internal re-configuration) of a separate general specialist obstetrics and gynaecology service within the academic department at Tygerberg hospital, overseen and managed by the author, since 1 January 2010. A diagrammatic representation of the final drainage pattern within the geographical service delivery area (during 2012) is shown in Figure 3.3.1.

Figure 3.3.1 Final drainage routes after implementation of the service shifts.



No changes were made in the rural referral pattern or to the Helderberg/Macassar/Grabouw drainage area.

The preparation for the Site B shift (from its previous drainage to Metro West) used the same principles as discussed above (using the 2010 delivery numbers). There were 2410 deliveries in Site B MOU in 2010 and they theoretically represent 47.5% of all deliveries originating in that area. This means  $(2410 \div 47.5) \times 100 = 5073$  potential deliveries will need to be accommodated in the new system per year.

Of these 5073 deliveries, 35.3% (n=1800) will need to be managed at the new Khayelitsha hospital, 13.7% (n=695) will need referral to the general specialist platform (regional hospital) at Tygerberg hospital and 3.5% (n=177) will need referral to the tertiary part of Tygerberg hospital. The number of admissions to the labour ward (n=8239 in 2010)

exceeded deliveries by a factor of 1.35. The expected additional admissions to the labour ward was calculated as  $(695 + 177) \times 1.35 = 1177$  women per year. As there are no bed norms available for maternity care, and the labour ward was already running at a daily bed occupancy rate of  $>100\%$ , there was no refined way of working out the additional number of beds needed. The percentage increase in admissions was calculated at  $1177 \div (8239 + 1177) = 12.5\%$  and this percentage was used as the estimated factor with which to increase capacity. A summary of the key steps in the complete move is shown in Table 3.3.1.

Table 3.3.1. A summary of the key steps in the preparation and actual shifts.

Institution	Date	Operational planning	Preparing health staff
Karl Bremer	January-June 2008	Open 10 additional maternity beds (this used to be Kangaroo Mother Care (KMC) beds for the future Khayelitsha hospital)	Develop new/ adapt existing protocols for use at district hospital level. Train staff
Bishop Lavis MOU	June 2008	Train staff to distinguish between level 1 and Level 2/3 referrals	Develop new/ adapt existing protocols for use at MOU level.
Elsies Rivier MOU	June 2008	Train staff to distinguish between level 1 and Level 2/3 referrals	Develop new/ adapt existing protocols for use at MOU level.
Kraaifontein MOU			No change in existing drainage
Khayelitsha Hospital	January-July 2008	Open labour ward within Tygerberg hospital premises Open elective theatre Share emergency theatre with Tygerberg hospital Open a triage area (1/11/2008) Establish a high risk clinic at Michael M MOU	Appoint and train new staff Develop protocols and train newly appointed staff
Khayelitsha hospital	1 July 2008	The full 20-bed ward for antenatal, post-natal and 10 KMC beds commissioned.	
Michael Mapongwana MOU	1 July 2008	Khayelitsha hospital take over Michael M referrals	Risk mitigation done and contingency plans put in place to manage the shift
Tygerberg hospital	January-December 2008	Assist the newly opened Khayelitsha labour ward with consultant guidance and a 'twinning' arrangement where nursing staff and doctors rotate between the two labour wards to gain experience.	
Khayelitsha hospital	December 2010	Move to a 24 hour independent service, still within Tygerberg hospital	
Tygerberg hospital	June-December 2011	Preparation for the Site B shift. Increase labour ward bed capacity with 6 beds, and 6 additional antenatal and 6 postnatal beds added in wards.	Two additional specialists and 2 new medical officers appointed to accommodate the expected increase in numbers. Staff orientated on the impact of the move Change management done with all staff

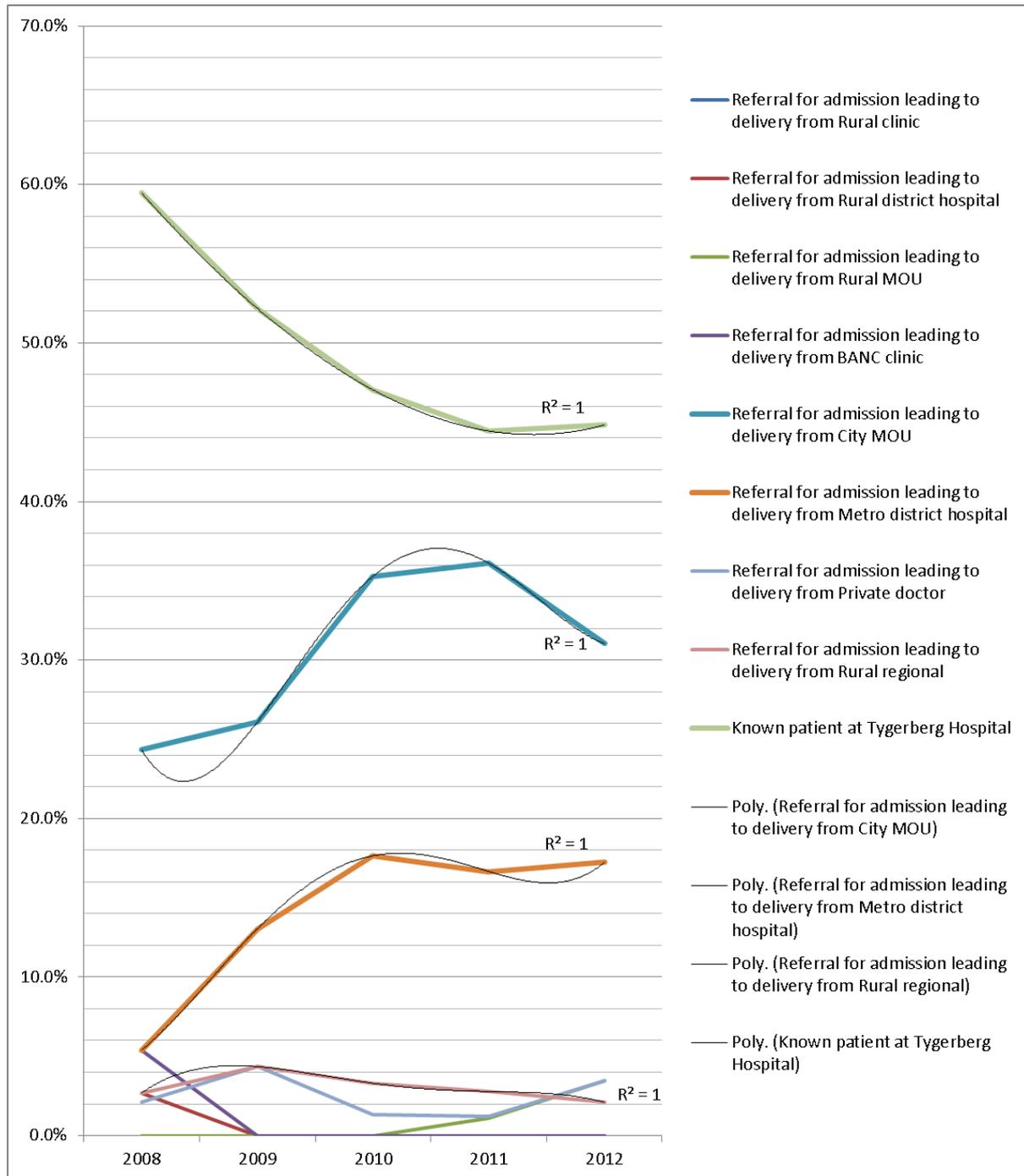
Tygerberg hospital	January 2012	Commission an additional theatre for elective caesarean sections	Additional theatre staff appointed
Tygerberg hospital	Planned for 2012, but delayed until 2014, completed end 2014	Redesign and renovation of labour ward to have 7 single delivery rooms, 8 acute antenatal beds, 4 antenatal beds for induction of labour and a separate critical care unit with 8 beds and an additional 8 step-down beds	Change management done. Complete labour ward had to be decanted for the full year that renovation was taking place. All staff orientated on the new design.
Tygerberg hospital	2012	Develop new triage area for acute obstetrics and use principles of the SA Triage System to manage patients	Staff trained in the use of triage tools
Khayelitsha hospital	February 2012	Move to newly built premises in Khayelitsha	
Khayelitsha hospital	March 2012	Take over Site B MOU as well	Complete shift of Site B drainage from its prior Metro West drainage to Metro East.
Department of health		Establish ultrasonography service in each of the four sub-districts  Expanded MOU and basic ante-natal care (BANC) capacity within Metro East, including commissioning of a new MOU in Delft	

### 3.4 Annual snapshot [point prevalence] survey of maternity care 2008-2012 at Tygerberg hospital.

To analyse the variance in the levels of care of women referred over the next 5 years an annual point prevalence study was performed on all deliveries in the first week of July each year (Monday-Sunday) in Tygerberg hospital, from the start of the regionalisation (2008) up to July 2012, when all the shifts were completed. The referral pattern for admission is shown in Figure 3.4.1. This is for the admission leading to the delivery and shows the level of care where the patient was managed directly prior to admission. Trend lines were added to the graphs to show the relationship between the number of patients and the timeline. R-squared ( $R^2$ ) is a measure of the goodness of fit of the trend line to the data and values can range between 0 and 1, where a value of 1 is a perfect fit. Polynomial (curved) trend lines were used, as the data fluctuates. This is abbreviated as *Poly* in the Figures.

As can be expected, the number of patients that attend clinic at Tygerberg hospital prior to admission (e.g. already known to the higher level of care) decreased as their care were gradually phased out to less specialised levels. This is demonstrated in the increase in patients referred for admission from primary care (MOU and district hospital) but needing specialised care only during delivery.

Figure 3.4.1. Origin of referral leading to admission for delivery.



The level of care where women present for their first antenatal (booking) visit is depicted in Figure 3.4.2 (a). The majority of patients booked close to their home at their respective community health clinic or MOU. This number steadily increased until 2011, after which it slightly declined to 79%. The reason for this declined is depicted in Figure 3.4.2 (b), which contains the same data as in Figure 3.4.2 (a) but restricted to the lowermost 10% only. More

women booked at community clinics (Basic Antenatal Care or BANC). Very few patients booked primarily at specialist or subspecialist clinics. The number of BANC clinics in the city is small and they only book a limited number of women per week, but there is a steady increase in community clinics offering BANC through a concerted effort by the department of health. There were also a higher number of unbooked women during 2012, which could be the influence of the addition of the Site B municipal district to the drainage in 2012.

Figure 3.4.2 (a). Level of care at first booking for a new pregnancy.

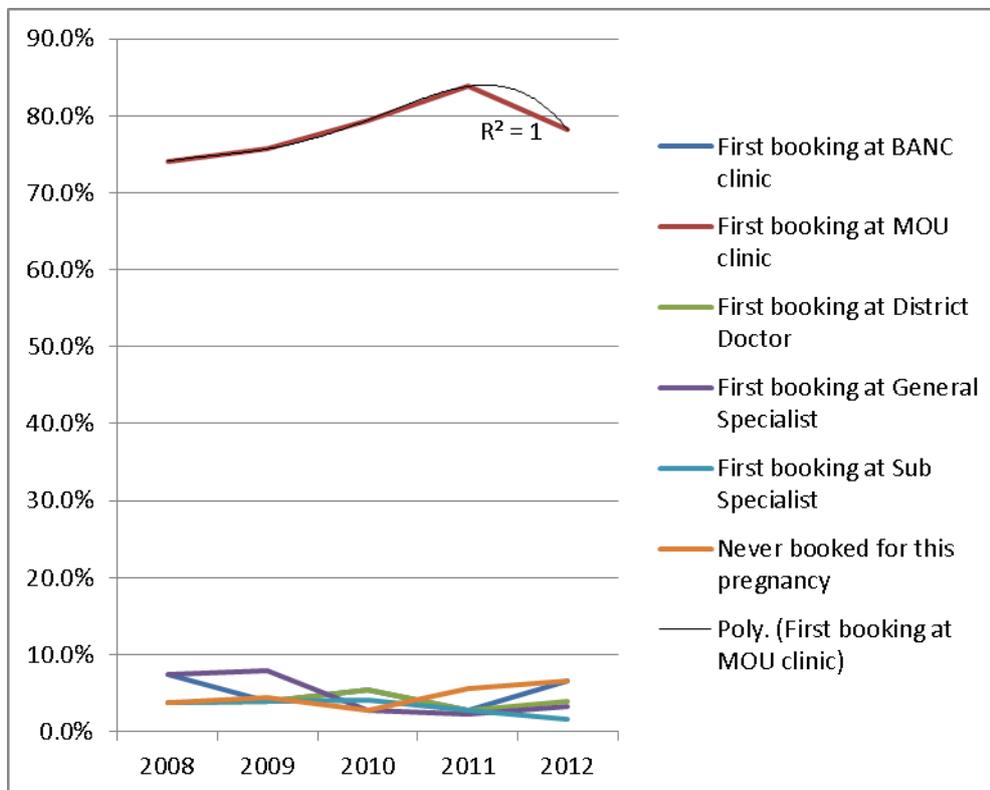


Figure 3.4.2 (b) First antenatal booking other than at a community MOU.

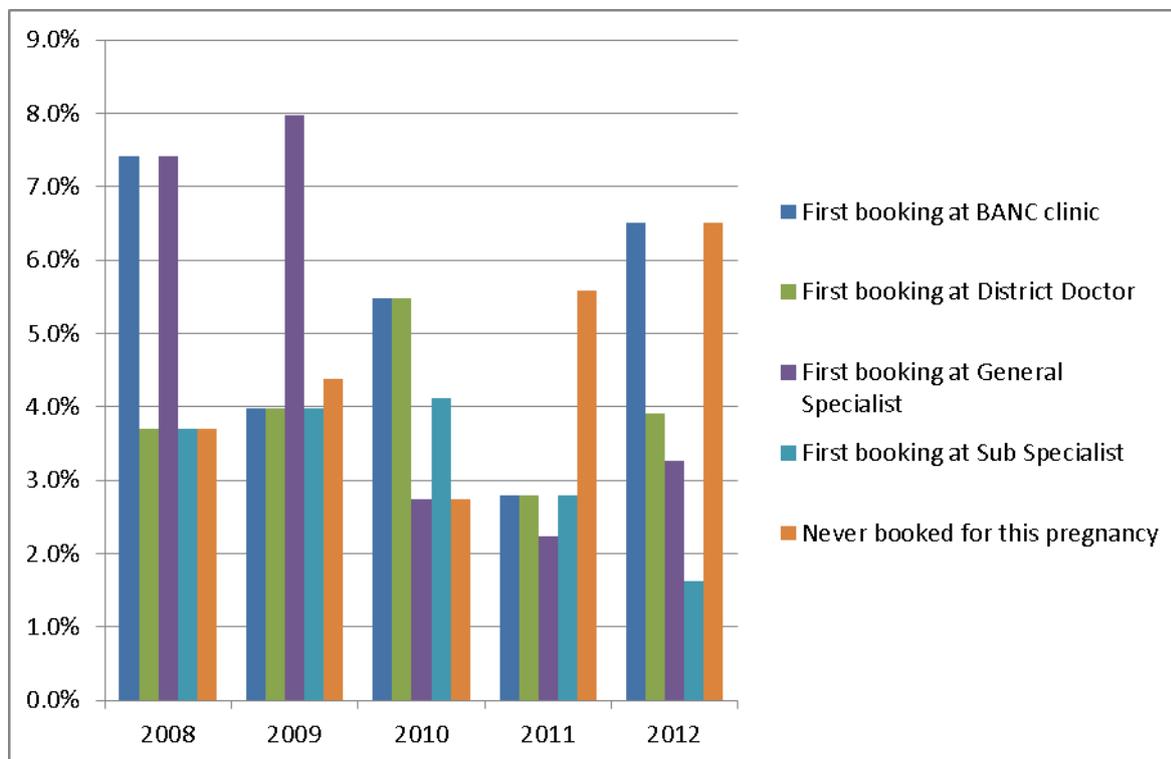
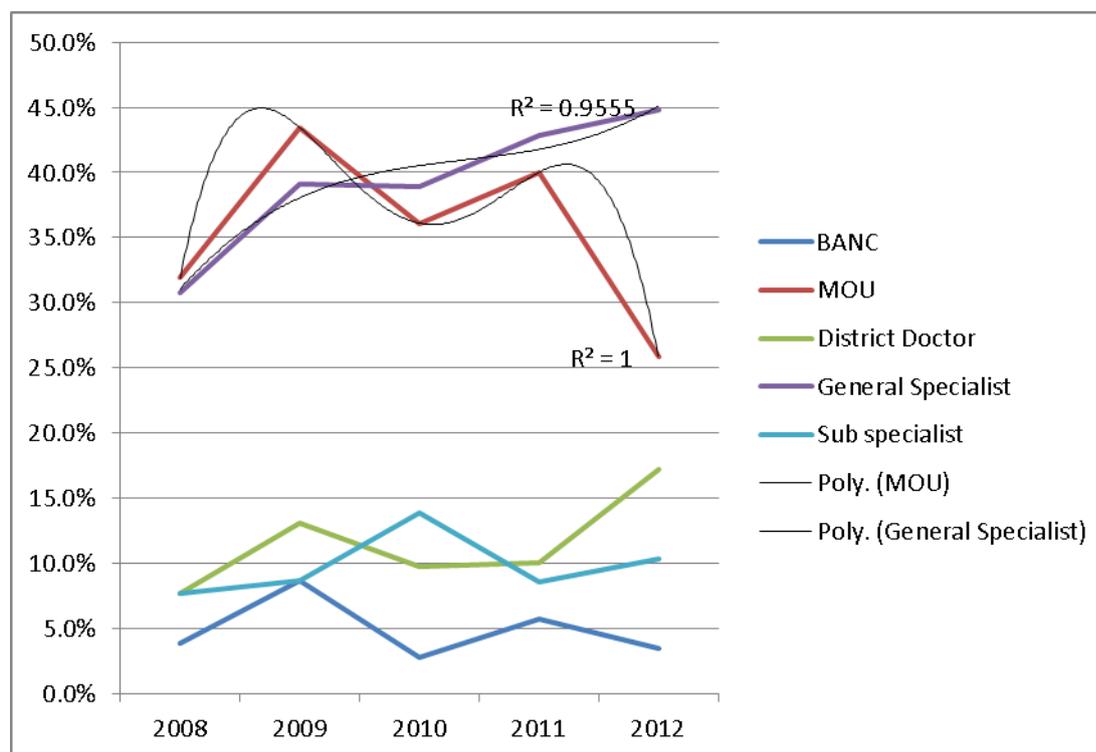


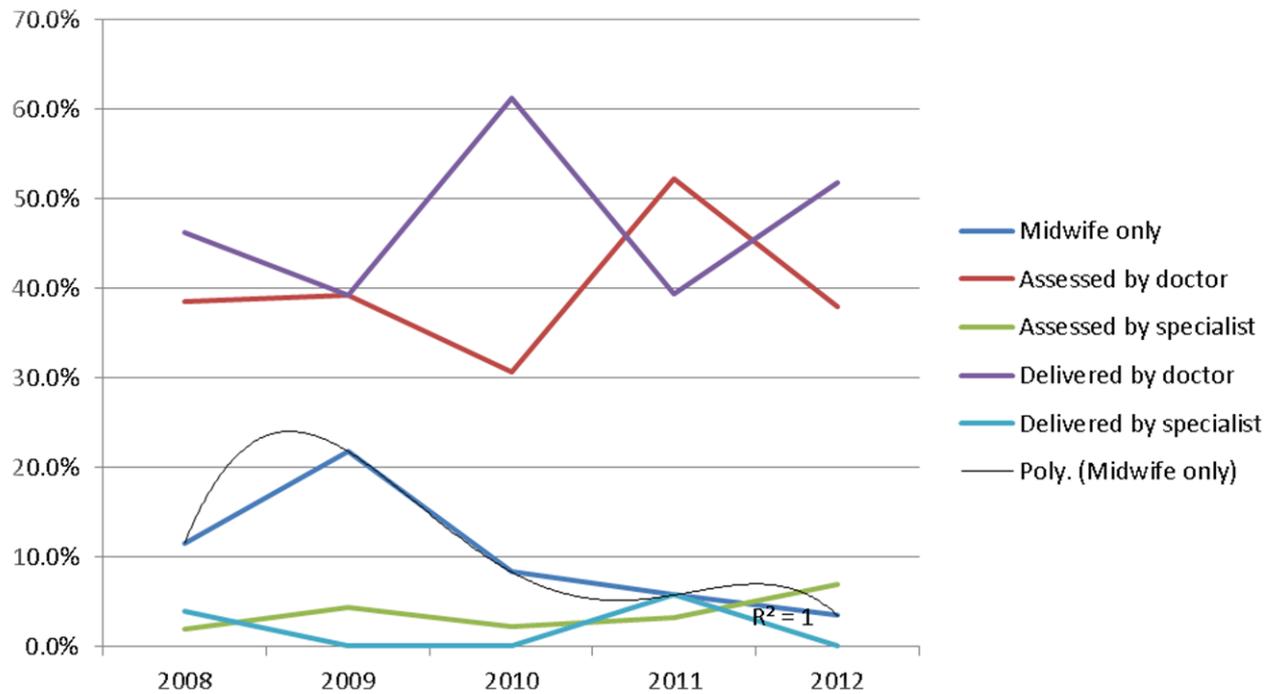
Figure 3.4.3 shows where these patients are subsequently managed after booking, but before the incident leading to admission for delivery at the central hospital. The number of women attending clinic at a specialist level has increased from 32.5% to almost 45% by 2012. There was a concomitant drop in women receiving care at the community level and a small increase in women managed at district doctor level. By 2012, 10% of antenatal care in Tygerberg hospital was provided by subspecialists. This include rural patients who attend the special care clinics for medical disorders or complicated diabetes. It also indicates (when compared to Figure 3.4.1) that many women who are known patients at Tygerberg antenatal clinic gain access to emergency transport (when they go in labour or experience sudden complications) from their closest MOU and not from home.

Figure 3.4.3. Level of care of antenatal provision (after booking but before delivery).



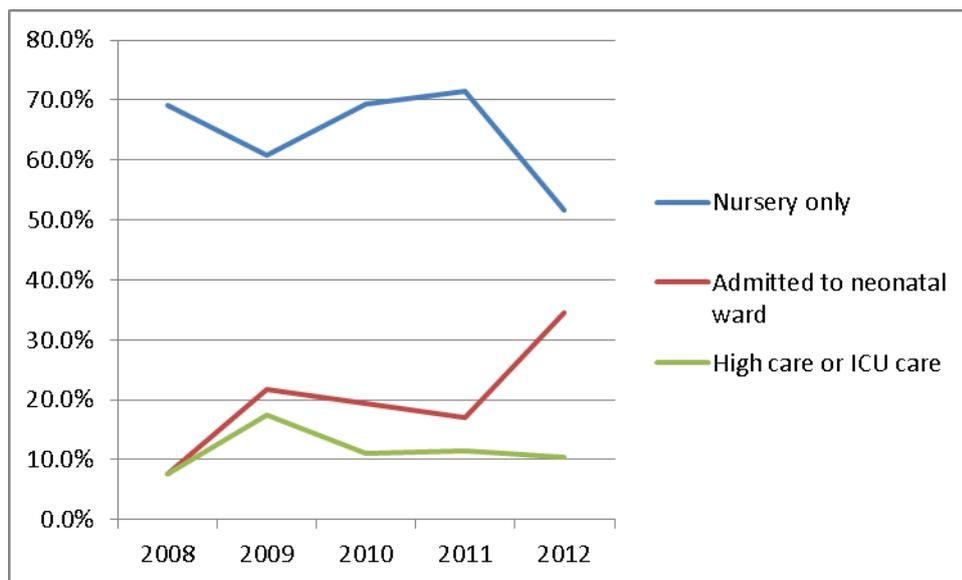
The involvement of medical personnel in the actual delivery is shown in Figure 3.4.4. The number of women in Tygerberg hospital delivered by a midwife only (without any intervention from a doctor) steadily decreased from 2008 to 2012. Doctors (medical officer or registrar) delivered more than 40% of all women and for a further one-third of women they provided intra-partum assistance or assessment. Women who delivered at Tygerberg hospital but did not need specialist attention (according to the levels of care) amounted to 1.2% of all deliveries.

Figure 3.4.4. Health care worker performing the delivery at Tygerberg hospital 2008-2012.



The immediate admission of the baby after delivery at Tygerberg hospital is shown in Figure 3.4.5. The number of babies who required no intervention from a doctor (baby stayed with the mother or in the postnatal ward nursery only) decreased from 70% to around 50% by 2012. Almost half of babies born to level 2/level 3 mothers needed the care of a neonatal team.

Figure 3.4.5 Level of care of neonates directly after delivery at Tygerberg hospital.



The model used to calculate bed numbers was tested with the actual deliveries in 2008 and 2012 to validate its use for future planning (Table 3.4.1).

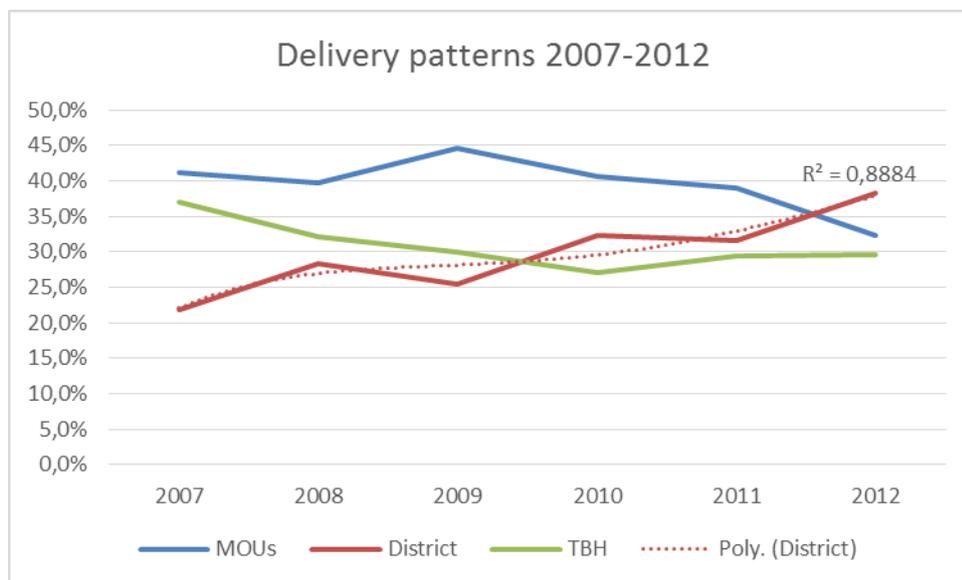
Table 3.4.1. Expected vs. actual delivery numbers 2009-2012 at Khayelitsha hospital.

	Modelling	Expected number of deliveries per year	Actual number of deliveries during 2008-2012
Khayelitsha phase 1 (2008/9)	118 per month	1416 per year	917* (2009)
			993* (2010)
			1314 (2011)
Khayelitsha phase 2 (2012)	Additional 1800 per year	3216 per year	3173 (2012)

\*Most Khayelitsha CS was still entered in the Tygerberg hospital labour ward register as both hospitals used the same emergency theatre.

By 2012, the pattern of deliveries according to the levels of care has changed and is shown in Figure 3.4.6. The percentage of women needing delivery in the central hospital has decreased from 42% to 32% and an increase is seen at district hospital level from 22% to 38%. Less than 35% of deliveries was at the MOUs by 2012. To determine the reason for the decline of low risk MOU deliveries, a folder review was undertaken at Karl Bremer hospital in 2012, to investigate the patterns of referrals to Karl Bremer. This is reported in Chapter 4. The change in delivery pattern and the reasons why they occur should be taken into account for future service planning.

Figure 3.4.6. Delivery pattern across Metro East: place of delivery 2007-2012.



### 3.5 The impact of regionalisation on Tygerberg hospital.

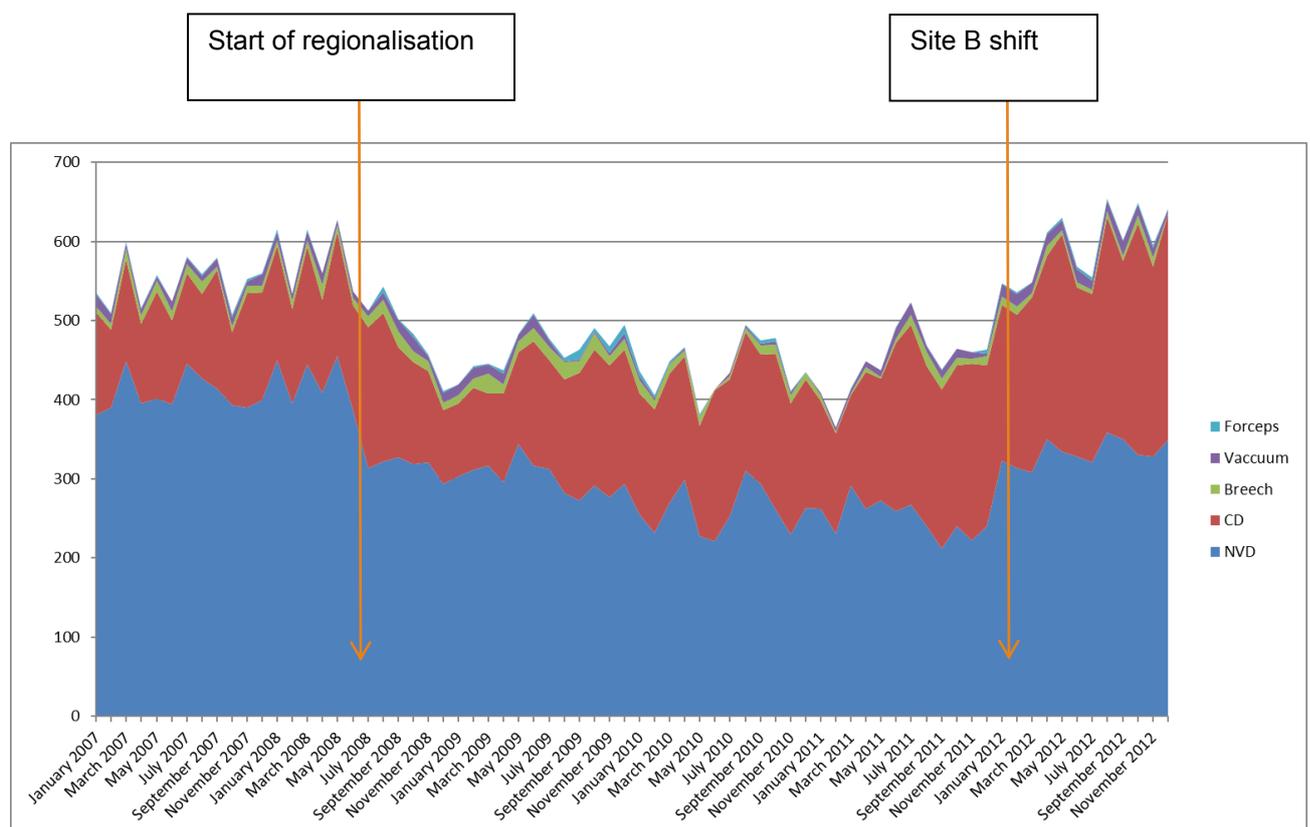
The impact of regionalisation on Tygerberg hospital was monitored by analysing the trends in method of deliveries, CS rates and neonatal and maternal mortality. There were two key steps in the impact, the service (level of care) shifts in July 2008 and the take-over of the Site B municipal district in March 2012. Whilst the 2008 shifts did not increase the case load, the 2012 shifts would add an additional case load to the services provided in Metro East.

There is not an electronic patient information system currently in place at Tygerberg hospital that captures every delivery. Routine hospital delivery data is derived by hand counting from the labour ward registers. This process is inaccurate as it relies on clerks without medical knowledge interpreting some clinical data. A parallel process is used for the perinatal mortality and morbidity database (Perinatal Problem Identification Program, PPIP(16)), where the same deliveries are counted by clinicians. There are often major discrepancies in the data and it is difficult to determine which is correct. To correct for this, for the purpose of this study and for future data collection at Tygerberg hospital, the delivery information of all women who delivered in the 6 years between January 2007 and December 2012 were obtained from the delivery registers and entered into a large Microsoft Excel™ database. This not only allows for accurate calculation of rates and numbers per weight category with the use of formulas, but also assist the verification of data using folder numbers across various databases.

CS rates were calculated using the number of deliveries in the hospital as denominator, but also with all the deliveries in the referral (drainage) area to work out the population based rates. Delivery numbers from the district services were obtained from routinely collected provincial data. Perinatal mortality numbers were obtained from the Tygerberg hospital PPIP database and maternal mortality numbers from the routinely collected mortality data at Tygerberg hospital.

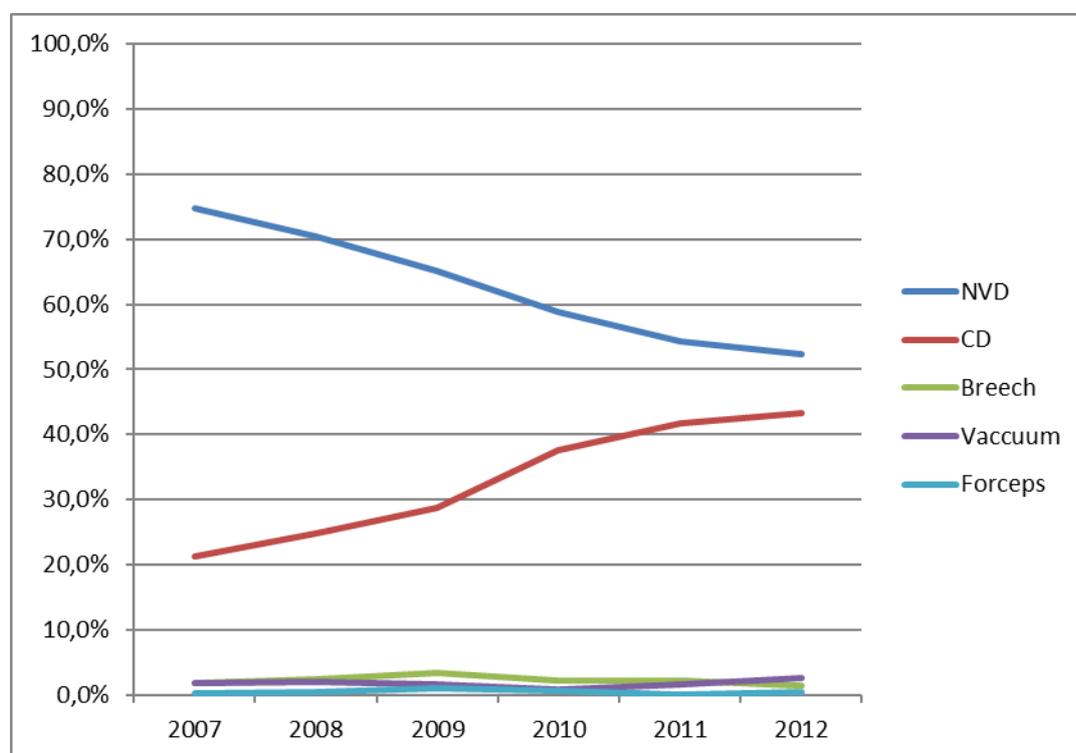
The changing pattern in deliveries at Tygerberg hospital is shown as a stacked area chart in Figure 3.5.1. This chart displays the relationship of the different delivery methods to the total number of deliveries over time. These are the actual delivery numbers and show the decline in numbers of normal vaginal deliveries after July 2008. With the addition of the Site B half of the Khayelitsha sub-district in 2012, there was a marked increase in the number of deliveries as well as CS, a change that was expected and prepared for.

Figure 3.5.1 Trends in deliveries at Tygerberg hospital, 2007-2012.



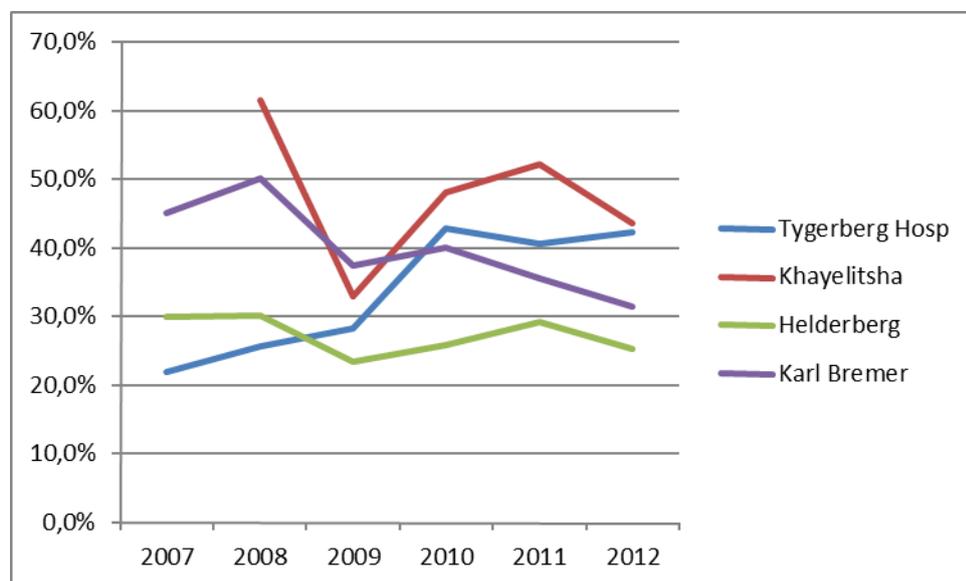
A more unassuming graph (Figure 3.5.2) shows the complexity of deliveries at Tygerberg hospital, with a decrease in the number of vaginal deliveries and an increase in the number of CS.

Figure 3.5.2. Method of delivery at Tygerberg hospital, 2007-2012.



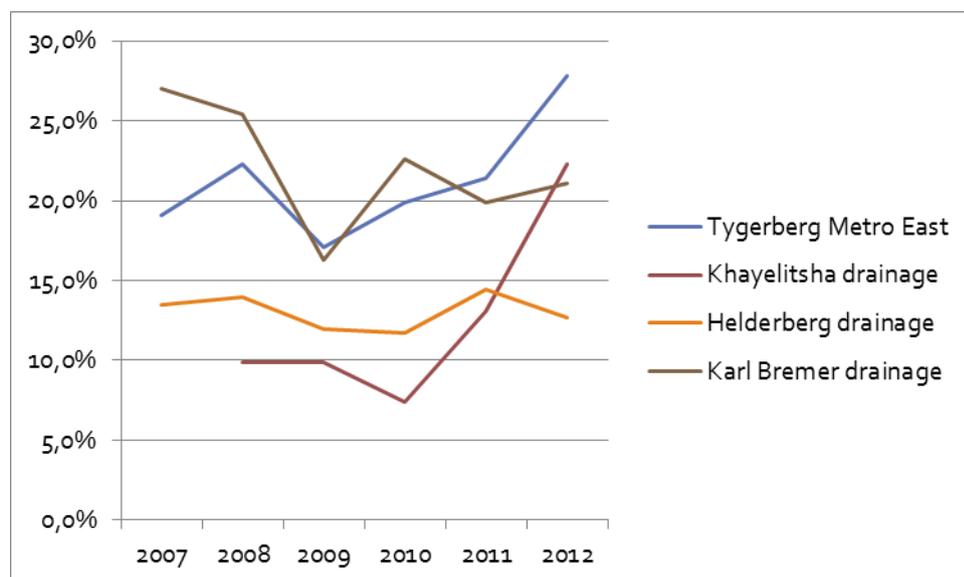
The CS rates for the different hospitals (hospital population only) are shown in Figure 3.5.3. The fledgling Khayelitsha hospital only started with a few deliveries in July 2008, mostly patients referred from Michael Mapongwana MOU to Khayelitsha hospital that required a CS, as the new doctors was still being trained in safe surgical delivery. The initial CS rate of 63% for 2008 must be interpreted in this light. The CS rate at Karl Bremer hospital declined after the change to a district level hospital and subsequent to a decline from 2008 to 2009 an increase is seen at the new hospital (Khayelitsha). At the referral hospital (Tygerberg) an increase is seen as the level one (district hospital) patients are no longer taken care of in this hospital.

Figure 3.5.3 Hospital-based Caesarean section rates 2007-2012.



As Tygerberg is a referral hospital only, a CS rate for the hospital alone will not be reliable as there are CS taking place at other hospitals within the drainage. A more accurate analysis of the CS rate must include all deliveries and CS in a geographical area. This is shown in Figure 3.5.4. The complete Tygerberg hospital drainage is represented as Metro East and include all deliveries and all CS in the metropolitan area served by Tygerberg hospital as a referral hospital.

Figure 3.5.4. CS rates for the various hospital drainage areas.



Since 2009, the CS rate has increased in Metro East for all three hospitals within the drainage area of the service shifts. There was no service shifts at Helderberg hospital and the rate has stayed constant during the period. Helderberg is included in the graph as they contribute to the full Metro East picture. CS rates are further discussed in Chapter 7.

The distribution of perinatal mortality according to weight categories in the PPIP program follows that of the provincial and national indicator sets (e.g. 500-999g, 1000-1499g etc). While this is useful for comparing data sets across the province, and for excluding the <1000g babies from perinatal mortality statistics, it is less useful when analysing trends for babies born at the limits of viability. Analysing data per 100g category for the birth weights 500g-1400g is analogous to the limits used by international databases such as the Vermont Oxford database (17). The Tygerberg hospital data was therefore separated into these birth categories (501g-600g, 601g-700g etc.) before analysis. The number of births (live births, still births as well as neonatal mortality) for these categories are shown in Table 3.5.1. Only babies born within Tygerberg hospital were included for the perinatal outcome analysis and not referrals born elsewhere, as they will be counted in the PPIP database of their birth hospital.

Table 3.5.1 Births at Tygerberg hospital 2007-2012 500g-1400g and &gt;1400g.

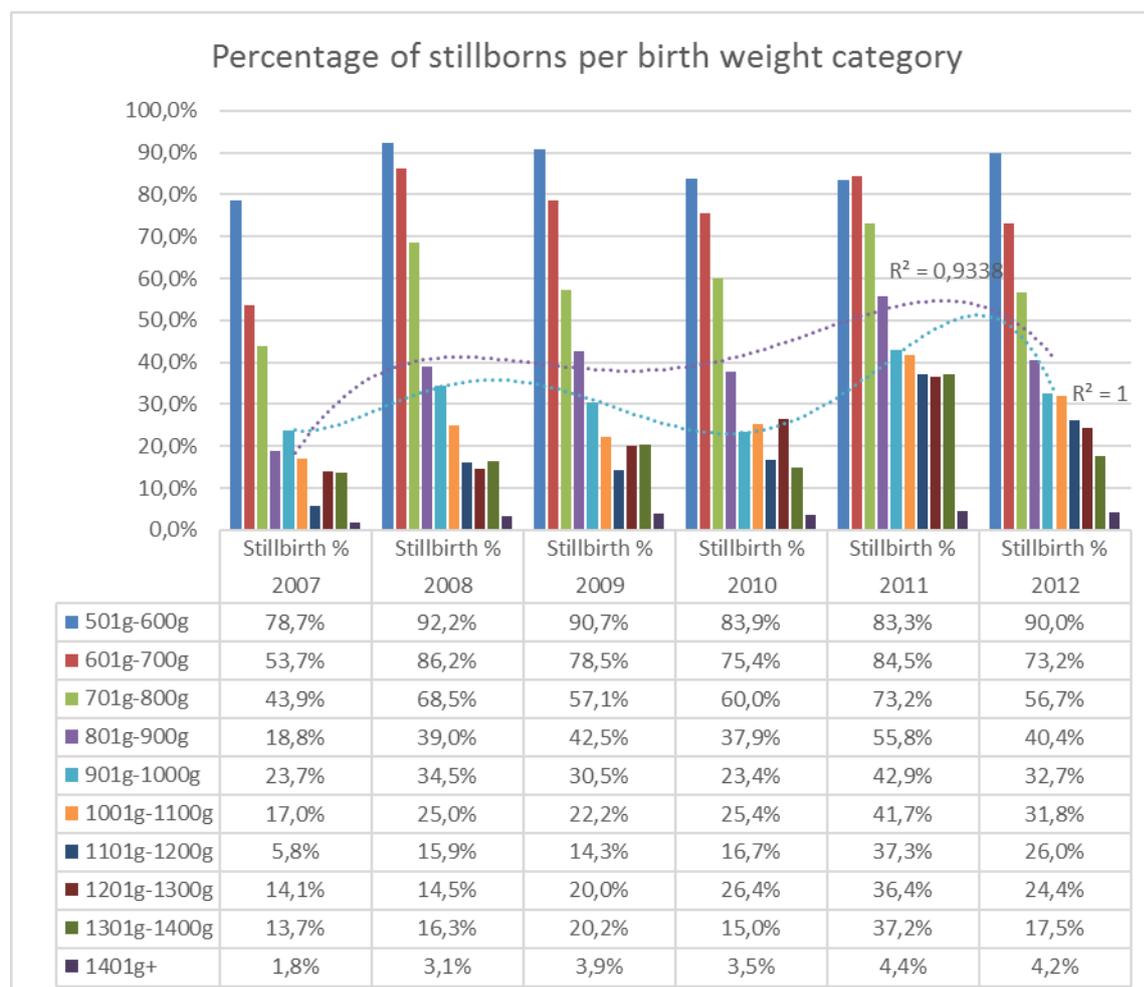
		501g- 600g	601g- 700g	701g- 800g	801g- 900g	901g- 1000g	1001g- 1100g	1101g- 1200g	1201g- 1300g	1301g- 1400g	1401g+	Total
2007	Births	47	54	57	64	59	53	69	71	73	7311	7858
2007	Live births	10	25	32	52	45	44	65	61	63	7208	7605
2007	ENND	10	9	11	6	3	8	3	2	2	26	81
2007	LNND	0	0	2	0	1	1	0	0	0	1	5
2008	Births	64	58	54	59	58	64	69	69	86	7072	7653
2008	Live births	5	8	17	36	38	48	58	59	72	6898	7239
2008	ENND	5	7	12	13	5	7	4	1	3	35	92
2008	LNND	0	0	2	3	2	4	1	0	1	7	20
2009	Births	75	65	70	80	95	81	84	85	94	5278	6007
2009	Live births	7	14	30	46	66	63	72	68	75	5106	5547
2009	ENND	5	6	10	12	9	4	5	1	1	41	94
2009	LNND	1	1	5	6	2	3	4	4	1	11	38
2010	Births	87	57	60	66	77	71	72	72	80	5415	6057
2010	Live births	14	14	24	41	59	53	60	53	68	5266	5652
2010	ENND	11	9	9	10	9	7	5	0	1	29	90
2010	LNND	2	1	4	5	3	2	1	0	1	2	21
2011	Births	66	71	56	43	42	72	51	44	43	5596	6084
2011	Live births	11	11	15	19	24	42	32	28	27	5461	5670
2011	ENND	9	10	9	7	12	8	4	1	2	28	90
2011	LNND	1	1	4	4	3	0	1	1	2	9	26
2012	Births	70	82	67	47	52	66	73	45	57	7017	7576
2012	Live births	7	22	29	28	35	45	54	34	47	6866	7167
2012	ENND	6	18	21	11	3	2	5	3	1	39	109
2012	LNND	1	3	4	2	4	3	2	1	0	5	25

ENND (early neonatal death; within 7 days after birth) LNND (late neonatal death, after 7 days but within the first 28 days).

A graphic representation of the stillbirths per birth weight category is shown in Figure 3.5.5.

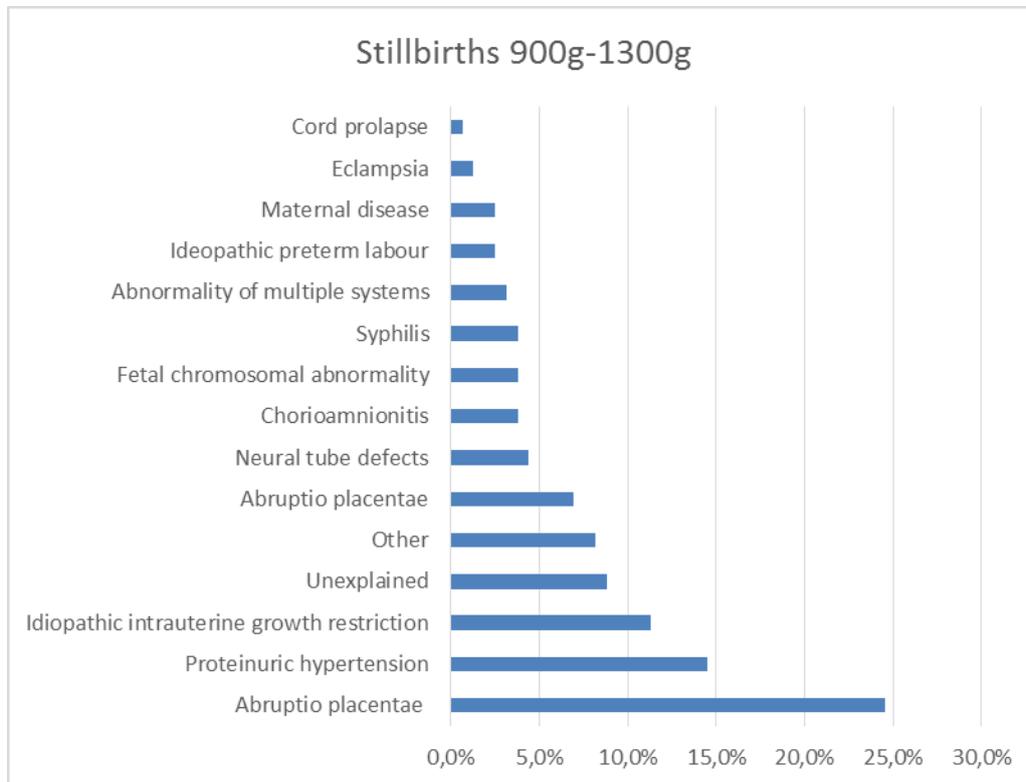
There was an apparent increase in stillbirths in the weight category 900g-1300g in 2011 and 2012 as shown by the trend lines. There were 151 stillbirths during these two years in this weight bracket (n= 37 in 2007; n=57 in 2008; n=76 in 2009; n=67 in 2010; n=83 in 2011; n=68 in 2012).

Figure 3.5.5. Stillbirths per weight category, Tygerberg hospital 2007-2012.



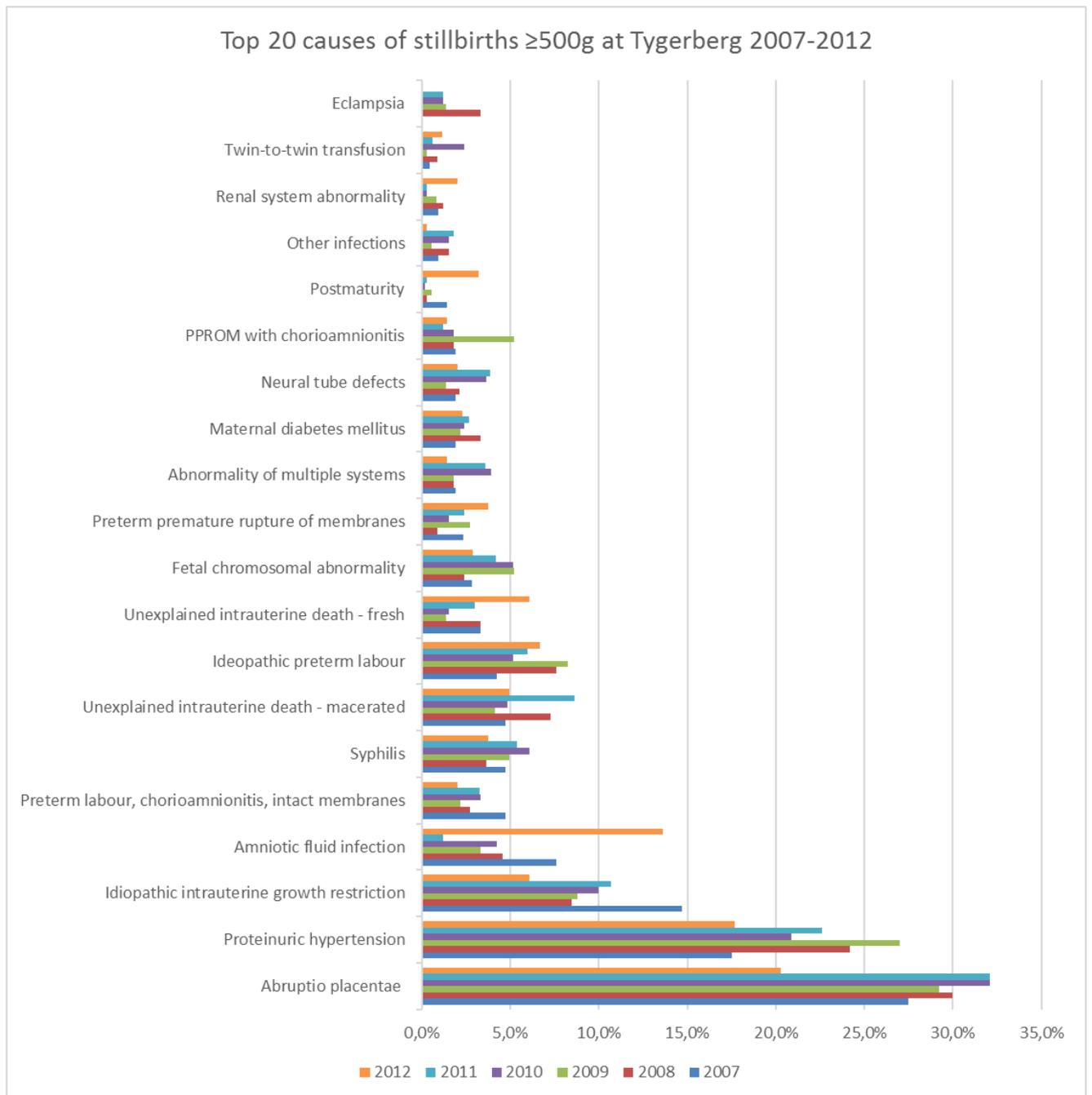
These stillbirths (900-1300g during 2011 and 2012) were analysed separately to see if there were any reason for a specific increase. This is shown in Figure 3.5.6. The main reasons for these deaths were abruptio placentae accounted (25% of deaths) but the causes of death were the same as for the larger group except that there were more unexplained intra-uterine deaths.

Figure 3.5.6. Stillbirths in the weight category 900g-1300g; 2011-2012, Tygerberg hospital.



The PPIP program classify deaths according to the primary cause (the obstetric event leading to the death) and the final cause (the neonatal reason why the baby died). Various other classification systems exist for categorising stillbirths and these are discussed in Chapter 8. The main single primary causes of stillbirths are shown in Figure 3.5.7. Analysis of causes grouped into diagnostic categories are further explored in Chapter 8.

Figure 3.5.7 Top 20 causes of stillbirths at Tygerberg hospital, 2007-2012.



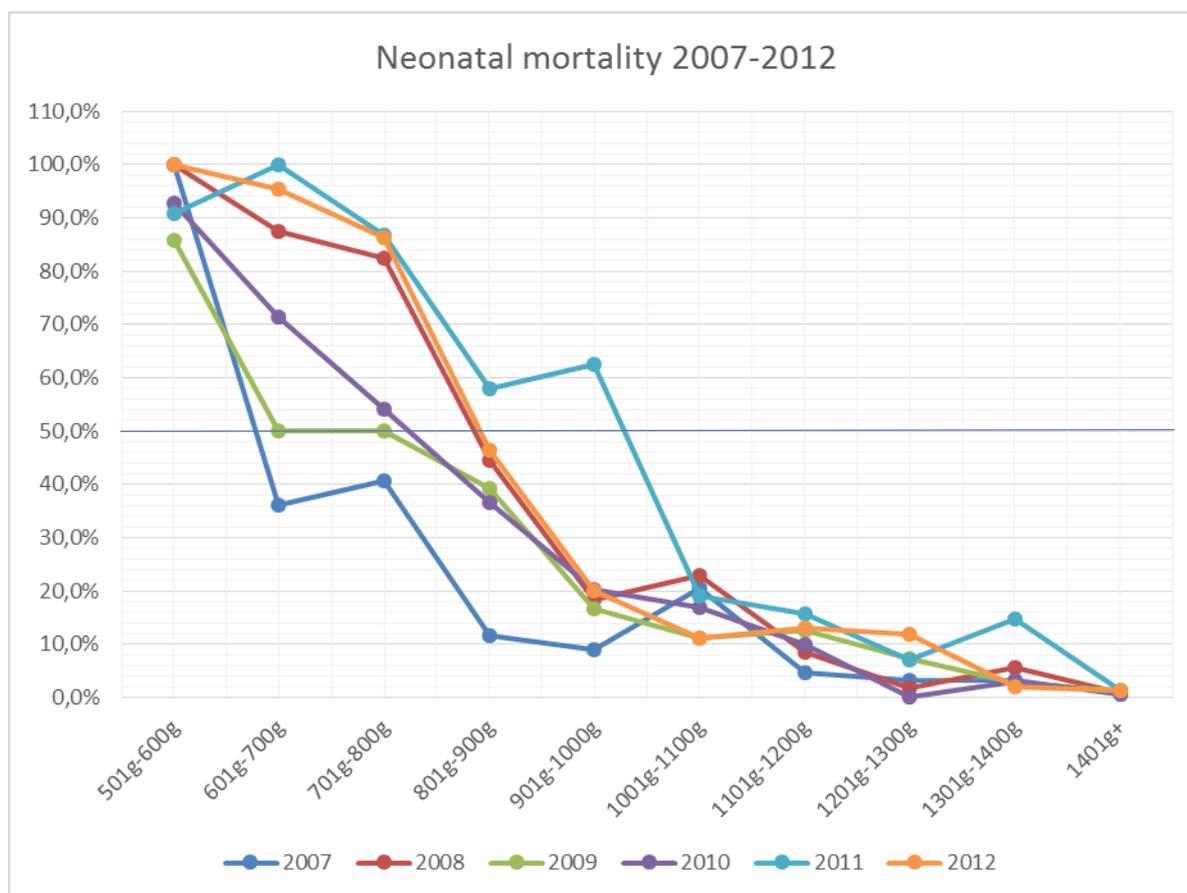
The mortality figures derived by aligning the neonatal deaths according to weight categories in the PPIP database, with their respective live birth weight categories from the Tygerberg hospital labour ward data is shown in Table 3.5.2 and a graphical representation in Figure 3.5.8.

Table 3.5.2 Live births and mortality at Tygerberg hospital 2007-2012 according to weight categories (death 0-28 days after birth).

		501g- 600g	601g- 700g	701g- 800g	801g- 900g	901g- 1000g	1001g- 1100g	1101g- 1200g	1201g- 1300g	1301g- 1400g	1401g+
2007	Live births	10	25	32	52	45	44	65	61	63	7605
2007	Mortality	100,0%	36,0%	40,6%	11,5%	8,9%	20,5%	4,6%	3,3%	3,2%	0,5%
2008	Live births	5	8	17	36	38	48	58	59	72	7239
2008	Mortality	100,0%	87,5%	82,4%	44,4%	18,4%	22,9%	8,6%	1,7%	5,6%	0,8%
2009	Live births	7	14	30	46	66	63	72	68	75	5547
2009	Mortality	85,7%	50,0%	50,0%	39,1%	16,7%	11,1%	12,5%	7,4%	2,7%	1,2%
2010	Live births	14	14	24	41	59	53	60	53	68	5652
2010	Mortality	92,9%	71,4%	54,2%	36,6%	20,3%	17,0%	10,0%	0,0%	2,9%	0,8%
2011	Live births	11	11	15	19	24	42	32	28	27	5670
2011	Mortality	90,9%	100,0%	86,7%	57,9%	62,5%	19,0%	15,6%	7,1%	14,8%	1,3%
2012	Live births	7	22	29	28	35	45	54	34	47	7167
2012	Mortality	100,0%	95,5%	86,2%	46,4%	20,0%	11,1%	13,0%	11,8%	2,1%	1,3%

Mortality is the percentage of live births that died within 28 days after delivery (most were early neonatal deaths)

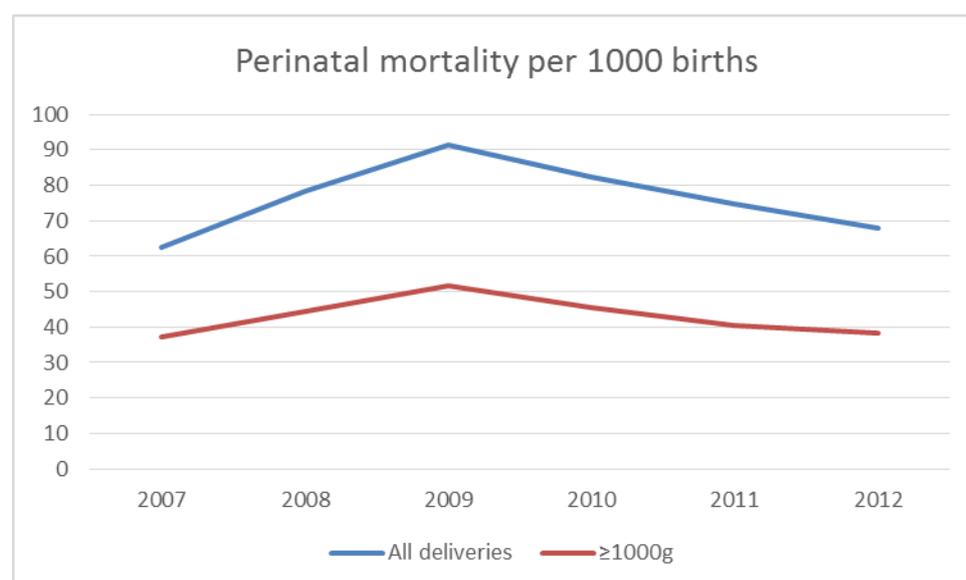
Figure 3.5.8 Neonatal mortality for births at Tygerberg hospital, 2007-2012.



It is evident from this graph that with only a few exceptions, more than 80% of babies born in Tygerberg hospital with a birthweight above 900g survived to discharge. The biggest difference could be seen in the 600g-800g birthweight group, who had mortality below 50% before regionalisation. This is a reflection of the increase in the number of deliveries from women referred with complicated pregnancies after July 2008. The increase exceeded the capacity of the neonatal high care and intensive care wards at Tygerberg hospital. There was not an increase in neonatal beds or personnel during the 2008 service shifts because (as with obstetrics) it was a resource-neutral shift. There was a capacity increase for the 2012 addition of Site B to the hospital drainage. By 2012, more than 50% of babies delivered with a birthweight above 800g survived.

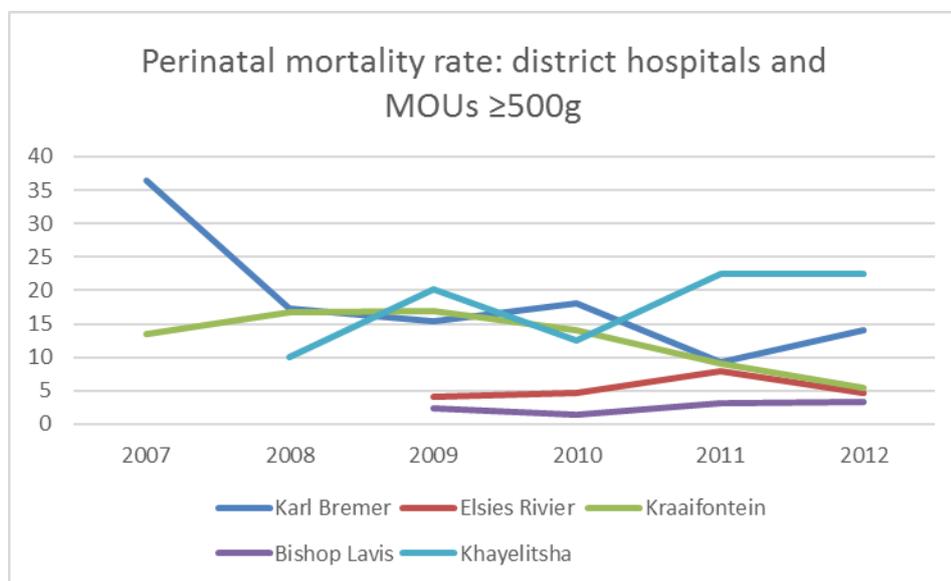
The perinatal mortality rate (calculated as the sum of stillbirths and early neonatal deaths divided by all births, per 1000 deliveries and expressed as either all births  $\geq 500\text{g}$  or  $\geq 1000\text{g}$ ) changed from 2007 to 2012 with a peak during 2009. This is shown in Figure 3.5.9. One of the likely reasons was that the newly opened Khayelitsha hospital within the Tygerberg hospital infrastructure delivered their complicated cases in the Tygerberg hospital theatres and these deliveries were counted in the Tygerberg hospital statistics, but the vaginal Khayelitsha deliveries were not added to the denominator as it was not possible to separate these deliveries from the Tygerberg labour ward statistics. From 2010 they were entered into a separate Khayelitsha register and there was a continued decrease in perinatal mortality rates after that.

Figure 3.5.9 Perinatal mortality rate for Tygerberg hospital births 2007-2012.



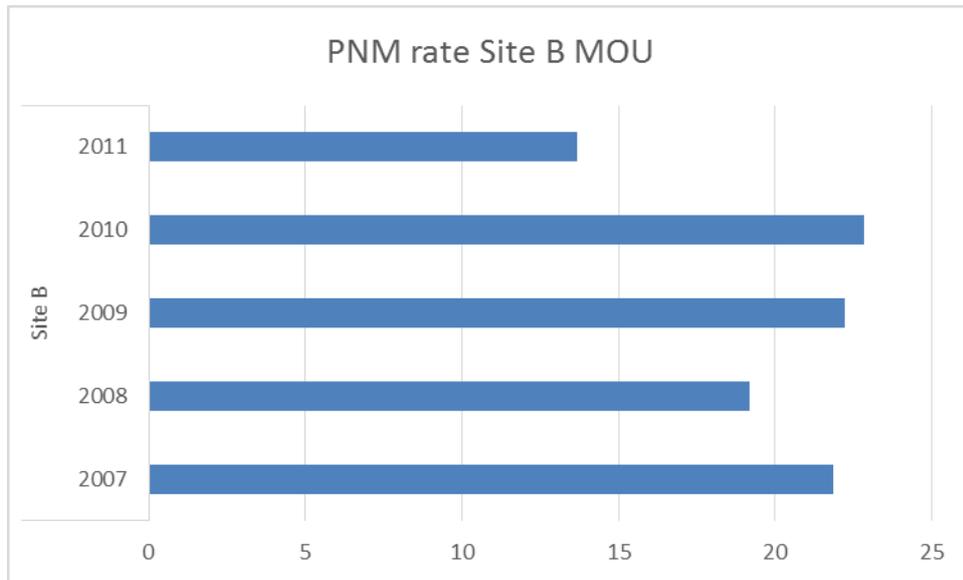
As with CS, perinatal mortality rates should ideally be population based and not hospital based, as a decrease in mortality at the referral hospital could also reflect barriers to access the service, with babies dying at the primary care hospital. The delivery and perinatal mortality numbers for the drainage hospitals was obtained with permission from the provincial PPIP office. The perinatal mortality (PNM) rate for the hospitals involved in the service shifts is shown in Figure 3.5.10.

Figure 3.5.10 PNM rate in the catchment area (excluding Tygerberg hospital; all births  $\geq 500\text{g}$ ).



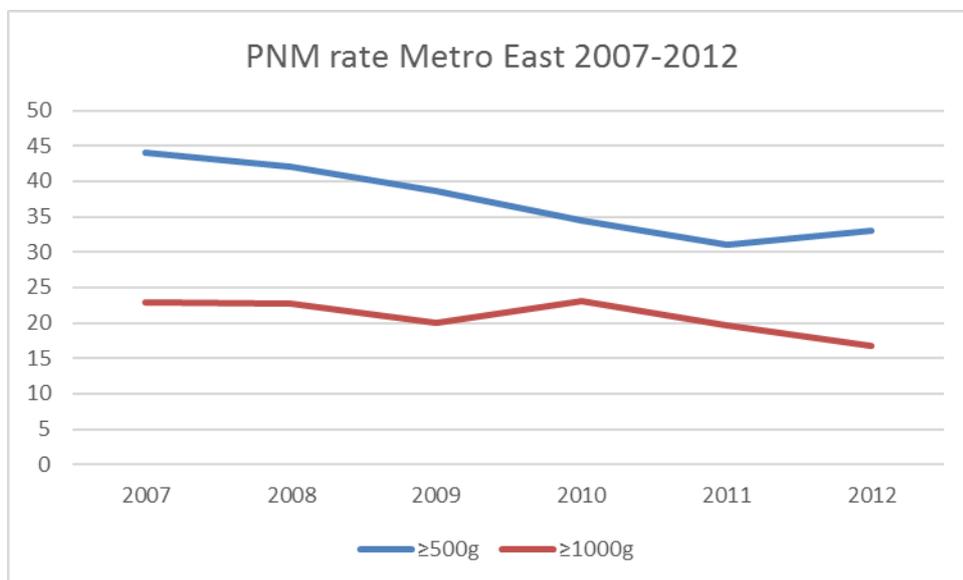
The number of stillbirths and neonatal deaths at the MOUs are small- about 2 per month. The exception is Site B MOU, where the PNM rate before the drainage changed to Metro East was 20 per 1000 or more for babies  $\geq 500\text{g}$  (Figure 3.5.11). From 2012, these numbers are included in the Metro East statistics.

Figure 3.5.11 PNM rate at Site B MOU (all births  $\geq 500\text{g}$ ).



The total perinatal mortality rate for all deliveries in Metro East over the period 2007-2012 is shown in Figure 3.5.12.

Figure 3.5.12. Perinatal Mortality Rate in Metro East 2007-2012.



There was a decline overall in the perinatal mortality rate during the study period which can be attributed to many factors, including overall improvement in clinical care as technology develops. A number of babies born at Site B MOU and Khayelitsha hospital were referred to

Groote Schuur hospital for neonatal management, but this will not influence the PPIP data as deaths are captured at the place of delivery and not of death. No in-utero transfers were made from Khayelitsha hospital to Groote Schuur hospital. As most of the neonatal deaths (76%) and stillbirths (77%) occurred in Tygerberg hospital, the decrease seen in Metro East is largely attributed to the decline at Tygerberg hospital.

The number of maternal deaths in the Western Cape is low with a maternal mortality ratio (MMR; 75.9 per 100 000 deliveries in 2011-2013) well below the national average (MMR of 158.3) (18). As maternal death is a rare occurrence, it cannot be used as an indicator of safety. Nevertheless, the yearly number of maternal deaths reported in the Tygerberg hospital drainage during 2007-2012 did not change much. The increase seen during 2009 was attributed to the H1N1 pandemic during that year and is discussed in the comprehensive Saving Mother's report (19). The number of maternal deaths as well as the MMR for this drainage area only (Metro East) is shown in Table 3.5.3. Maternal mortality at Tygerberg hospital and within the Western Cape province is discussed in more detail in Chapters 5 and 10.

Table 3.5.3 Number of maternal deaths in Metro East during 2007-2013.

	Tygerberg hospital	Rest of drainage	Total number of deaths
2007	17	2	19
2008	11	5	16
2009	20	9	29
2010	15	7	22
2011	14	7	21
2012	17	7	24

### 3.6 Conclusions.

This chapter describes a journey that started during 2007 and concluded during the latter part of 2012. This is the first recent documentation of service shifts and their impact in maternity care in South Africa. The WHO estimates that at least 15% of pregnant women will require specialist intervention at some stage during their pregnancy to avoid death or serious morbidity (20). This evaluation is in agreement with that (starting out with a specialist intervention of 17.2% in 2007). By including all the rural deliveries in the Western Cape including the rural regional hospital data, the number of deliveries at specialist level during 2007 was 13.8%; but due to the vast distances separating women from regional hospitals it may be an underestimation. By 2012, it was evident that more women in Metro East received the attention of a specialist during their pregnancy or delivery. Only 1.2% of patients delivered at specialist level were at the 'wrong' level of care (they could have been redirected to a less specialised level during the antenatal period), confirming a perceptible increase in complicated pregnancies since 2007.

Using provincial delivery data for 2014, 32.5% of deliveries in the metro were in the MOUs, 44.4% in district hospitals, 15.3% in regional and 7.8% needed tertiary care. This equates to 23% of patients needing the attention of a specialist by the time they deliver. A large number of these are patient with a high body mass index (BMI). A BMI of 40 or more (morbid obesity) is delivered at specialist level, as they have more complications during labour (including anaesthetic concerns) (21). The increase in deliveries at specialist level could reflect the increasing trend of obesity in South Africa (22). It may also indicate that women now have better access to care and that some complexities may previously have been managed at a lesser level of care than they deserved. The numbers of women referred for specialist care is still lower than that reported in developed countries: specialist referral rates from doctor-led practices of around 35% were reported in the United States (23)(24)(25).

As more than 80% of women managed at Tygerberg hospital booked at primary care level, 45% received specialist care during their pregnancy and only 30% of women in Metro East delivered at Tygerberg hospital it shows a good utilisation of the levels of care in all directions. The number of deliveries at MOUs have stabilised at 32% by 2014, but there was an increase in deliveries at district hospitals, who now manages almost half of all pregnant women in the metropolitan Cape Town. The future focus of health care worker training should include the nuances specific to management at district level and the large metro district hospitals must be included in undergraduate and postgraduate student training programs.

In a developed country, where the CS rate at non-specialist doctor-led delivery units was compared to midwife-led and consultant-led units, there was no difference in total operative deliveries between the three units: 16.3% in a midwife-led unit; 18.0% in the doctor-led unit; and 18.8% in the consultant-led unit (26). In this analysis, CS rates for district and central hospitals has not stabilised yet and this trend will need continuous monitoring. CS in South Africa is not a safe procedure (27) and ongoing training of health care workers should focus on doctors working in district hospitals, as the bulk of deliveries and CS will take place here. The minimum standards for safe CS in South Africa was set recently (28).

Viability is historically defined as that gestational age where 50% of babies born will have a reasonable chance of survival. Viability is defined differently in different socioeconomic environments. In high income countries the threshold of can be anything from 22 weeks with 24-25 weeks gestational age most often used. There is not currently a worldwide, uniform gestational age that defines viability. This variation is driven by resource constraints and the availability of neonatal intensive care units. In South Africa, with the best case public sector scenario (tertiary hospitals), survival is <50% for babies born with a birth weight 801-900g (slightly better in the Western Cape). Nationally, about 50% of babies born at a birth weight

of >900g and managed under ideal conditions will survive to discharge. In the Western Cape this limit may be set lower due to the existing infrastructure and high level of neonatal care. A summary of data from South African centres is presented in Table 3.6.1. The best survival was in a study from Tygerberg hospital and the analyses presented here supports setting the lower limit of viability in this hospital at 800g.

Table 3.6.1. Survival of neonates born at the limits of viability in South African tertiary hospitals.

Birth weight	Mortality	Hospital
801-900g	63%	Chris Hani Baragwanath hospital (29)
801-900g	62%	Charlotte Maxeke Johannesburg Academic hospital 2006-2010 (30)
801-900g	72%	Charlotte Maxeke Johannesburg Academic hospital 2006-2007 (31)
801-900g	30.4%	Groote Schuur hospital 2014 (Dr N Rhoda, personal communication)
<750 g	44%	Tygerberg hospital 2007-2009 (32)
780g	50%	Tygerberg hospital 2012 (this analysis)

This analysis did not focus on morbidity markers, but the author did participate in an ongoing audit of babies born with asphyxia at the new Khayelitsha hospital since 2012 when it opened its doors to the Site B MOU as well. Due to a lack of capacity at Tygerberg hospital neonatology, babies with complications from Site B (after delivery) were still redirected along its previous routes to Groote Schuur hospital neonatal ICU. The rate of babies born with hypoxic ischaemic encephalopathy (HIE) was 7.9 per 1000 in the first year and dropped to 6.2 per 1000 by 2014. The neonatal death rate from HIE is 3.6 per 1000 in South Africa (33) and the rate of HIE seen at Khayelitsha was certainly the highest in the province amongst hospitals that actually measures this indicator. The causes for his high rate is multifactorial and still being investigated as part of an ongoing audit registered at Groote Schuur neonatology. The Site B MOU had more stillbirths than any of the other MOUs. The reasons

for the higher stillbirth rate is unclear. The underlying pathology and reasons need to be explored. Improved access to care may partially explain the decline.

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## Chapter 4

Clinical governance in a changing obstetric service: audit of a district hospital maternity service- Karl Bremer Hospital.

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## Chapter 4. Clinical governance in a changing obstetric service: audit of a district hospital maternity service- Karl Bremer Hospital.

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## 4.1 Introduction.

The model of doctor-led care and the role and function of the South African district hospital was described in chapter 2. This chapter will focus on the large Western Cape metropolitan district hospital model and specifically on Karl Bremer hospital, a large metropolitan district hospital providing maternity care in Metro East. Karl Bremer hospital has 12 antenatal beds, 27 postnatal beds and 6 delivery beds and the labour ward has a dedicated obstetric theatre. The hospital delivers more than 6000 women annually and receives referrals from four MOUs within its catchment area. The hospital is the only district hospital with maternity care in the Tygerberg and Northern municipal substructures of Cape Town and therefore receives referrals from more than one sub-district. A new hospital is envisaged for the Northern substructure in the future.

The re-engineering of the South African health service with its strong emphasis on the district hospital as the central hub in a specific geographical area (based on municipal wards) was described in chapter 2. The remodelling was planned with three interventions. The first intervention (also called 'streams') is ward-based primary health care outreach teams and the second integrated school health teams (1). The third intervention is district-based specialist teams that will oversee the clinical governance in a specific area but who will also do clinical outreach and support at all the district hospitals within their specific territory (2). Their first objective was to improve maternal, child and new-born care. A district clinical specialist team (DCST) would be located in each of the 52 health districts in South Africa and would consist of a family physician, obstetrician-gynaecologist, a primary health care nurse, an advanced midwife, a paediatrician and a paediatric nurse. Their roles and functions are described in a comprehensive DCST clinical governance manual (3).

There are two important differences in the Western Cape (WC) approach to the DCST concept. As discussed in chapter 2, the 6 health districts in the WC are organised into 5 geographical service delivery areas (GSA) each governed by a regional hospital with specialists in the major disciplines. These specialists do outreach to the district hospitals and clinics within their drainage area. They provide support to the family physician at the district hospital, who in turn do outreach and support to the surrounding clinics. This was already in place since the turn of the twenty-first century and the model was further developed and described in the comprehensive services plan (4).

The WC has the lowest poverty level of all the provinces (6.4% of the population live below the poverty line compared to 23.8% in KwaZulu Natal) (5). The province also has a far lower than average share of the rural population (about 10% of the WC population live in rural areas while the SA average is 42%) (6). Establishing a DCST in an area that already has a specialist overseeing the clinical governance in a mostly urbanised population living above the poverty line would not necessarily have the same impact as in the rural, under-resourced districts. In addition, it may create problems with the lines of responsibility. The province received national funding for 5 district specialists in September 2012 and these posts were used to strengthen the O&G departments of the regional hospitals in each GSA. By 2013 only 17 of the 52 national district obstetricians were appointed (of which all 5 posts in the WC were filled) (7).

There are risks involved in the appointment of O&G specialists outside of a regional or tertiary hospital. These include the loss of clinical skills, isolation from their peers in terms of clinical support and continuing education and a potential inability to retain specialists at this level of care. Many of the same concerns were voiced by Nathan and Rautenbach (7) in a critique of the DCST concept. The package of level one gynaecology care does not include laparoscopic surgery or major gynaecological procedures such as elective hysterectomy,

one of the keystones of regional and tertiary O&G skills. These were all reasons why the WC took a different approach to the DCST and rather used the DCST obstetricians to strengthen the regional teams.

The second major difference in the WC is the emphasis on the large metropolitan district hospital. These hospitals are significantly larger than the rural WC regional hospitals but are not staffed by specially trained family physicians instead of discipline-specific specialists (8). Family medicine became a new speciality in South Africa in 2007. This new cadre of specialists had 4 years of postgraduate training and was introduced in the district health service from 2011 (9). By 2014, analysis of the effect of family physician specialists on the district health system in the WC showed a significant impact on health system performance (10). A unique *family physician impact assessment tool* shows that their major impact is at clinical governance and service delivery level and not as much on community-orientated primary care (11).

During the development phase of the new Khayelitsha and Mitchell's Plain district hospitals there was concern from the academic O&G institutions that any maternity service, even at district hospital level may experience complications that will require the skills of an obstetrician-gynaecologist. These include intractable bleeding during routine, uncomplicated caesarean section (CS) that necessitates hysterectomy or other life-saving procedures that currently falls outside of the skills of a family physician (12). The question was how often this would occur and whether a specialist service should be provided on-site or via outreach.

Weinstein already proposed the idea of a hospital-based obstetrician to improve patient safety in 2003 (13). In this model, O&G specialists (called 'laborists') care for all women in the labour suite and manage obstetric emergencies, thereby relieving their private

practitioner colleagues from labour ward responsibilities (14). This model is very similar to the full-time public sector hospital O&G specialist platform in the regional hospitals in the Western Cape, where general O&G specialists support doctors and midwives in the labour ward with evidence based clinical protocols and management. This is also a model that would work well in the private O&G practice in South Africa, where medico-legal liability is crippling the service (see chapter 9).

With 39 district hospitals in the Western Cape alone, some very small, it is obvious that a full-time O&G specialist will not be feasible for all. As there were no norms available, a judgment call was made to staff all district hospitals where more than 200 deliveries are conducted per month with a permanent on-site O&G specialist during office hours and with an on-call specialist at night for life-threatening emergencies. This specialist will support the on-site family physician. The allocation of work would be clinical service delivery, teaching and on-site risk management by the O&G specialist with clinical governance, outreach and administrative functions overseen by the family physician. This was then implemented at Karl Bremer and Khayelitsha hospitals.

This district hospital-based specialist had a job description much the same as that of the recently established DCST but with an important difference. They would be hospital based and will have close co-operation between the general specialist team at the regional hospital. This model also puts the responsibility of risk management, protocol development, quality and performance improvement and standardisation of care in the hands of the on-site O&G specialist (15).

There are thus two closely-linked concepts- the regional (referral) hospital, staffed by O&G specialists and providing a specialist O&G service and the large metro district (primary care)

hospital, staffed by general doctors and a single O&G specialist providing a district level of care. The WC department of health produced a position paper in 2014 to delineate the clear difference between the two.

The service at Karl Bremer hospital follows this large metro district hospital model. There is a single O&G specialist and service delivery is provided by general medical officers supported by a family physician specialist. The theatre is staffed from the main theatre and therefore competes with other emergency cases in terms of availability of personnel. The package of care rendered is the district package (level 1). Karl Bremer hospital serves as a training platform for undergraduate students from Stellenbosch University but there is no postgraduate training program in the maternity service. After-hours consultant advice is available on a telephonic basis and an O&G specialist with a part-time appointment is on standby from home for intra-operative emergencies.

The hospital is only 3 km away from Tygerberg hospital, its secondary and tertiary referral hospital and the community clinics and MOUs are all within a radius of 10 km from the hospital. The four MOUs referring to Karl Bremer are Elsies Rivier, Bishop Lavis, Kraaifontein and Delft. There is an antenatal clinic for level 1 high risk women at the hospital and they manage less severe maternal disease (e.g. well controlled epilepsy or asthma, maternal age 47-50 years, poor fetal growth but normal Doppler etc.) according to the level of care policy. There is a neonatal nursery that can provide positive airway ventilation (CPAP) and the hospital has a general paediatrician that oversees the neonatal service. There is also capacity for kangaroo mother care (KMC).

The integral part that Karl Bremer hospital played in the maternity shifts in Metro East was discussed in Chapter 3. An analysis of the perinatal care at the hospital should therefor

demonstrate the typical activity of a large metropolitan hospital functioning according to the level 1 model. This was the main purpose of the audit reported in this chapter. Every hospital has its own internal issues regarding staffing norms, working hours and the number of beds that may not meet the need of the population, but the purpose of this audit was not to examine the idiosyncrasies of the specific maternity department.

Access to ultrasound is beneficial in the management of maternity services at district level as multiple pregnancies, placenta praevia and fetal anomalies can be referred for tertiary care in time and accurate gestation will reduce the number of deliveries for presumed post-term pregnancy. Ultrasound services are a scarce resource and are guided by a provincial policy to ensure appropriate utilisation of the service. The audit also investigated the use of ultrasound and adherence to the ultrasound policy of the Western Cape. A protocol violation was regarded as a request for ultrasound without a valid indication.

## 4.2 Objectives.

An audit of the O&G service at Karl Bremer hospital for a full month was undertaken to answer a few specific questions, some of them raised in Chapter 3:

- What are the exact levels of care (case mix) rendered at the district hospital?
- Why has there been a decline in deliveries at the MOUs since 2007?
- What are the barriers (if any) for referral to specialist services?
- Is there adherence to the provincial ultrasound policy?

Aspects of patient safety:

- What number of patients needed a specialist decision or intervention in their management?
- Is progress of labour plotted on a partogram and if a partogram was used, was it used correctly?
- What is the typical waiting time for CS (decision to delivery time) at a district hospital?
- What were the indications for induction of labour and how was it performed?
- What was oxytocin use during 1<sup>st</sup>, 2<sup>nd</sup> and 3<sup>rd</sup> stages of labour?
- How was fetal heart rate monitoring documented and acted on?

Quality of care aspects:

- What method of pain relief was used during delivery?
- Was an adequate discharge summary completed?
- What was the provision of family planning methods?

### 4.3 Methods.

This was a retrospective case note review of all admissions to the Karl Bremer hospital emergency obstetric unit during July 2012. The month of July was chosen to co-inside with the similar review done at Tygerberg during July 2012 and July can be regarded as a typical month with an average number of deliveries (refer to Figure 1.1.1). All admissions were analysed to determine the number of down referrals (back to MOU care), direct discharges (no acute problem needing admission), admission to the labour ward and referral to a more specialised level of care (Tygerberg Hospital). The admissions to labour ward were then scrutinised and clinical information extracted and entered into a similar Microsoft Excel™ database as used for the annual July folder review at Tygerberg hospital, with the addition of data elements on ultrasound services. The audit counted the most specialised (highest) level of care received even if it was only for a single visit to that level.

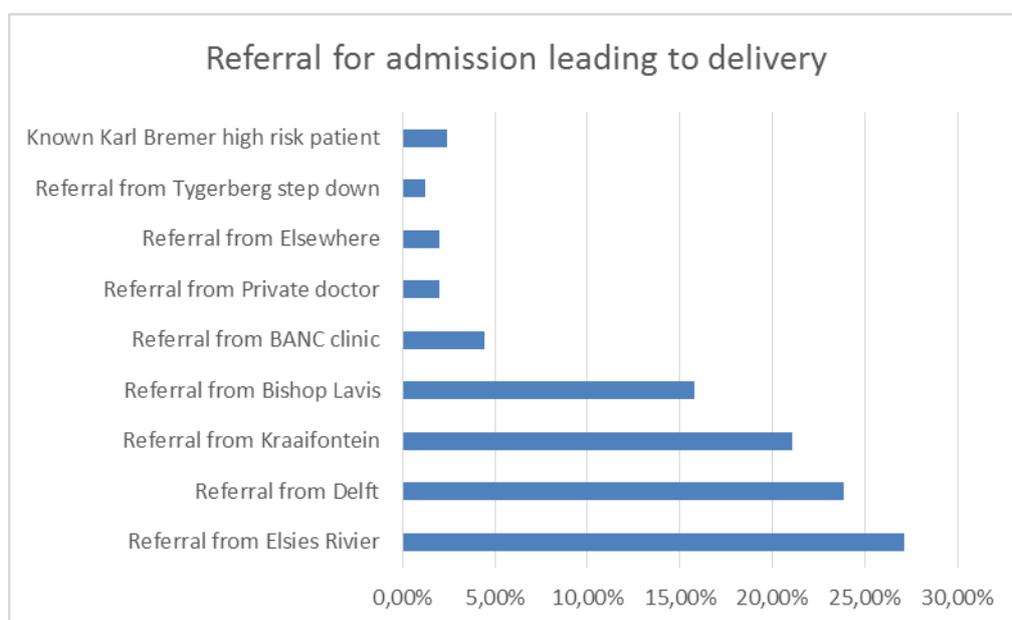
Partogram practise was audited for correct use using a standardised provincial audit tool. The partogram audit tool checks if all relevant blocks were filled in and gives a score out of the total number of possibilities. This only measures compliance with completing the partogram but not whether it was interpreted correctly or whether the correct action was taken depending on the circumstances. For this chapter, this last aspect was also evaluated using the clinical findings and outcome to answer a yes/no question on correct interpretation of the results.

Documentation of fetal heart rate patterns was audited in a descending order of availability. The best evidence that it was done was the presence of the actual cardiotocograph (CTG) paper strip within the folder. If this could not be found, evidence for its use was sought in the doctor's notes. Failing that, documentation of the fetal heart rate only (no interpretation regarding variability or decelerations) was sought on the partogram and in the clinical notes.

## 4.4 Results.

There were 615 admissions to the labour ward during July 2012 of which 530 delivered. Of the admissions, 33 women (5.3%) were self-referrals from residential areas outside of the drainage area of the district hospital. They were appropriately out-referred for delivery to their correct drainage as only 2% of eventual deliveries were from outside of the hospital drainage area. Of the 530 folders requested for audit, 92% was available with sufficient notes to do the audit. There were 5 stillbirths and one neonatal death during the audit period. The mean age of women admitted was 25.6 years with a range from 13 years to 50 years of age. The referral pattern for the admission leading to delivery is shown in Figure 4.4.1; the majority of referrals are from the four midwife obstetric units (MOUs) in the hospital drainage.

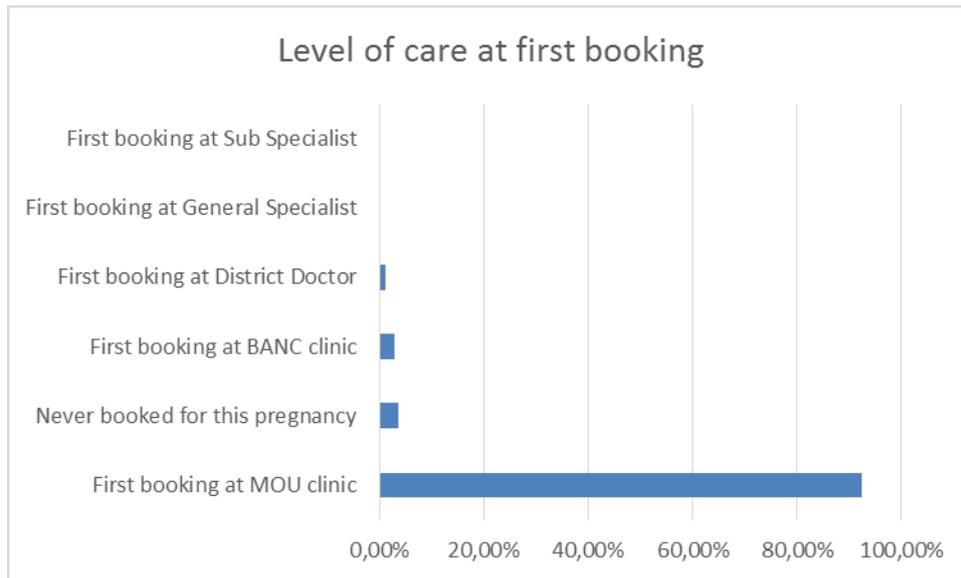
Figure 4.4.1. Level of care at the time of referral to Karl Bremer hospital, July 2012.



BANC= Basic antenatal care clinic

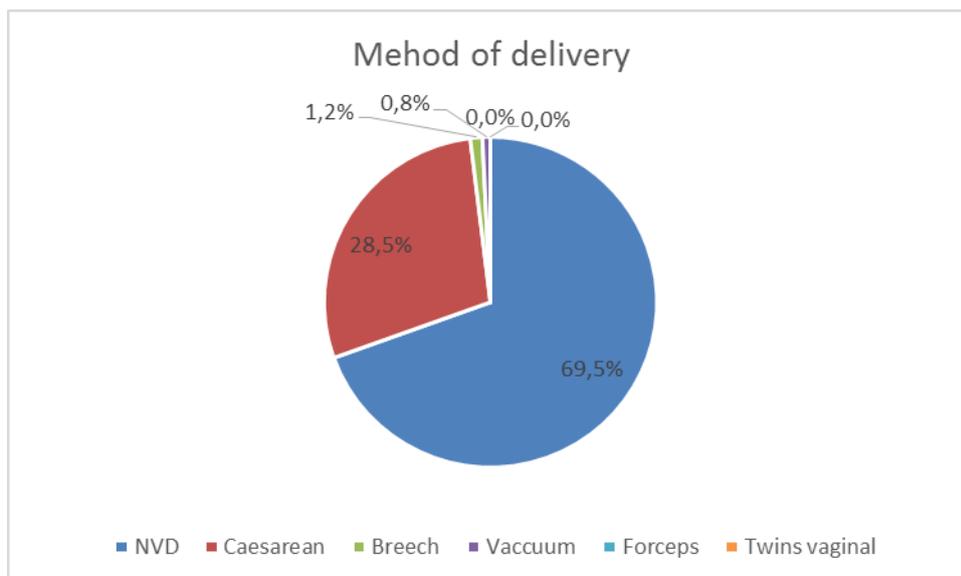
No patients that delivered at Karl Bremer booked at a specialist or subspecialist clinic. This is appropriate and all first bookings are intended to be in the community, with appropriate referral after booking based on risk assessment. This is shown in Figure 4.4.2.

Figure 4.4.2. Level of care at booking.



The method of delivery is shown in Figure 4.4.3. There was a CS rate of 28.5% for this specific month (in the hospital population). The CS rate for 2012 was 29.9%.

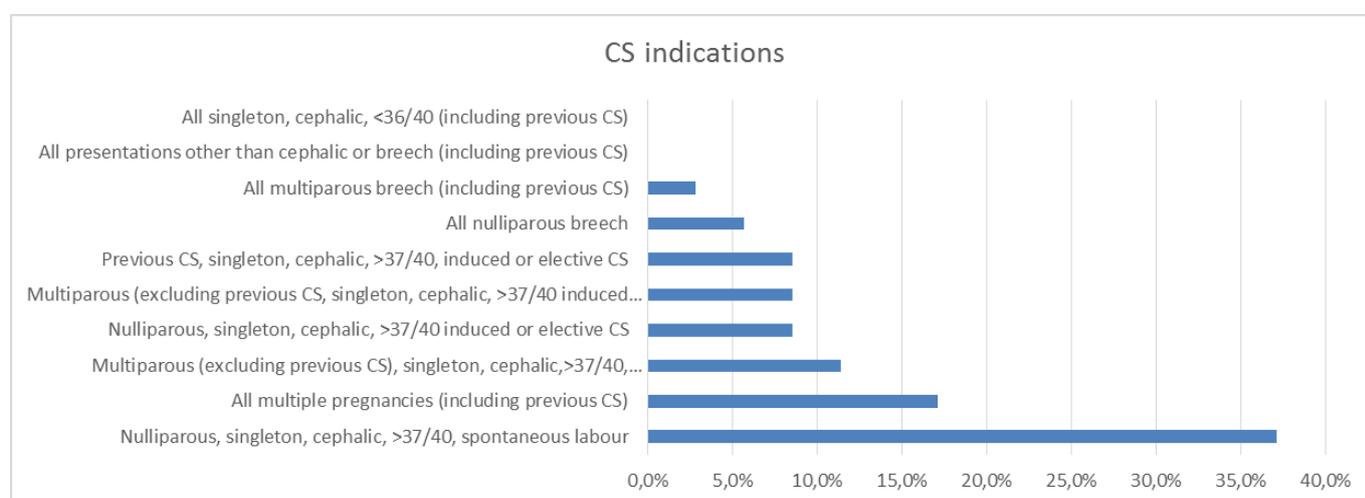
Figure 4.4.3. Method of delivery July 2012.



The indications for CS was classified according to the criteria of Robson (16) and is shown in Figure 4.4.4. Most CS expected at this level of care would be for reservations about fetal heart rate patterns or poor progress in the second stage, referred from the MOUs. There were no CS for deliveries with a gestational age <36 weeks or for presentations other than cephalic or breech. The nulliparous, term, singleton vertex (NTSV) CS rate was the highest, at 37%. Almost 60% of women with a previous CS and who qualified for a trial of labour after CS delivered vaginally.

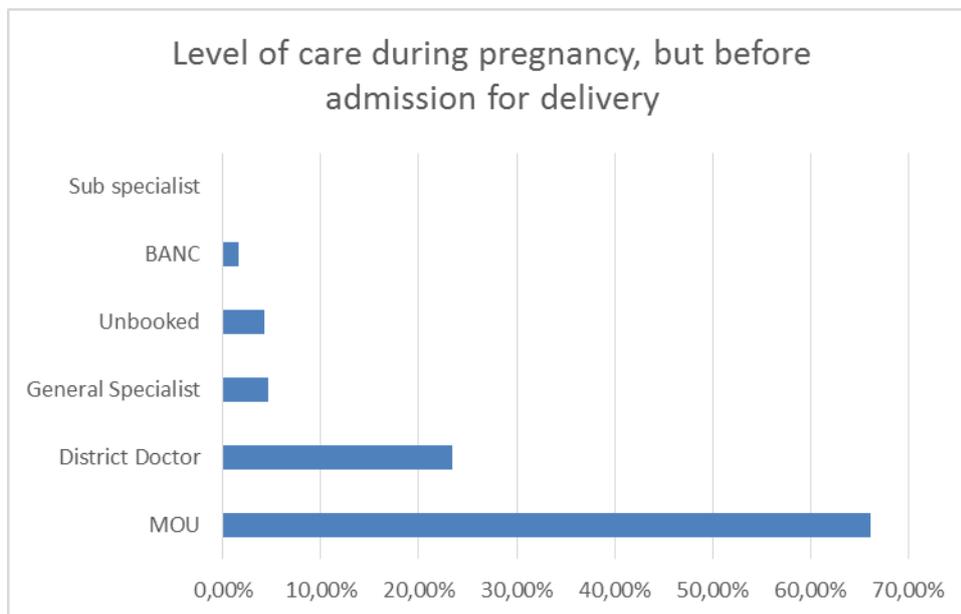
Access to theatre was measured by the time from the decision to do a CS was documented in the folder to the time the baby was delivered. The median amount of time was 60 minutes with a range of 35 minutes to 165 minutes; the longest delay was for a breech in early labour without fetal distress and therefore less urgency. The urgent category of CS is the NTSV rate, as they were mostly done for fetal distress or poor progress in the second stage for a patient who has already lost time with an ambulance transfer from the MOU. The median time to theatre for the NTSV category was 58 minutes with a range of 35 to 106 minutes.

Figure 4.4.4. Caesarean section indications and rates according to the Robson classification.



The most specialised level of care that women who eventually delivered at Karl Bremer hospital received during their antenatal period is shown in Figure 4.4.5. A small percentage of women received care at general specialist level at Tygerberg hospital but were stepped down at some point in their antenatal care to continue care at a less specialised level.

Figure 4.4.5. Most specialised level of care received during antenatal period.



Not all women who deliver at a district hospital needs to be delivered by a doctor, but as most of them are supposed to be referrals from primary care (where a midwife has already attended to the woman) it is expected that a doctor will at least assess every woman that is admitted. Only in 12.4% of folders was there no documented evidence that a doctor was involved in the assessment or delivery, and these were mostly self-referred women who arrived in very advanced labour and delivered shortly after. This highest level of care received during labour (first or second stage) is shown in Figure 4.4.6 and the health care professional delivering the baby (this includes CS) is shown in Figure 4.4.7.

Figure 4.4.6. Highest level of care received during labour.

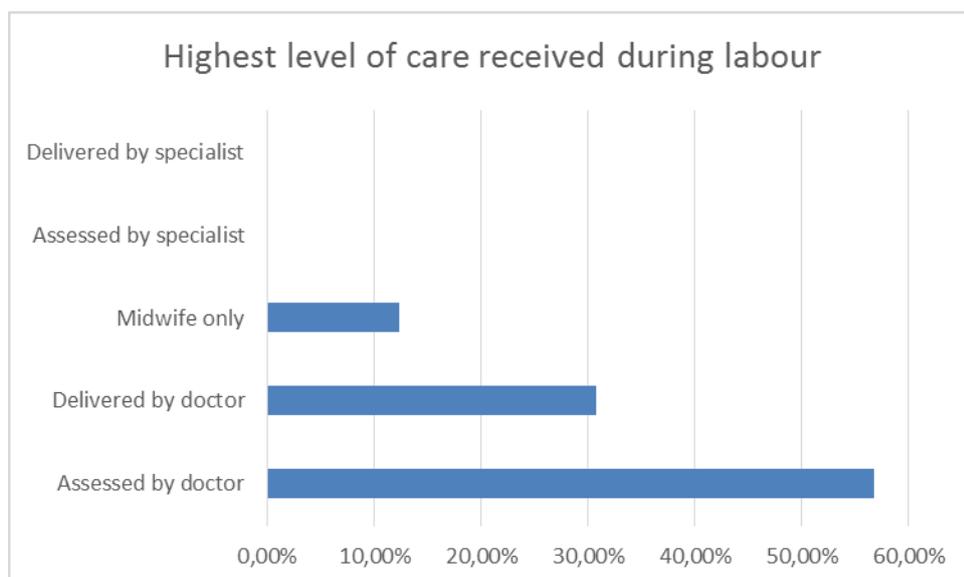
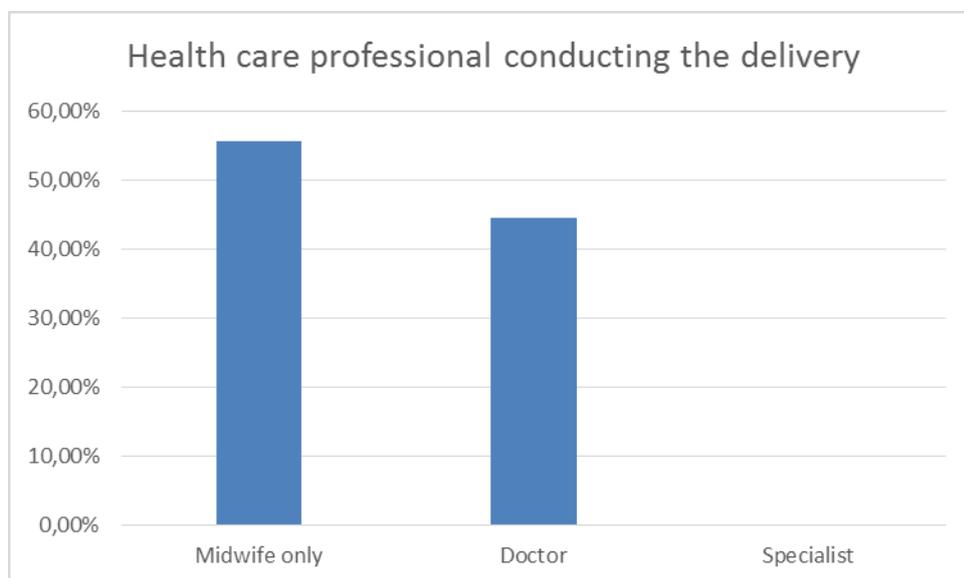
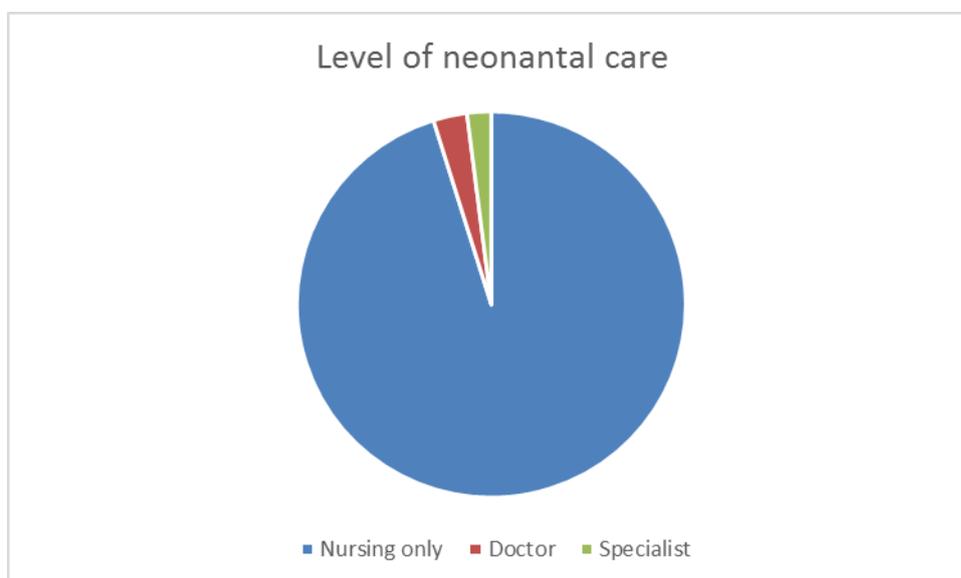


Figure 4.4.7. Health care professional conducting the delivery.



The audit only assessed the neonatal outcome until maternal discharge. Only a small percentage of babies needed more than routine nursery care and the vast majority stayed with the mother and was discharged home with her. This is shown in Figure 4.4.8.

Figure 4.4.8. Level of neonatal care up to maternal discharge.



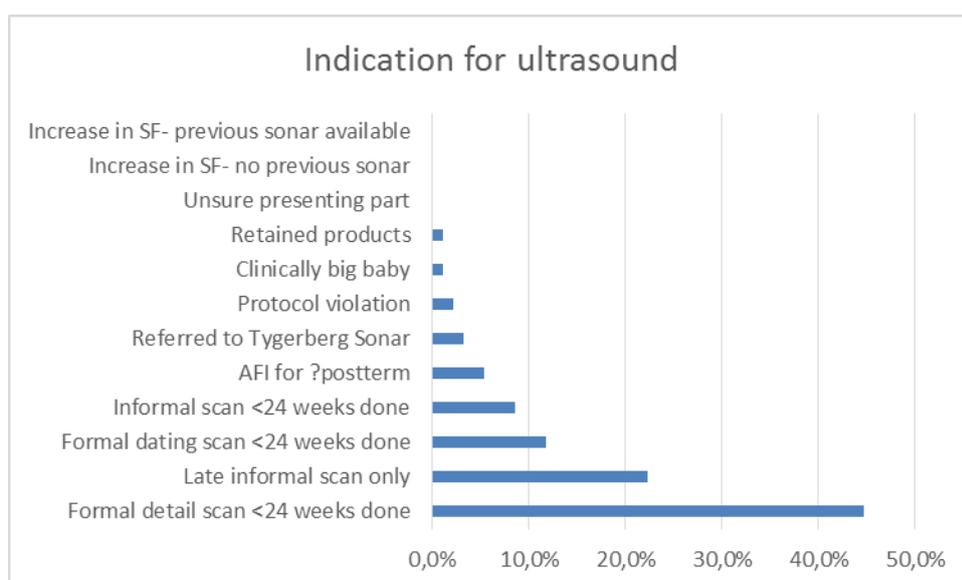
The next part of the audit investigated the use of ultrasound and adherence to the ultrasound policy of the Western Cape. There was evidence of ultrasound performed at any time during the pregnancy, delivery or postpartum period in 76.6% of folders assessed. Most cases of protocol violation (where ultrasound was requested without a valid indication) was for growth scans in the third trimester for estimation fetal growth without any clinical suspicion of growth outside of the 10<sup>th</sup> or 90<sup>th</sup> centile according to the symphysis to fundal measurements routinely used in the antenatal clinics. The numbers were small, but the other protocol violations were:

- Sure gestational dates and sonar, yet amniotic fluid index (AFI) and estimated fetal weight (EFW) requested at 40 and 41 weeks for possible post-dates induction of labour.
- Patient who already had an early dating scan, rescanned at 34 weeks when admitted to determine gestation.

- Review of low lying placenta at 28 weeks (too early) and then had to repeat the scan at 32 weeks.
- Umbilical artery Doppler test normal, but repeated several times thereafter for a clinical suspicion of reduced fetal growth (full fetal growth assessment with ultrasound would be more appropriate).
- Doppler requested for reduced fundal growth but full ultrasound assessment done even though the Doppler is normal and there was already a detailed sonar done earlier in pregnancy.
- Some women with chronic hypertension received serial umbilical artery Doppler tests even though the first Doppler was normal.

Formal dating or detail sonar was available for more than half of the deliveries. The reasons why women received ultrasound are shown in Figure 4.4.9.

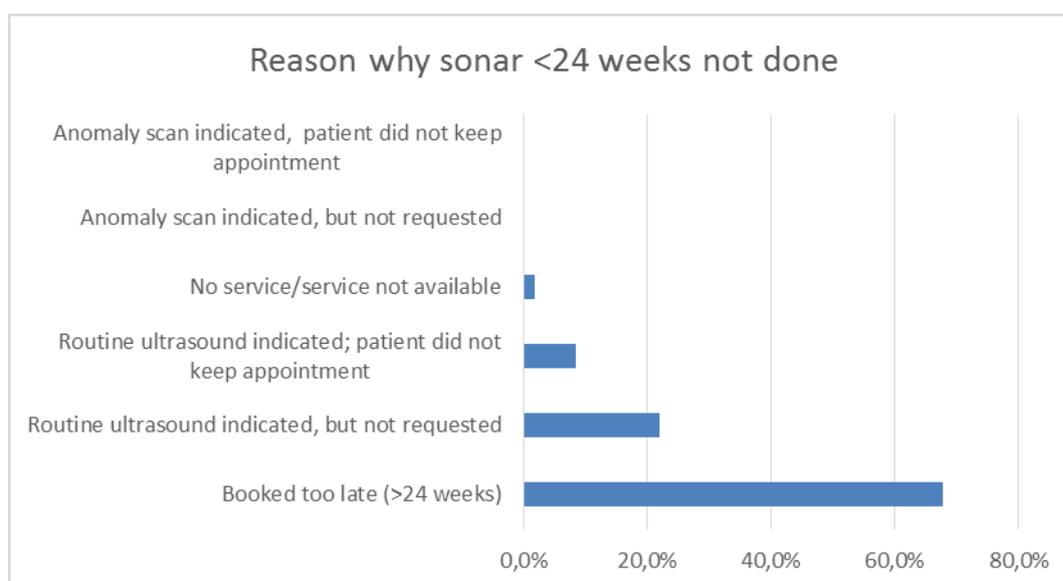
Figure 4.4.9. Reason why ultrasound was performed during the pregnancy



AFI = amniotic fluid index.

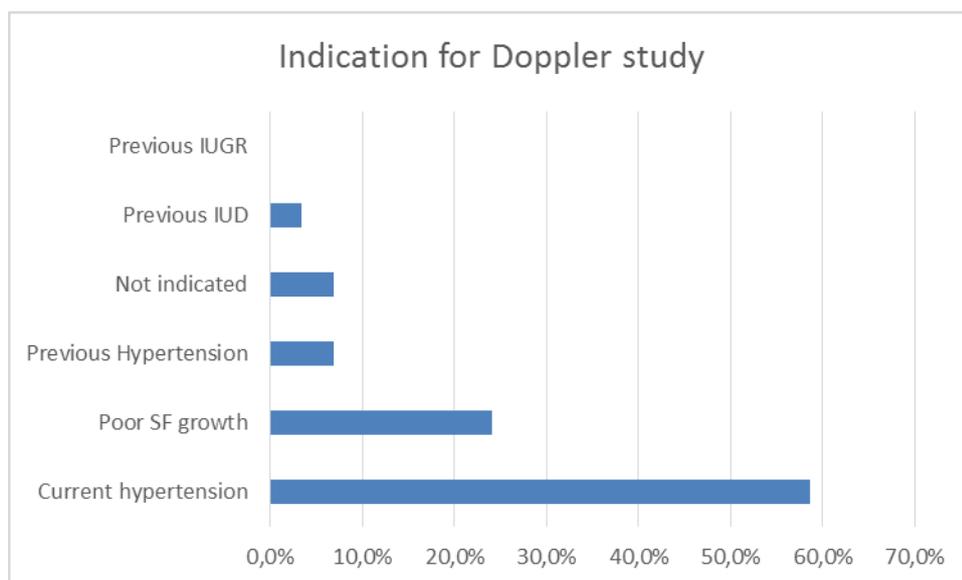
The provincial ultrasound policy dictates sonar for dating or detail before 24 weeks, in all women who book for pregnancy. When this was not done, the most common reason was late booking. The audit did not identify any woman who had an indication for a fetal anomaly scan (e.g. maternal age >40 years, use of teratogenic drugs) that was not requested or not done. Those with advanced maternal age all had evidence of correct referral for genetic counselling and detailed ultrasound. A small number of women did not go for their booked ultrasound appointments. This is represented in Figure 4.4.10.

Figure 4.4.10. Reasons why an early ultrasound was not performed.



There was evidence of umbilical artery Doppler tests in 24% of the folders. Most of these were requested as a baseline assessment of placental function in hypertensive conditions. This is shown in Figure 4.4.11. There were a number of Doppler tests requested without valid indications as discussed above.

Figure 4.4.11. Indication for Doppler studies



IUD = intra-uterine death

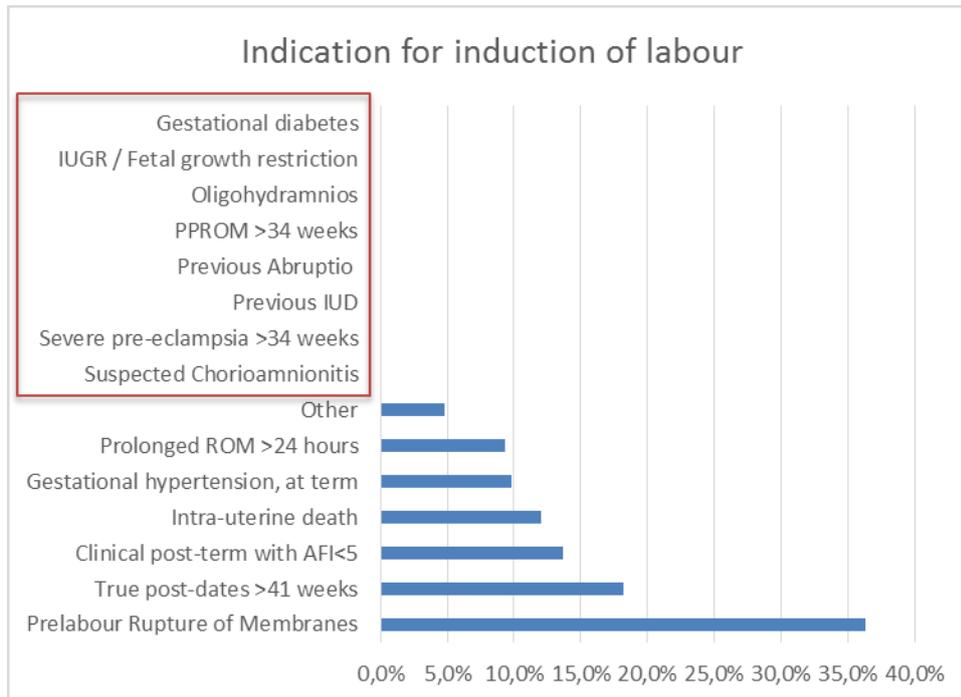
IUGR = intra-uterine growth restriction

SF = symphysis fundal growth

Most patients (78.9%) went in spontaneous labour and 17.6% was induced. Only 3.6% had a scheduled (elective) CS. When labour was present, a partogram was used in 73% of women to plot the progress of labour and no evidence of its use was found in 27%. In 15% of deliveries with a completed partogram it was incorrectly interpreted.

The indications for women receiving induction of labour are presented in Figure 4.4.12. There are inductions that should not take place at a district level of care and these are indicated at the top of the figure in red. These were specifically included in the audit to see whether inappropriate inductions did occur. Most inductions were for prelabour rupture of the membranes (no contractions after 24 hours of conservative management at the MOU).

Figure 4.4.12. Indications for induction of labour.



IUGR=intra-uterine growth restriction

IUD= intra-uterine death

ROM = rupture of membranes.

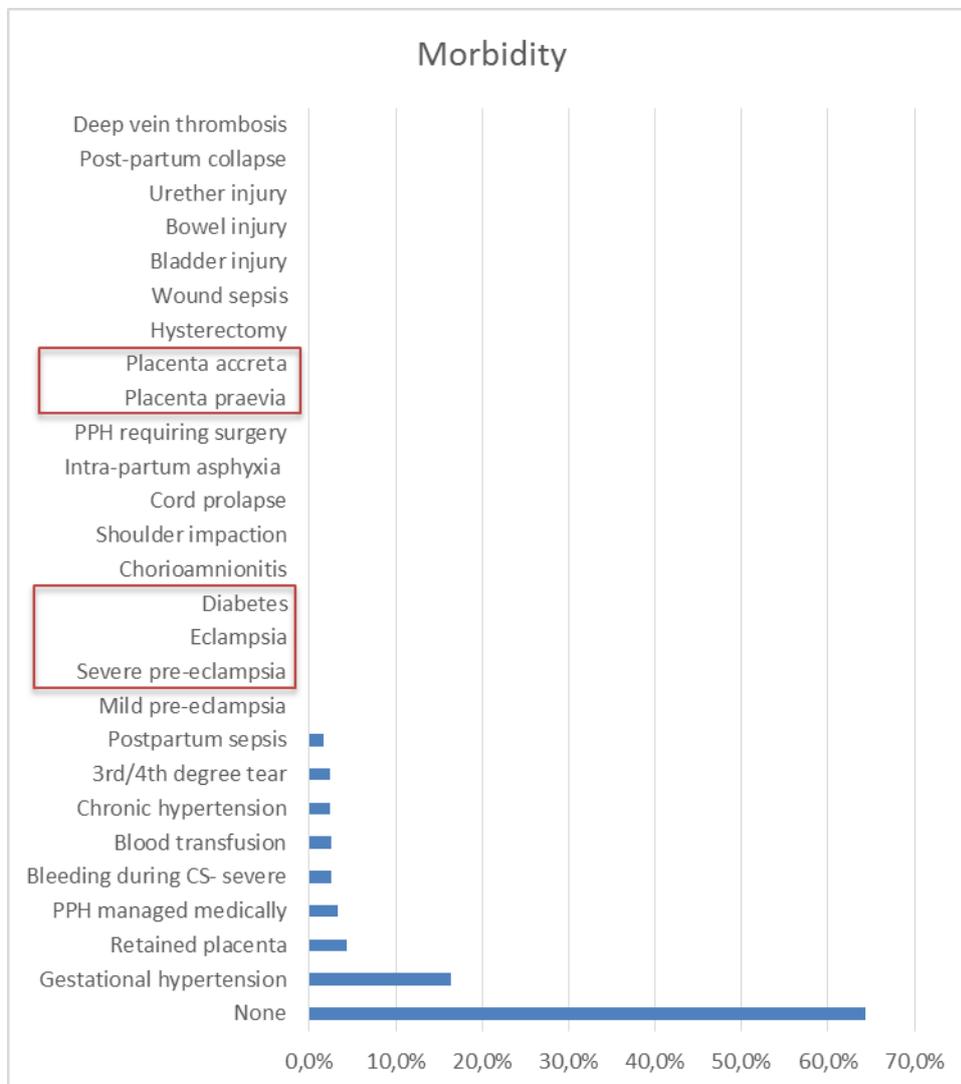
AFI = amniotic fluid index.

Oxytocin during the first or second stage of labour was used in 14.8% of all deliveries. The main indication was for stimulation of contractions (induction of labour) (68%) and the second most important use was for augmentation of labour in a primigravid woman (34%). There was no instance of oxytocin use outside of a prescribed protocol.

Morbidity can be expected at district level (e.g. sudden intra-operative blood loss requiring emergency hysterectomy) but certain morbidities can be predicted and referred in time and should not deliver at a district hospital (e.g. placenta praevia). The more common morbidities as obtained from the folder review are listed in Figure 4.4.13. Again, the audit looked for morbidity or complications that occurred with patients that should not deliver at the district

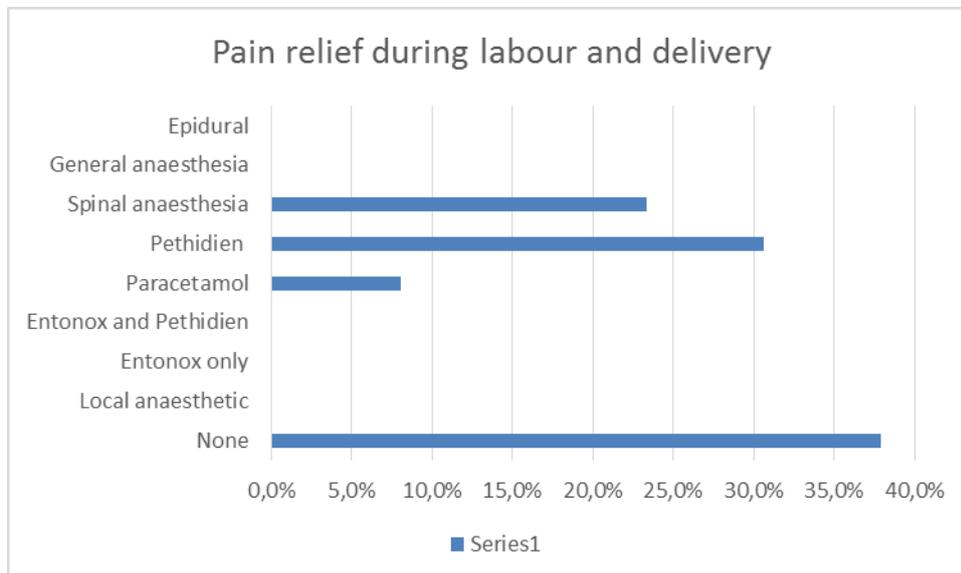
hospital (marked in red) and their absence from the results can be an indication that an effective referral and transport system is in place. There was no emergency hysterectomy for severe post-partum haemorrhage or sepsis during the audit period. Septic patients can be referred in time, but intractable bleeding during inoperative delivery cannot be referred. Scrutiny of the theatre register for the entire year showed 7 hysterectomies for severe intra-operative bleeding, of which only 2 occurred after hours.

Figure 4.4.13. Morbidity during labour and delivery.



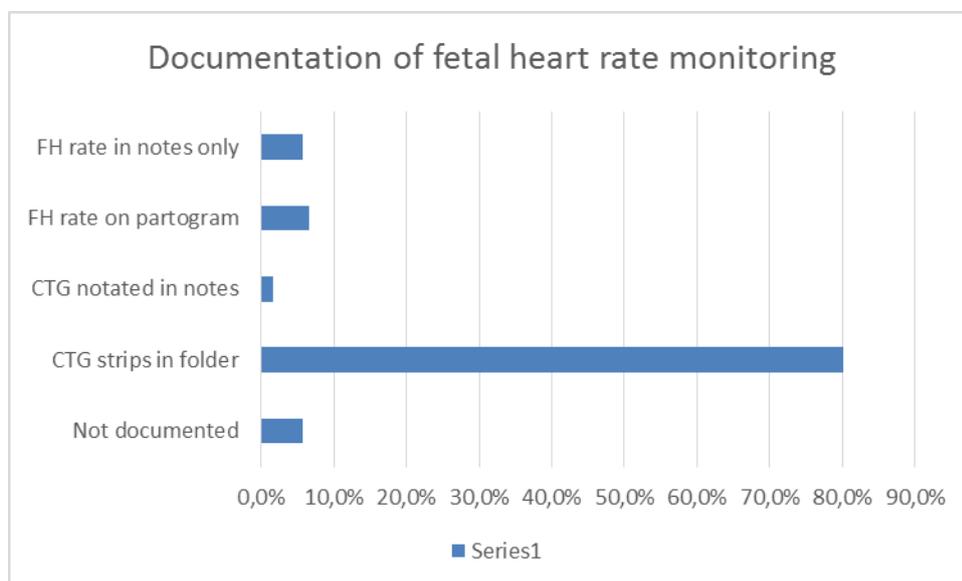
Pain relief during labour and delivery was measured as a quality of care factor and is depicted in Figure 4.4.14. Only documented instances of medication or methods given could be audited. No usage of nitrous oxide (Entonox™) as inhalation analgesia method was detected in the nursing notes, doctor's notes or prescription charts. If it is used at all, it was not documented. Spinal anaesthesia was performed for CS only. A routine epidural service is not part of the package of care delivered at a district hospital.

Figure 4.4.14. Pain relief during labour.



Documentation of fetal heart rate patterns occurred in more than 90% of deliveries. This is shown in Figure 4.4.15. Most folders had the physical CTG printouts in the folders. When no CTG was present, documentation of fetal heart rate alone was present in a further 11% of folders.

Figure 4.4.15. Documentation of fetal heart rate patterns.



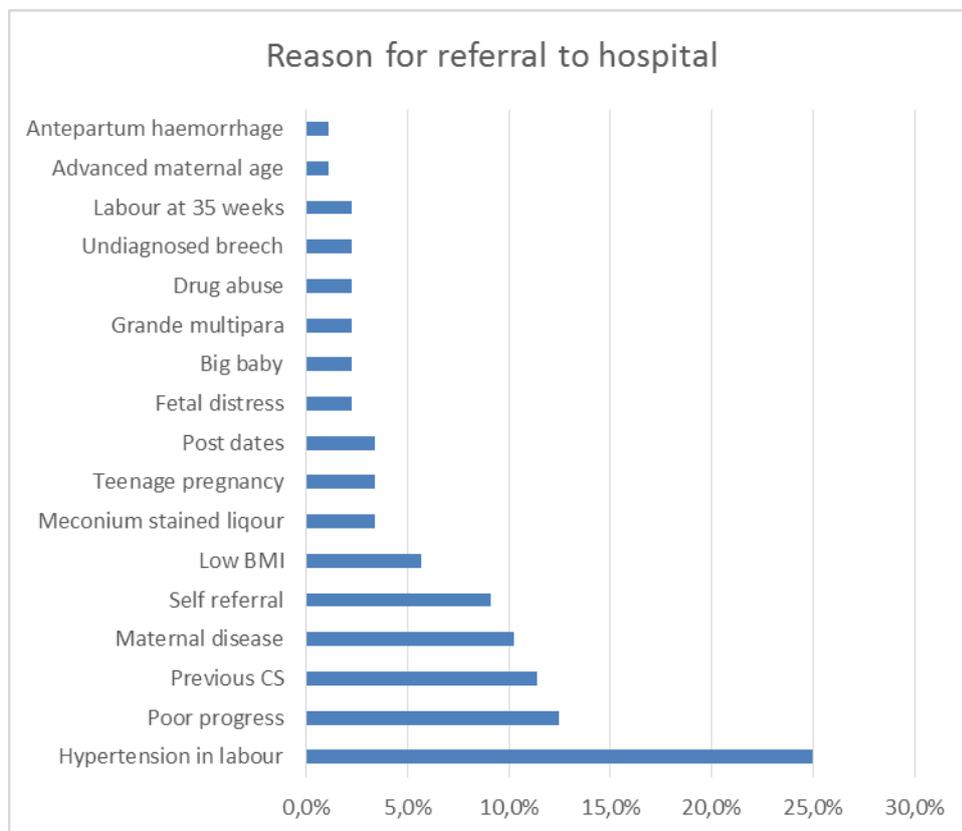
FH - Fetal heart

CTG - cardiotocograph

The active method of delivering the placenta is standard practice and evidence of its use after vaginal delivery could be found in 96.6% of folders. Completion of the patient discharge summary is essential for communication with the postnatal and baby clinics. This was completed in 97% of cases. Documentation that adequate family planning methods was discussed and administered could be found in 89% of folders.

Lastly, the reason for referral to the district hospital was investigated to confirm that the correct package of care is provided at that level of care. This is shown in Figure 4.4.16. All of these indications are valid and appropriate for a district hospital package of regionalised care. There are quite a large number of women (9% of deliveries) who arrive in advanced labour without any risk factors for delivery at that level of care.

Figure 4.4.16. Reasons for referral to a district hospital service.



BMI – Body Mass Index

CS- Caesarean section

## 4.5 Discussion.

The audit confirmed that the level of service rendered during the month of the audit was at the correct level of care as expected from a large metro district hospital. Most patients seen were appropriately managed at the referral MOUs and referred to the correct level of care when complicated. Most CS was for nulliparous term pregnancies with a singleton baby in cephalic presentation, again appropriate for this level of care as this was mostly low risk women with poor progress in the first stage of labour (Figure 4.4.4).

Despite the availability of a specialist (at least on standby) for 24 hours per day, there was no hysterectomy performed during the audit period and less than one per month for the entire year. Septic patients can be referred in time, but intractable bleeding during inoperative delivery cannot be referred as easily. Even though the incidence is rare, a maternal death from bleeding during CS will be difficult to defend (morally and legally) in such close proximity to a tertiary hospital. Khayelitsha hospital on the other hand is 40km away from the tertiary hospital and situated within an under-resourced community with high levels of crime and gang activity. It is dangerous to drive there at night and there were no specialists willing to do stand-by for afterhours cover. Day-time teaching focus a lot on intra-operative management of complications including the use of balloon tamponade, uterine tourniquets and abdominal packing to transfer unstable women with intra-operative bleeding (17). As more district hospitals are planned in the metro, this may very well be the model of afterhours cover to follow.

Placement of O&G specialists at district hospitals without specialist care in Ghana showed a decrease in maternal mortality and CS rates with an increase in instrumental deliveries (18). This improvement in care can be expected, but an unexpected finding was an increase in neonatal mortality. This was speculated to be due to an influx of high risk women seeking

specialist attention. The increase in hypoxic ischaemic encephalopathy seen at the opening of the new Khayelitsha hospital (reported in chapter 3) may be due to the same reason. At Karl Bremer hospital the situation was slightly different. Prior to 2009, the hospital was functioning at regional level of care with an existing specialist in O&G and paediatrics which were then retained when the hospital was reclassified as a district hospital. In the obstetric laborist model, there is data that shows improved new-born and maternal outcomes in hospitals with laborists in the perinatal unit (19).

The audit aimed to find the reason(s) for the decline in low-risk deliveries at MOUs between 2007 and 2012 (see Figure 3.4.6 on page 86). The local protocol for the management of meconium stained liquor changed in 2010. Meconium stained liquor is a referral criteria for transfer to a district hospital to provide intra-partum fetal heart rate monitoring and care during delivery (20). The incidence of meconium-stained liquor in low-risk pregnancies is about 16.6% and is a risk factor for adverse outcome (21). However, the majority of women with MSL have a normal neonatal outcome (22). In this audit, 4.8% of referral to district care was for meconium-stained liquor. A further 3% of referrals were for fetal distress detected during labour and it can be speculated that most of these also had meconium stained liquor. This change in referral pattern could explain the decreased number of deliveries at the MOU. It will be worth investigating this impact on a larger scale in terms of neonatal outcome to continue to justify this referral criterion.

The 35% of low-risk deliveries occurring at community level is comparable to other local and international figures. Danilack and colleagues analysed more than 10 million births in the US using vital registration data. They identified low risk pregnancies as those meeting all of 19 specific criteria that is very similar to the definition of a low risk pregnancy in the WC. Only 38% of pregnancies met all the low risk criteria (23). In a black rural urban community in Atteridgeville, Gauteng province of South Africa, 33% of pregnant women could be managed

at community level for the duration of antenatal, intrapartum and postnatal care (24). In both these studies the next level of care was a specialist hospital and not a general doctor-led district hospital.

The presence of a daytime specialist did not extend to actual assessment or delivery of women during the audit period. District doctors assessed and/or delivered almost 85% of all women. This finding emphasises the role of the district specialist as clinical governor and overseer of the service rather than primary caregiver.

More than half the women who delivered had ultrasound confirmation of their dates. There were some instances where protocol violation of the provincial policy occurred. Randomised trials have shown the benefit of ultrasound assessment of gestational age at the first antenatal visit (25). Ultrasonographers are a scarce resource in South Africa as there are very few training institutions and the career opportunities and remuneration are much more lucrative in private practice than in the public sector. It is therefore of critical importance that the hospital service is used responsibly to ensure that every woman has access to at least one ultrasound during their antenatal care. This should ideally occur in mid gestation as a 2011 study in this same population could not find value in adding an additional gestation-determining scan at first booking (26). The most important issue detected was the request for growth scans for suspected big babies at term (Figure 4.4.9). An elective CS was then booked for all babies with an estimated weight of >3800g which is not evidence based. This has since been addressed at clinical level.

The Lucas classification of urgency of CS is widely used (27) and is also adopted as a good practice guideline by the RCOG (28). Most of the CS done at KBH fall into the second category of urgency, namely severe maternal or fetal compromise that is not immediately

life-threatening. The 60 minutes waiting time (decision-to-delivery interval or DDI) for CS is comparable to international standards (29). At a tertiary hospital in Nigeria the mean DDI was 106 minutes (30). At Tygerberg Hospital it was 59 minutes for category 2 cases (30). The DDI is significantly increased in Tygerberg hospital for women with two or more prior CS and also increases significantly with increasing obesity (31). Both of these conditions (two or more previous CS and body mass index  $\geq 40\text{kg/m}^2$ ) are referral criteria for specialist intervention and should not be managed at Karl Bremer hospital.

The safety aspects examined in the audit showed acceptable standards for oxytocin use and inductions of labour (Figure 4.4.14). Almost 30% of women had no form of pain relief documented during labour. A *Maternal Patient-Centred Care* initiative was launched in the Western Cape in 2014 to improve the patient experience and this includes provision for adequate pain relief during labour (32). Women in this population is poorly informed about the expected severity of pain during labour and the various methods available (33). In low-income countries in Africa up to 90% of women do not get any form of pain relief during hospital care for labour (34) and this includes South Africa (76% of women delivering in a regional hospital in Limpopo did not get any form of pain relief) (35). Clearly there is still room for improvement in pain management at KBH.

Almost 9% of women who delivered did not have an indication to deliver at the hospital but should have delivered at the MOU (Figure 4.4.16). This may be another reason for the decreased number of MOU deliveries. The suburbs to the northwest of KBH do not have a MOU and those women have to drive past KBH to reach the MOU a few kilometres down the road. It is more convenient for them to arrive in established labour at the hospital when it is too late to refer them out. This strategy puts them at risk of delivery before arrival with its

consequences. This is an important aspect for the further planning of large metropolitan district and regional hospitals, of which at least four will be built by 2030.

With the dwindling number of women who qualify for no-risk care and the increased availability of brand new hospitals right on their doorstep, the requirement for MOUs as they are used in Cape Town may become obsolete. The concept of an on-site midwife-led birth unit staffed and funded by the primary care services but on the premises of a district or regional hospital is a logical alternative arrangement. This was successfully piloted in the Eastern Cape and may be a more cost-effective model (36).

## 4.6 Conclusion

This audit showed that a large metropolitan district hospital can function efficiently and manage large numbers of women referred for specific indications. The presence of a resident O&G specialist during office hours ensures clinical governance and patient safety. This model can be considered as an option where a large number of women requires obstetric care within in a public health service.

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## Chapter 5

# Caesarean section rates at Tygerberg hospital.

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## Chapter 5. Caesarean section rates at Tygerberg hospital.

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## 5.1 Introduction.

It is important to measure the caesarean section (CS) rate of a specific institution, as operative delivery is a big cost driver in obstetric health care. The caesarean section (CS) rate is often interpreted out of context, as the denominator for the rate should be all deliveries in the catchment area of the hospital and not only hospital deliveries. Nevertheless, a CS rate indicates the level of operating activity at a specific unit and can be monitored to observe trends over time (1).

The CS rate for public sector women in the Tygerberg hospital drainage was around 13% for the time period 1975-1994 (2). In this same population, the majority of women prefer vaginal delivery (3). The World Health Organisation (WHO) recommends an ideal CS rate for a country of 10-15%, above which there is no evidence of improved outcomes (4). This is based on an analysis of 2005 delivery data from 159 countries representing 98% of global live births (5). The South African national average facility based CS rate was 23.1% in 2011-2013 (6) and 22.7% in 2014-2015 (7). The private sector CS rate is substantially higher at almost 70%, according to the SA Council for Medical Aid Schemes (8).

Other middle income countries also struggle with disproportionately high CS rates. In Brazil, 85% of private and up to 45% of public sector women are delivered via CS, making it one of the highest in the world (9). In India, two different models of public-private partnership for deliveries were compared by Bogg et al (10). Not surprisingly, in the model where private practitioners were paid more for a CS than vaginal delivery the CS rate increased from 26.6% to 40.7% while the rate decreased to single digits when compensation was the same regardless of the route of delivery. In China, social factors are the primary indication for CS in up to 36% of sections (11).

Several CS classification systems exist, making it possible to compare specific indications between hospitals and health districts. The best known is the Robson 10 group system (12). A recent systematic review of all the classification systems concluded that women-based classifications in general and Robson's classification in particular, would be most appropriate to develop as an internationally applicable CS classification (13). The WHO proposed the Robson classification as the global standard for assessing and comparing CS rates in its 2015 statement on CS Rates (14). One arm of the Robson classification is the nulliparous term singleton vertex (NTSV) section rate, where the only obstetric indication for operative deliveries would be intra-partum complications. Use of the NTSV rate make for more meaningful comparisons of CS rates between institutions and over time.

The CS rate at Tygerberg and in Metro East for 2007-2012 was discussed in Chapter 3. This chapter will put the data from 2007-2012 in perspective with the time frames before and after that and with the provincial figures in general. It will address the CS rate after the Site B Khayelitsha shift.

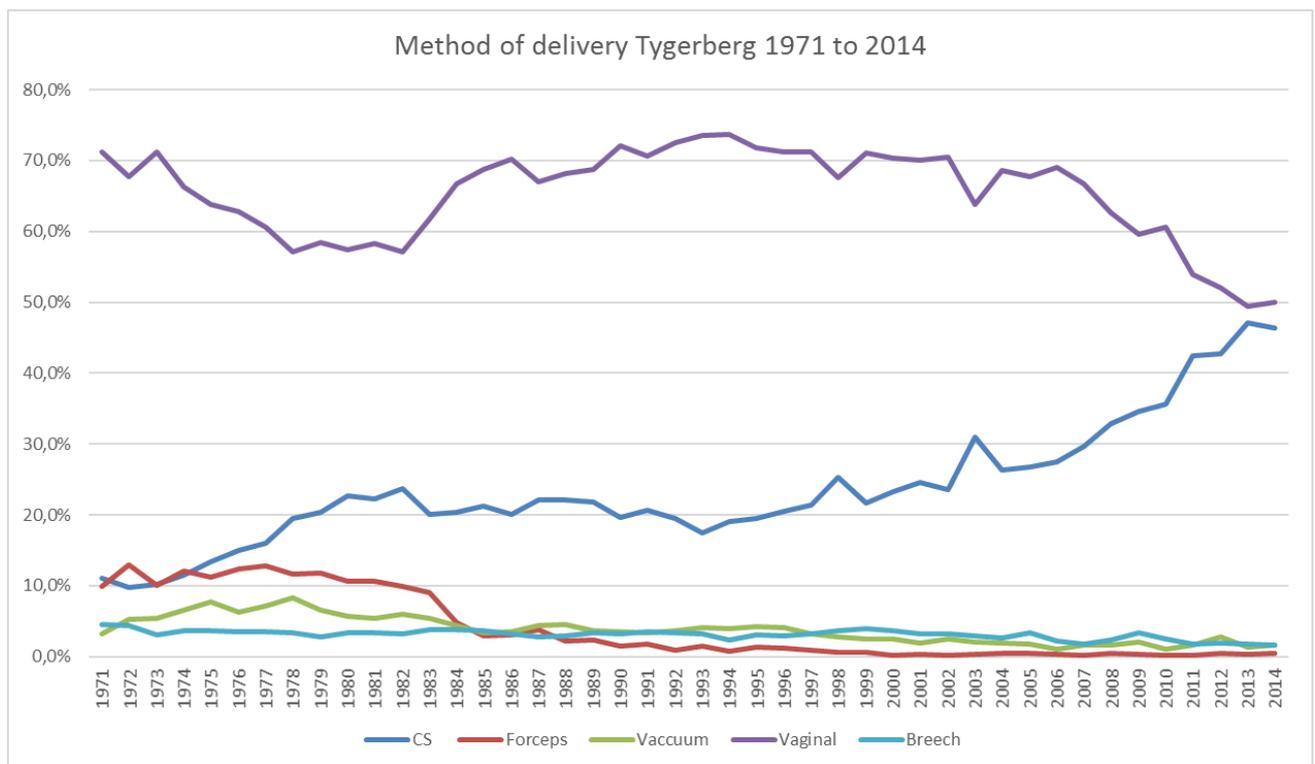
## 5.2 Methods.

All delivery data since the inception of Tygerberg hospital were recounted from the original birth registers to correct for any data errors in the electronic information system. For 2007 and 2011-2013, the folders of all CS were also analysed to obtain the exact indication as proposed by Robson. Data was entered into an Excel™ database for analyses.

### 5.3 Results.

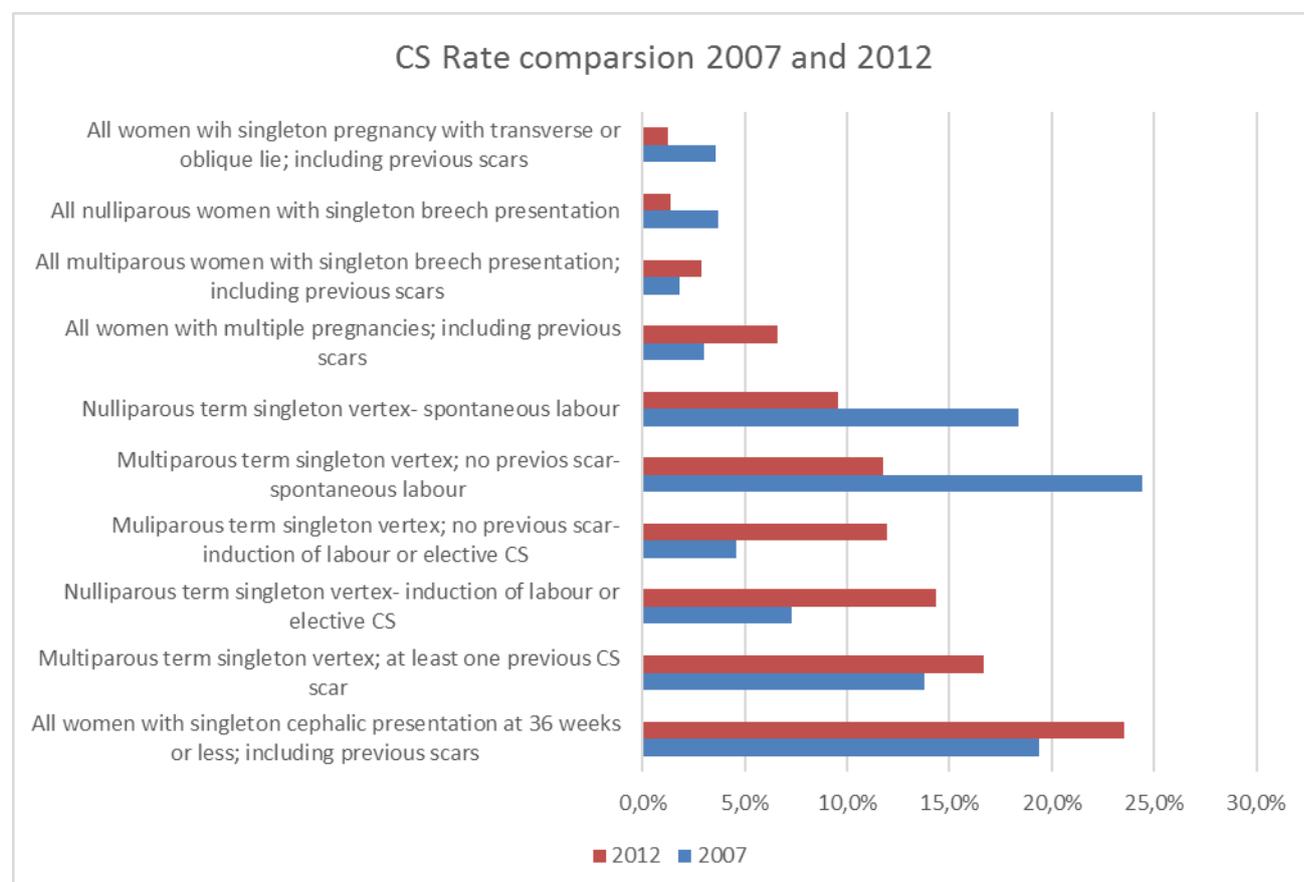
The method of delivery as a percentage of total deliveries since the inception of Tygerberg hospital until 2014 is shown in Figure 5.2.1. There was a decrease in forceps deliveries after 1980 with a rise in the CS rate. A policy of obligatory forceps delivery for every preterm delivery was in place up to 1980. Another change in obstetric practice during the early 1980s was to allow 1-2 hours after full cervical dilatation for the head to descent. The practice up to then was bearing down as soon as the cervix was fully dilated. After 1983 a new head of department introduced a more scientific approach to obstetrics. The CS rate continued to increase and the increase was more dramatic after 2006.

Figure 5.2.1. The method of delivery at Tygerberg hospital 1971-2014.



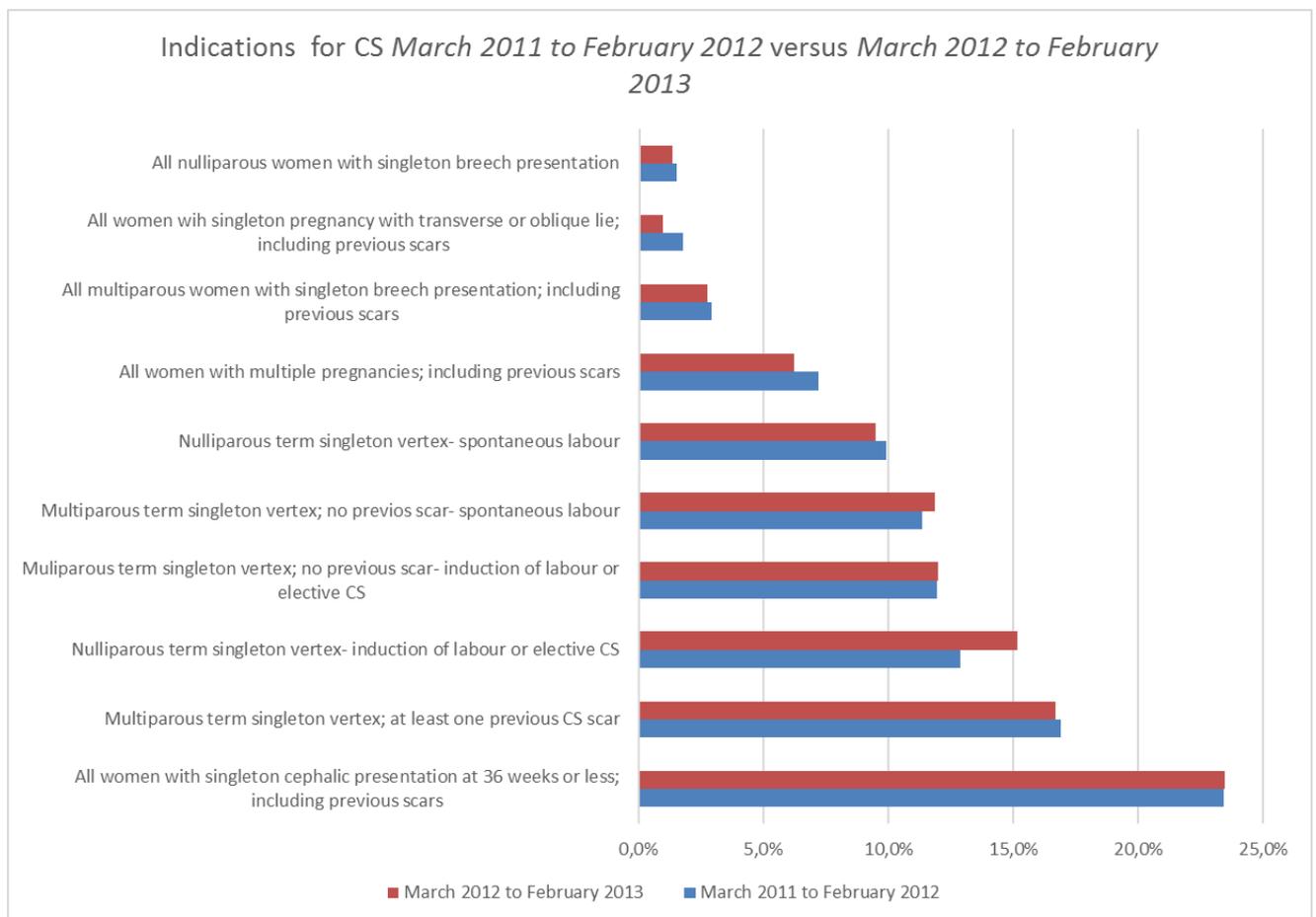
A comparison between CS indications for Tygerberg hospital, using the Robson classification, between 2007 and 2012 is shown in Figure 5.2.2. The biggest decrease was in the NTSV and multiparous term vertex group with spontaneous onset of labour, as these are mostly the relatively low risk patients who were by 2012 delivering at the appropriate district hospital. The biggest increase in CS rates were seen in women undergoing induction of labour. Most of the indications for induction of labour (see also chapter 10) at Tygerberg hospital is for the hypertensive conditions of pregnancy and diabetes and most of these are specialist referrals. There was also an increase in the number of CS for multiple pregnancies.

Figure 5.2.2. Comparison between 2007 and 2012 for Tygerberg hospital caesarean section rates using the Robson classification.



To measure the impact of the Site B shift that happened in March-2012, the CS indications for the year before and the year after the shift was calculated and is shown in Figure 5.2.3. The changes in CS rates before and after the shift were less dramatic and this was expected, as there were additional patients in the system but the level of care remained the same. The biggest change was a small increase in CS for induction of labour.

Figure 5.2.3. Comparison of caesarean section indications before and after the Site B shift.



Although the total number of deliveries has increased after the shift, it has quickly stabilised. The number of deliveries and CS per month prior to the shift is given in Figure 5.2.4 and the monthly number of deliveries and CS since the shift is depicted in Figure 5.2.5. The average number of CS increased from 200 to 287 (43.5%) and the number of deliveries from an average of 502 to 624 per month (24%).

Figure 5.2.4. Deliveries and caesarean sections before May 2012 at Tygerberg hospital.

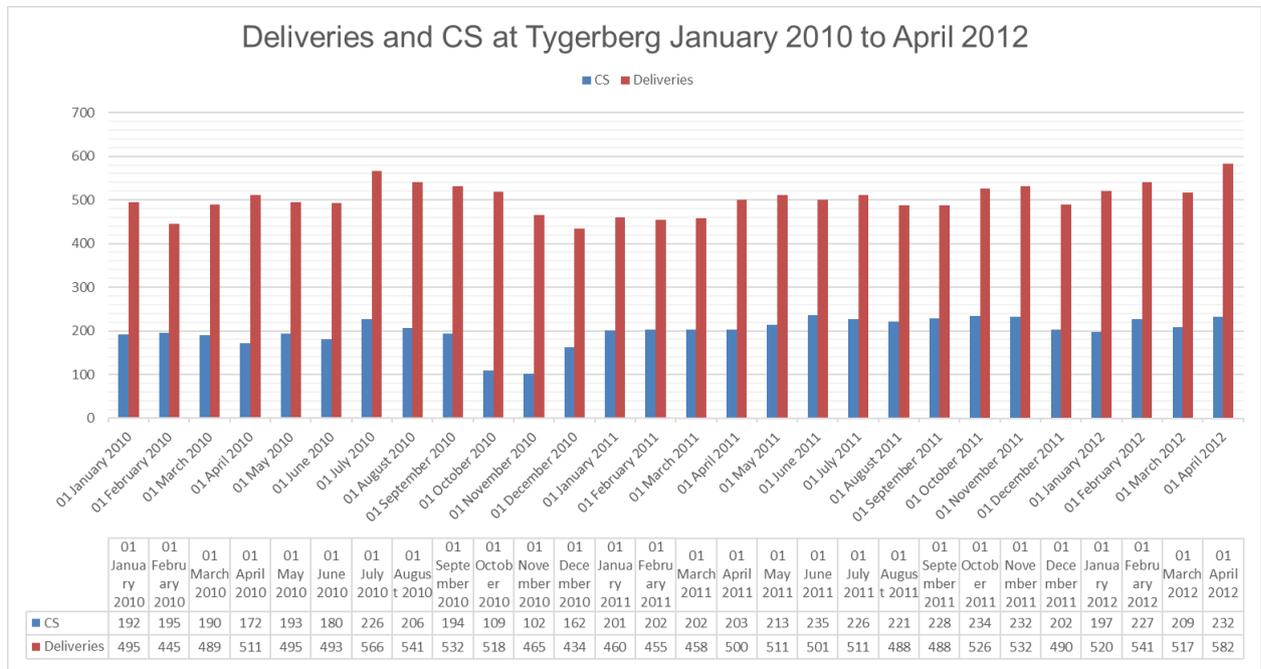
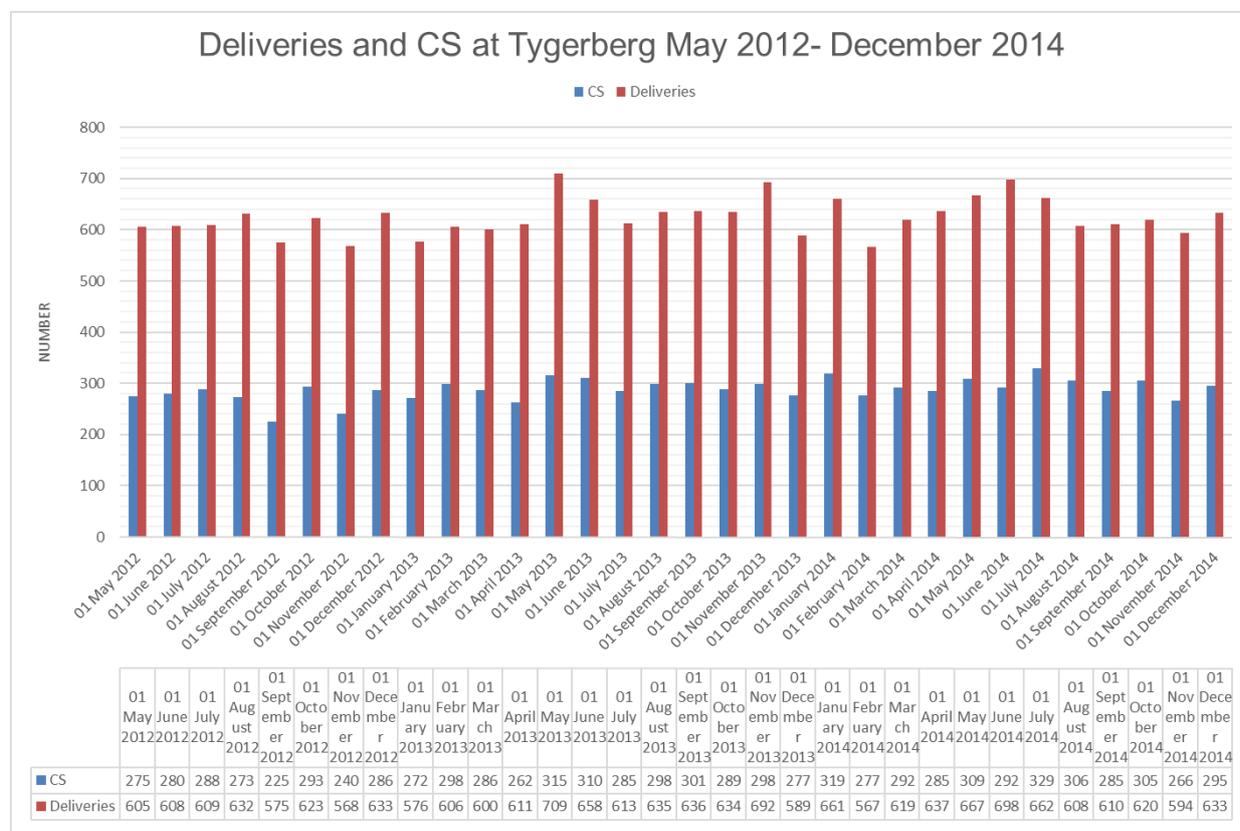
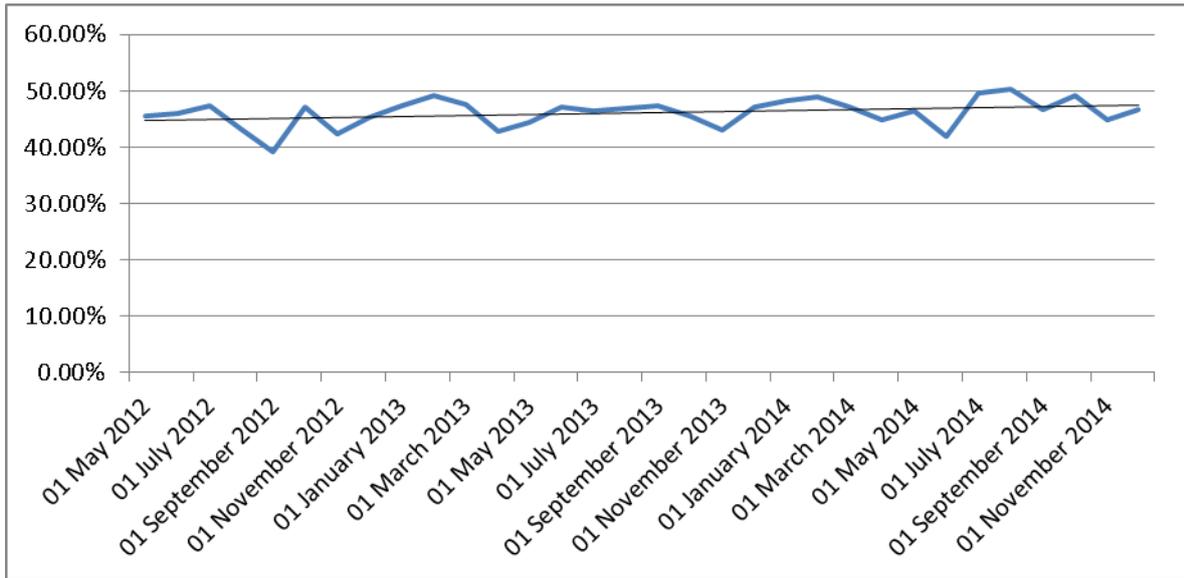


Figure 5.2.5. Deliveries and caesarean sections after May 2012 at Tygerberg hospital.



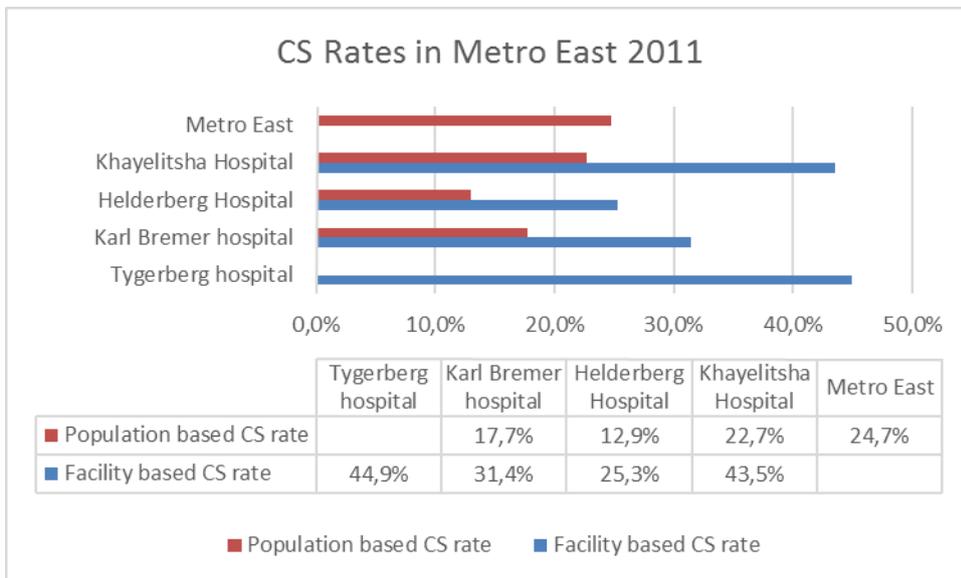
The CS rate (facility based) for Tygerberg hospital has stayed constant around 47% since the shift, although there is a non-significant trend upwards. This is shown in Figure 5.2.5.

Figure 5.2.5. CS rate at Tygerberg hospital since May 2012.



The CS rates for Metro East prior to the shift is given in Figure 5.2.6. It shows the facility based as well as the population based CS rate. The overall CS rate for metro east was 24.7%.

Figure 5.2.6. Caesarean section rates in metro east during 2011.



### 5.3 Discussion

The 24.7% CS rate in metro east is higher than the 15% recommended by the WHO but is the same as the average CS rate for South Africa. South African provinces with a CS rate below 17% (Limpopo, North West province and Mpumalanga) has the worst case fatality rate for deaths associated with CS in SA (6). CS rates in neighbouring Zimbabwe ranges between 2.2% and 16.8% (15) and in Mozambique 12.6%-20.6% (16).

The actual number of CS increased much more than the total number of deliveries after the Khayelitsha service shift. The reason may be found in the population itself- the CS rate for women in the Khayelitsha sub-district was the highest (59.2%) in Cape Town during the 2008-2009 district health survey. There was no shift in level of care with this move, and a possible explanation can be the difference in pelvic anthropometric measurements in African women. Khayelitsha is a predominant indigenous Xhosa community. White women have a wider pelvic inlet and outlet than African-American women (17). The only indication that showed a slight increase was the induction of labour group. Women of African ethnicity book later in pregnancy (18). Of the super-obese women managed at Tygerberg hospital, 32.6% is of African origin (19). Both of these can contribute to a higher incidence of induction of labour for presumed post-term pregnancy when accurate dating is not available.

There was a policy change at Tygerberg hospital regarding deliveries of multiple pregnancies in 2011 (Figure 5.2.2), following the new NICE guidelines on multiple pregnancy (20). All multiple pregnancies with undetermined chorionicity were subsequently managed as monochorionic pregnancies with elective delivery at 36 weeks and uncomplicated twin deliveries were electively delivered at 37 completed weeks. This could explain the rise in CS rate for multiple deliveries, as many women book too late for accurate chorionicity determination.

A global reference for CS rates using a mathematical model can generate a customised rate based on the specific case mix of a population (21). The reference population in this study (which included data from Brazil, India and China) has an overall CS rate of 18.5%.

The CS rate at Tygerberg hospital has remained stable from 2012-2014 but needs continuous monitoring and the indicator is included in the maternity dashboard (see Chapter 12). The capacity of the maternity section will not be able to absorb any further growth in the population. New hospitals are planned for Metro East including a new regional hospital close to Tygerberg hospital, but that is still several years away.

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## Chapter 6.

Trends in the measurements of perinatally-related losses at Tygerberg Hospital 1972-2014.

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## Chapter 6. Trends in the measurements of perinatally-related losses at Tygerberg Hospital 2003-2014.

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## 6.1 Introduction.

The leading causes for total perinatally related losses for Tygerberg hospital was published in 1986 (1), 1993 (2) and 2006 (3). There is now a need to investigate the perinatal data for the years following that and especially for the time period before and after the shifts discussed in the preceding chapters. This chapter will use the Tygerberg hospital perinatal data from 2003 to 2014 to provide a more comprehensive overview of perinatal losses at Tygerberg and to put this in perspective with the delivery data, including all deliveries  $\geq 500\text{g}$ .

The perinatal mortality (PNM) rate is the number of stillbirths and early neonatal deaths (within 7 days of birth) expressed per 1000 total births (dead and alive). The World Health Organisation (WHO) defines the onset of the perinatal period as 22 gestational weeks (154 days of gestation) and it ends seven days after birth (4). The duration of gestation is measured from the first day of the last menstrual period. Perinatal mortality rates are not part of the vital registration data but is used as an indicator of overall perinatal care (5). The inclusion of fetuses with birth weights 500g-999g in national statistics may improve the coverage of the losses  $\geq 1000\text{g}$  (6). The birth weight is normally 500 g by 22 weeks. The international classification of disease (ICD-10) recommends exclusion of all babies  $< 1000\text{g}$  from international comparisons as it disrupts the validity of comparisons (6).

Perinatally-related wastage (PNRW) gives a comparable overview of perinatal care but is an older definition that includes all stillbirths, deaths before discharge from hospital (even after 28 days) and all late abortions (stillbirths 500-999g). The PNRW rate includes all deaths within one year after discharge, but Pattinson and de Jong modified it to death before discharge, as it is more practical to use in a South African setting (1). It was originally proposed by Whitfield et al as a more realistic index for the audit of perinatal care (7).

World-wide, almost 99% of neonatal deaths occur in low- and middle income countries and the highest mortality rates are in sub-Saharan Africa (8). Stillbirths are not counted in the millennium development goals but it is estimated that 55% of an estimated 2.6 million third-trimester stillbirths per year occur in sub-Saharan Africa (9). There are challenges with data, as less than 5% of neonatal deaths and even fewer stillbirths are registered with home affairs offices (10).

Another challenge with international comparison between countries is the multiple classifications systems for deaths that exist. According to Keeling, the aim of a classification system is to understand the causes of perinatal deaths and to derive strategies to prevent mortality (11). One of the first classification systems, by Baird and co-workers from Aberdeen described a clinico-pathological approach using mainly clinical information (12). Their argument was that a post-mortem examination can determine the final cause of death but not necessarily the origin of that cause. Wigglesworth proposed a simple system in 1980 (13). His first approach was to investigate the cause of death within birth weight groups (<1000g, 1001-1500g, 1501-2000g, 2001-2500g and > 2500g). Each death could then be classified in one of five pathological subgroups (normally formed macerated, congenital malformations, immaturity, asphyxia conditions and other conditions not included in the rest). A large number of stillbirths using this classification can end up as 'unexplained' (up to 47%) (14).

The Nordic-Baltic perinatal death classification focus on potential avoidability and offers a good insight into the underlying condition (15). The ReCoDe system (relevant conditions at birth) re-classify almost 50% of 'unexplained' stillbirths as fetal growth restriction (16). The disadvantage of this system is its reliance on accurate gestation which is not always feasible in developing countries (17). The impact of facility-based perinatal audits in several middle- and low income countries (including SA) showed reductions in PNM rates of 20-44% (18).

The perinatal problem identification program (PPIP) used in SA is based on the Aberdeen classification (12), modified by Whitfield (7) and then again by Pattinson in 1989 and 1995, to include different tiers of avoidable factors (19).

The PNRW was used in the previous published comparisons of Tygerberg data, and specific reference will be made to the PNRW when it is used in preference to the PNM rate. For practical purposes, the PNRW rate is very close to the PNM rate when calculated for deaths  $\geq 500\text{g}$ , as most neonatal deaths occur in the first 7 days after delivery and very few after 28 days (but before discharge from the hospital). Fetal viability is now accepted to be lower than 28 weeks or 1kg birthweight, so the concept of 'late abortion' is also not used anymore. All PNM rates in this chapter, unless specifically stated otherwise, are for all deaths  $\geq 500\text{g}$ .

A further aim of this chapter is to present the complete perinatal mortality data in a way that can be used as baseline reference for all researchers in perinatal care interested in this time period.

## 6.2 Methods.

Reliable perinatal data is available in the hospital Perinatal Problem Identification Programme (PPIP) database since 2003. The data was systematically and prospectively interrogated since January 2010, when the author took over the responsibility for the PPIP data, ensuring that the monthly data is as correct as possible. A systematic effort also commenced retrospectively from that date, to ensure the accuracy and validity of the 2002-2009 data, by re-counting and re-calculating the monthly delivery and mortality data and investigating all the discrepancies by re-analysing the original patient case notes.

The PPIP data from 2003 to 2014 were checked for validity (a built-in feature of the software) to ensure all deaths in the database correspond to a death in the monthly data. The PPIP software was not used for any calculations. The raw data was exported and entered into a Microsoft Excel™ worksheet. The routine delivery data of the hospital, discussed in Chapter 3 was used as the denominator. All calculations of rates were done using Excel.

Each perinatal death is discussed at a weekly multidisciplinary mortality meeting where the coding is done by a team including obstetricians, neonatologists, fetal medicine specialists, anatomical pathologists and human geneticists. Placental histology was used since 2005 to help elucidate the cause of death. Histology is requested according to a local policy for all unexplained stillbirths or early neonatal death where the reason for death is not clear.

The data was analysed as follows:

1. Combined data (of the complete study period) to determine the major primary (obstetric) causes of death.

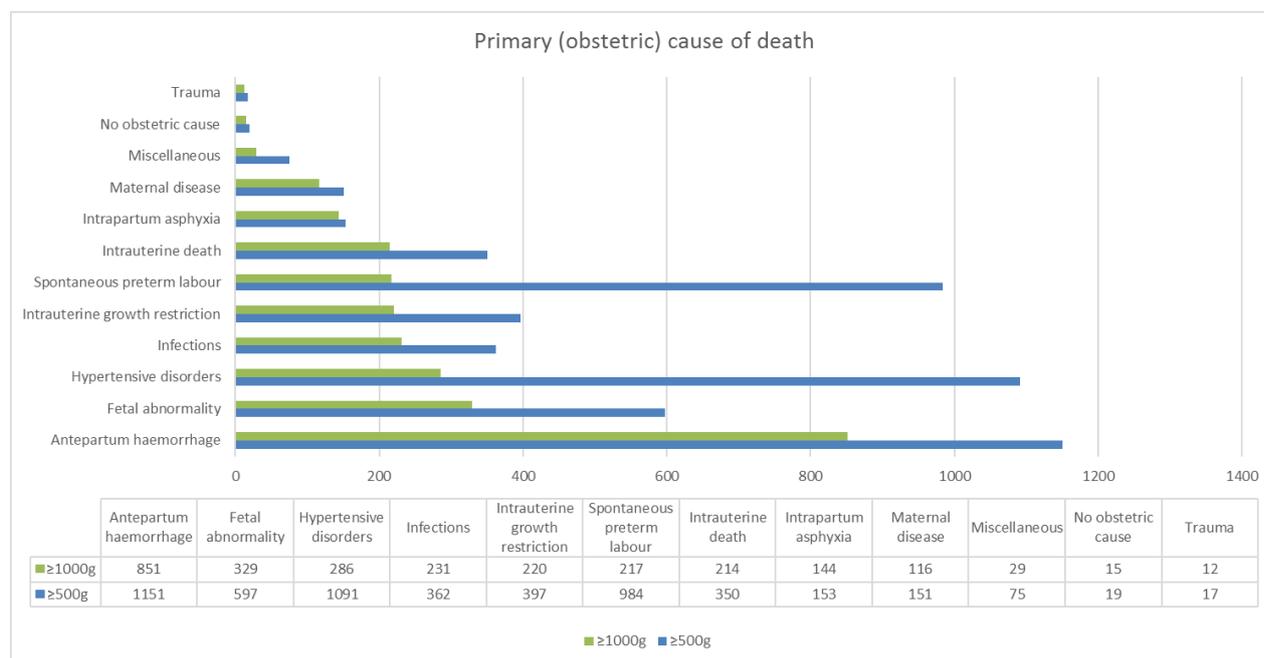
2. Combined data (of the complete study period) to determine the major final (neonatal) causes of death.
3. Total PNRW in numbers, clustered into weight categories and showing trends over the time period.
4. The PNRW rates, showing trends over time.
5. The perinatal, neonatal, early neonatal, late neonatal and stillbirth rates over the time period.

### 6.3 Results

There were 5347 stillbirths and neonatal deaths within this study period. As the deaths are relatively rare events, the first part of the data is presented collectively for the total time period (Figures 6.3.1-6.3.15).

The actual numbers of the primary obstetric causes of death (using the diagnostic criteria from PPIP) are shown in Figure 6.3.1. Antepartum haemorrhage was the leading obstetric cause of death. The term *intra-uterine death* is used for all causes of stillbirth where the obstetric cause was not obvious.

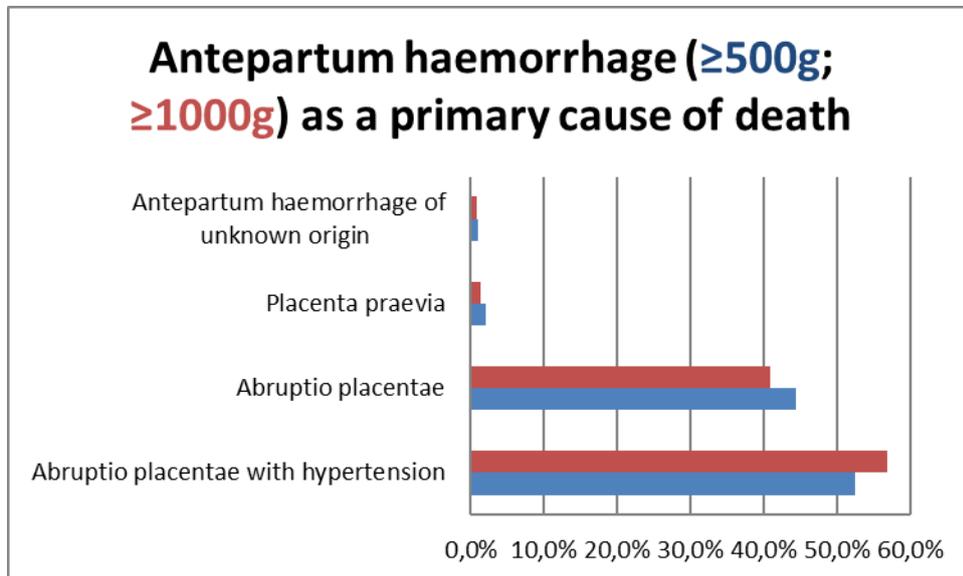
Figure 6.3.1. Primary (obstetric) cause of death- all diagnostic groups 2003-2014.



The major causes of death in each group was further analysed to identify the main causative factor. A breakdown of the antepartum haemorrhage group (n=1151 for ≥500g and n=851 for ≥ 1000g) shown that abruptio placentae is the major contributing factor. All patients with

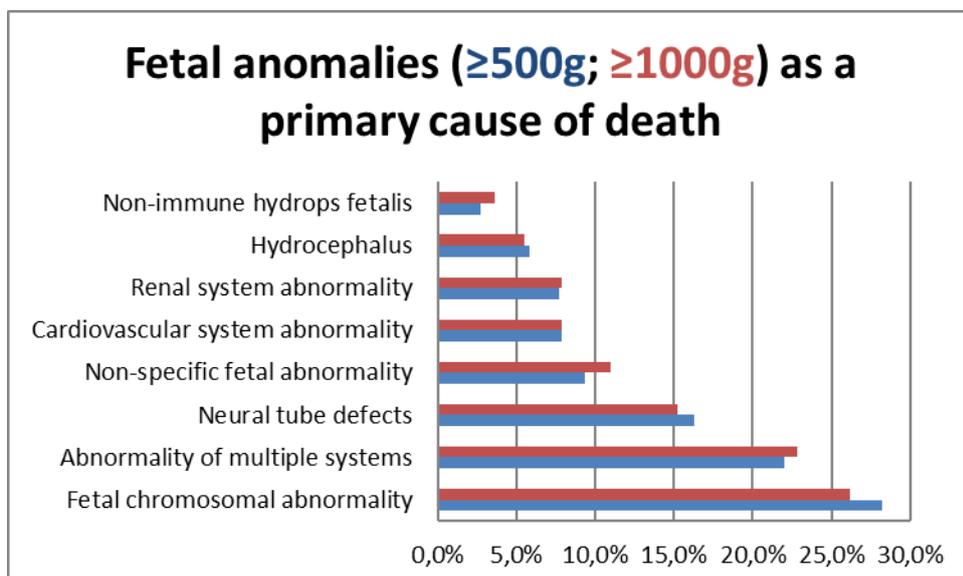
hypertensive disorders that developed abruptio placentae are included in this group. This is shown in Figure 6.3.2.

Figure 6.3.2. Primary cause- antepartum haemorrhage.



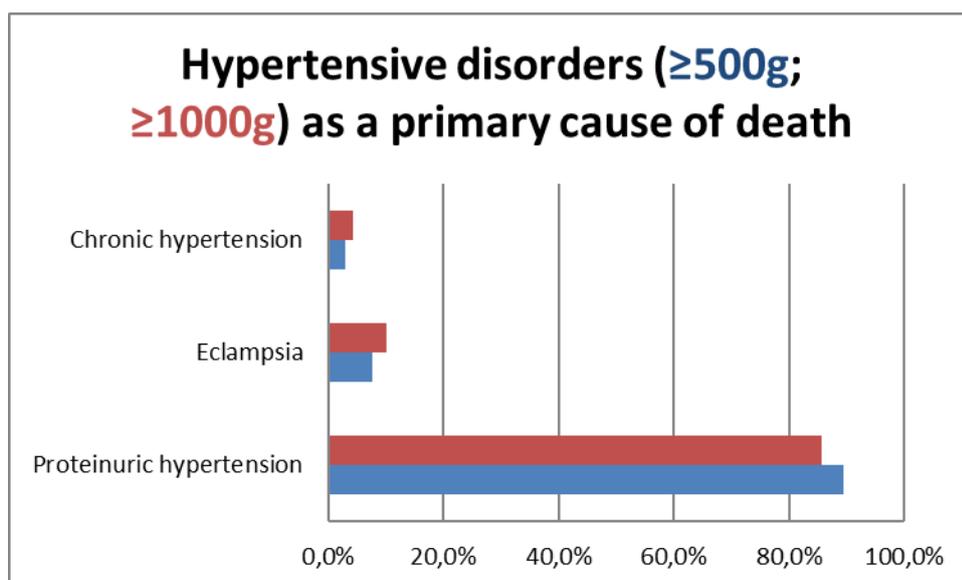
The second important cause of death is congenital fetal abnormalities (n=597 for  $\geq 500\text{g}$  and n=329 for  $\geq 1000\text{g}$ ). A breakdown of the causes is shown in Figure 6.3.3. Fetal chromosomal abnormalities and abnormalities of multiple systems dominate all the birth weights as leading cause of death.

Figure 6.3.3. Primary cause- fetal anomalies.



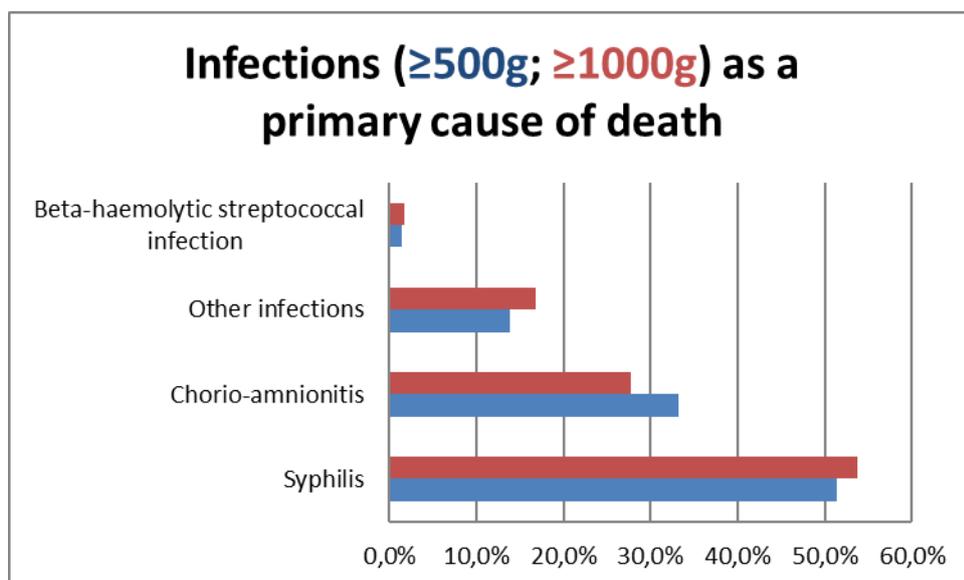
In the hypertensive group (n=1091 for  $\geq 500\text{g}$  and n=286 for  $\geq 1000\text{g}$ ), shown in Figure 6.3.4, the major contributor to death is pre-eclampsia (proteinuric hypertension). Most babies that die from pre-eclampsia are less than 1000g in birthweight.

Figure 6.3.4. Primary cause- hypertensive disorders.



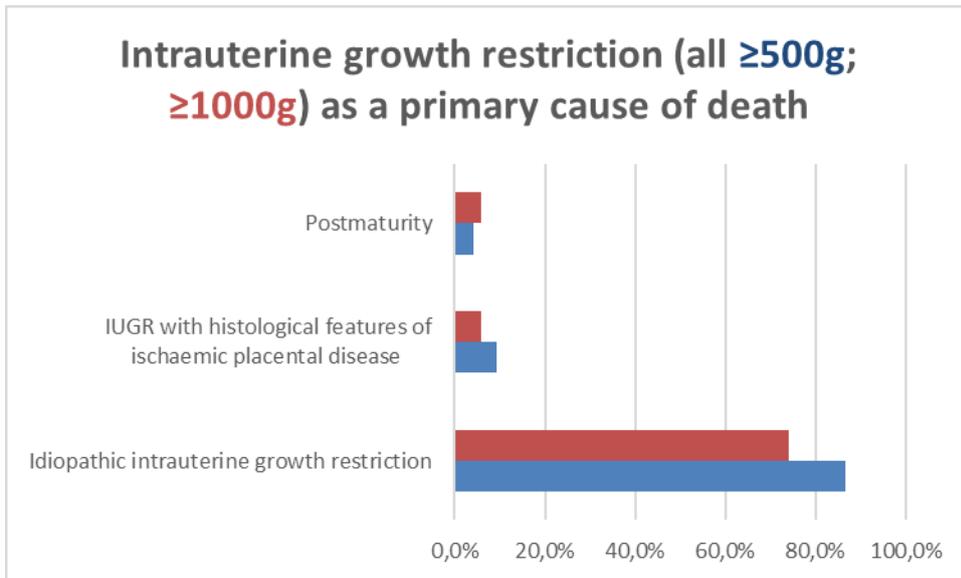
The infective causes are dominated by syphilis- more than 50% of babies that die from infective causes succumb to syphilis. This is shown in Figure 6.3.5. Although in the PPIP database, preterm labour with chorio-amnionitis is classified under preterm labour, for analysis purposes chorio-amnionitis is added to the infection group. In most cases of ascending infection, the infective process stimulates the preterm labour which is the secondary event.

Figure 6.3.5. Primary cause- infections.



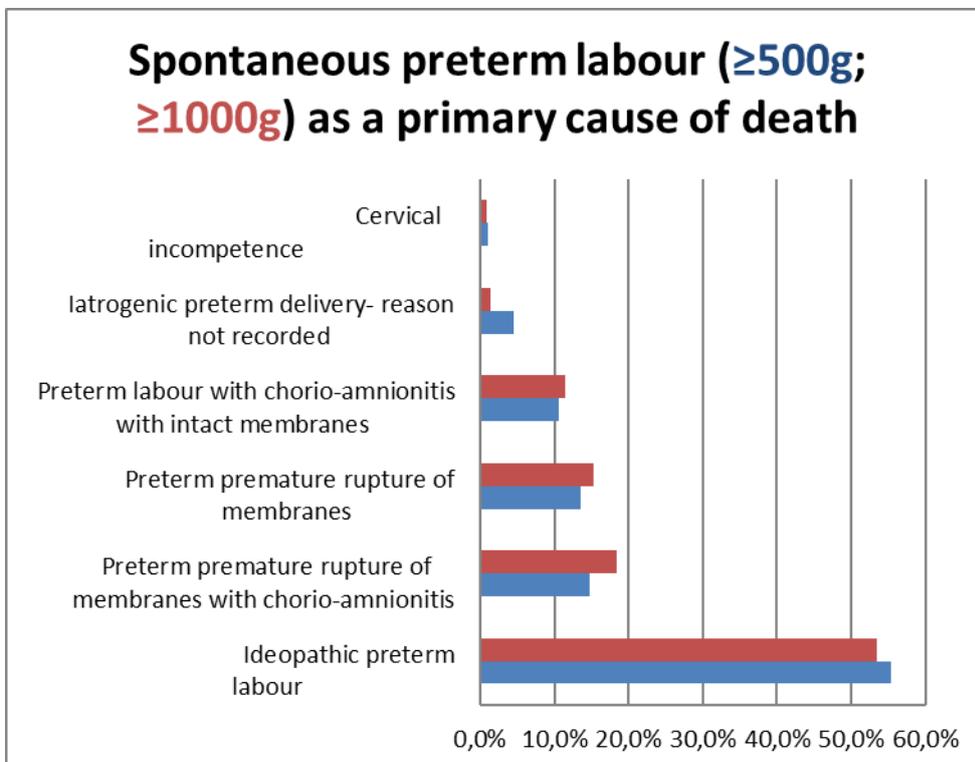
Intra-uterine growth restriction (IUGR) accounts for more than 5% of all deaths and the biggest contributor here is IUGR of unknown cause- depicted in Figure 6.3.6. All cases of IUGR where a cause was elucidated by placental histology are included in their respective disease categories in the appropriate graphs. IUGR due to placental ischaemia is included in this graph. IUGR diagnosed as part of the hypertensive disease groups was classified under hypertension. The unexplained IUGR are deaths where placental histology was either not available or informative enough to make a definitive diagnosis.

Figure 6.3.6. Primary cause- intrauterine growth restriction.



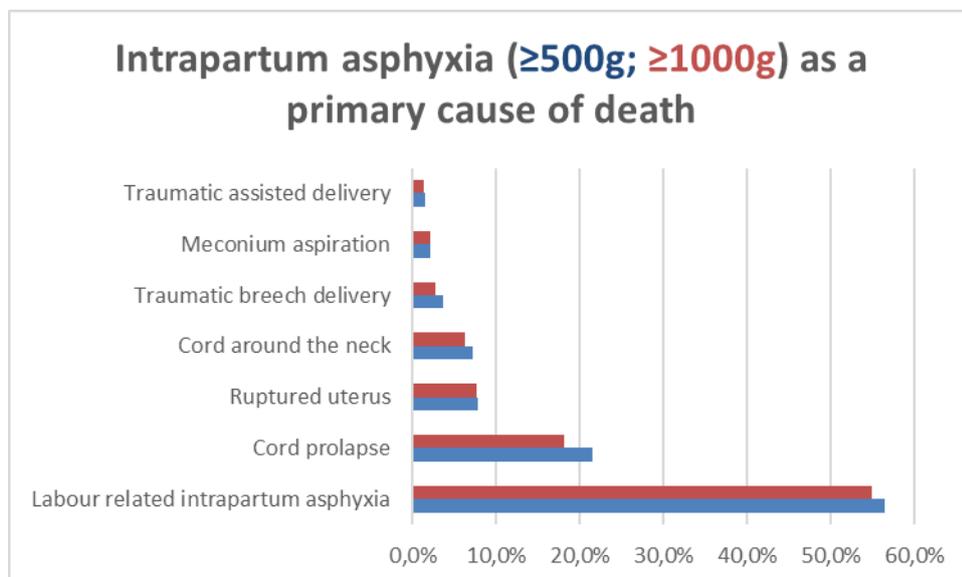
The preterm labour group is shown in Figure 6.3.7. Idiopathic (spontaneous) preterm labour was the most important reason for death during or after delivery.

Figure 6.3.7. Primary cause- preterm labour.



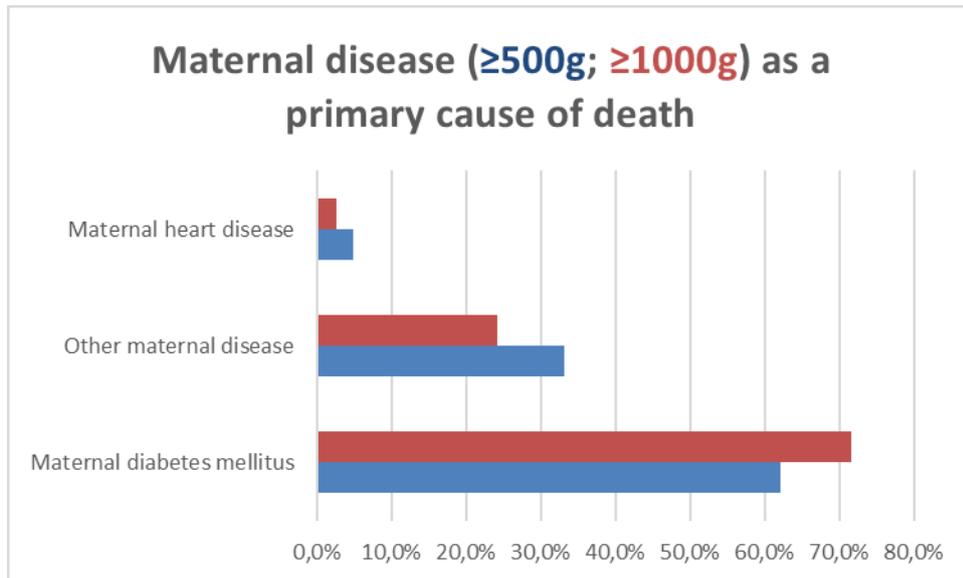
The contributors to intra-partum asphyxia are depicted in Figure 6.3.8. This group only accounts for 2.86% of deaths. Labour-related events are the most important in this group.

Figure 6.3.8. Primary cause- intrapartum asphyxia.



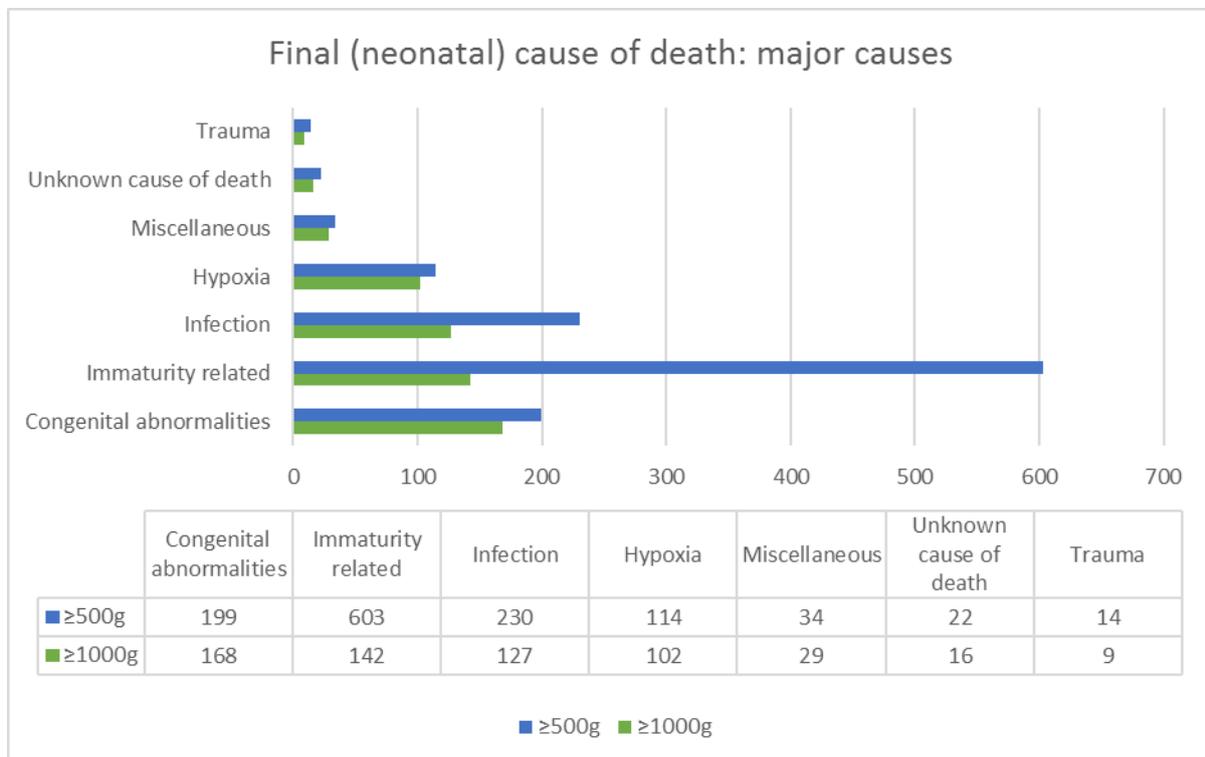
The most important underlying medical condition in pregnancy that contributed to a fetal death was diabetes mellitus. The group of other maternal disease (n=48 or 0.9% of all deaths) includes systemic lupus and other auto-immune diseases, maternal febrile conditions such as disseminated tuberculosis and HIV associated conditions as well as various other conditions that initiated the event that led to a death. This is shown in Figure 6.3.9.

Figure 6.3.9. Primary cause- maternal disease.



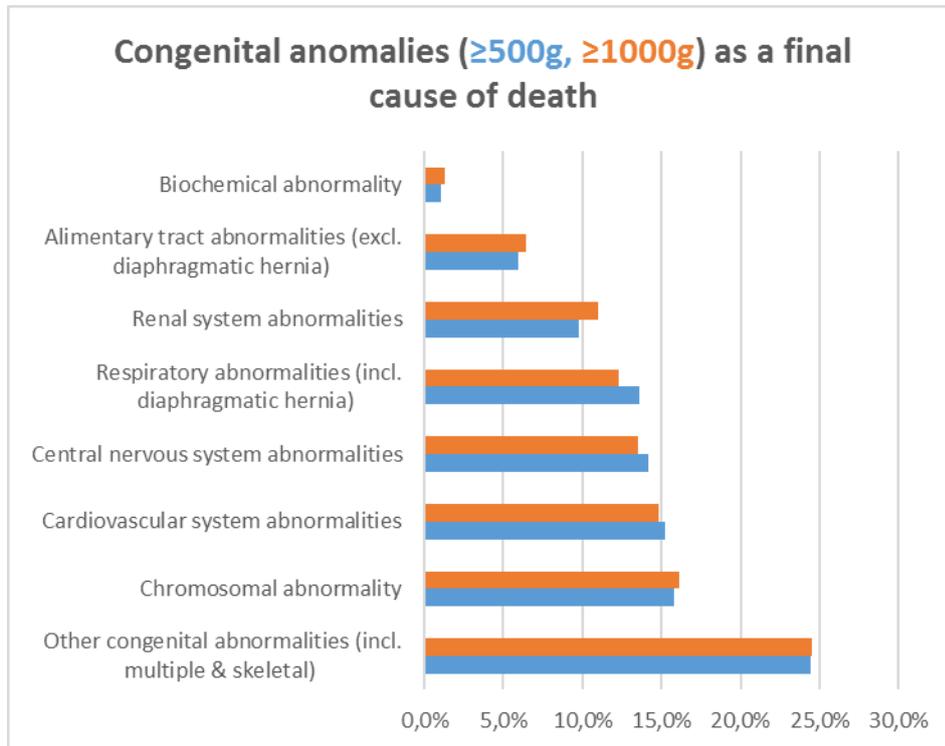
The next part of the results section is devoted to the final (neonatal) cause of death when not a stillbirth. This is the neonatal disease or event that led to the demise of the baby. The major causes (actual numbers from all diagnostic groups) for the total study period (2003-2014) is shown in Figure 6.3.10 and the individual breakdown of each cause in the figures that follow.

Figure 6.3.10. Final cause of death (all major diagnostic groups).



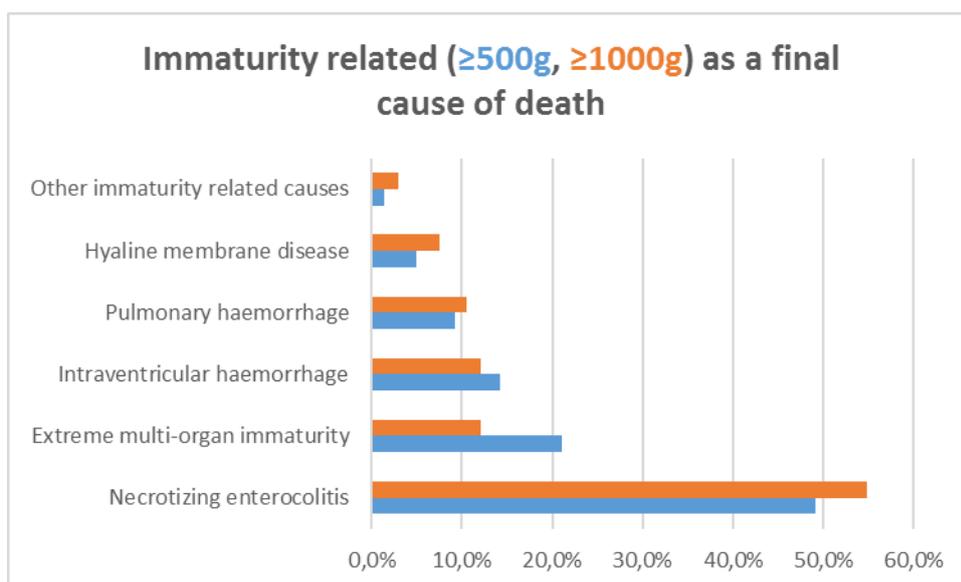
Congenital abnormalities are the most important cause of death for neonates >1000g that was born alive in Tygerberg hospital (16.4% of all neonatal deaths). Multiple system affectation and chromosomal abnormalities are the leading causes and this is shown in Figure 6.3.11.

Figure 6.3.11. Final cause of death- congenital anomalies.



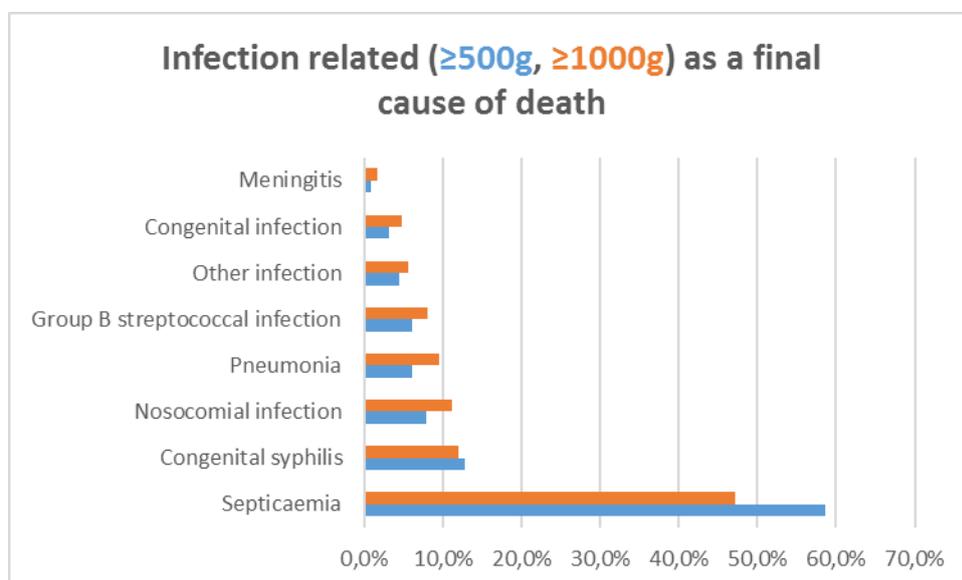
The leading cause of death in babies born  $<1000\text{g}$  are immaturity but in all weight groups necrotising enterocolitis is the main final pathway of death for prematurely born infants. This is shown in Figure 6.3.12.

Figure 6.3.12. Final cause of death- immaturity.



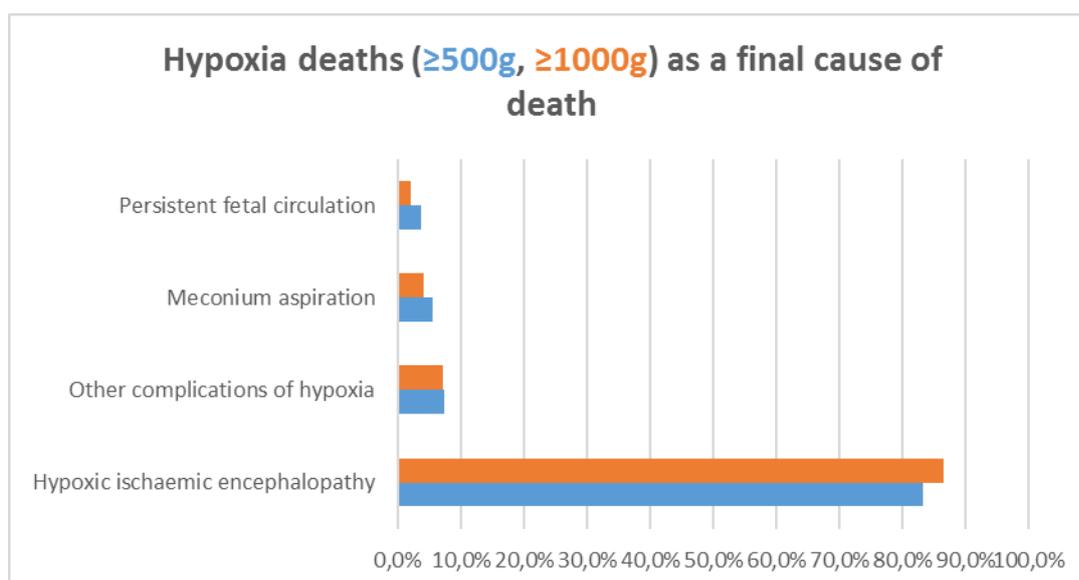
Most neonates that die from infective causes are due to septicaemia, syphilis and hospital acquired infection. This is shown in Figure 6.3.13.

Figure 6.3.13. Final cause- infection.



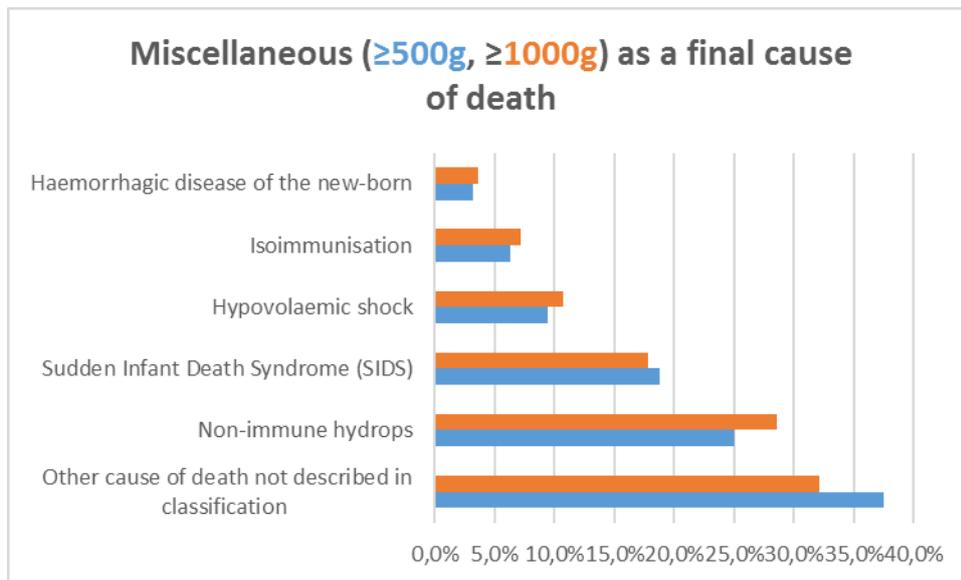
When the final cause is hypoxia, the main contributor is hypoxic ischaemic encephalopathy. There were 8 cases where the final cause for the hypoxic death were various rare events classified as *other complications*. This is shown in Figure 6.3.14.

Figure 6.3.14. Final cause- hypoxia.



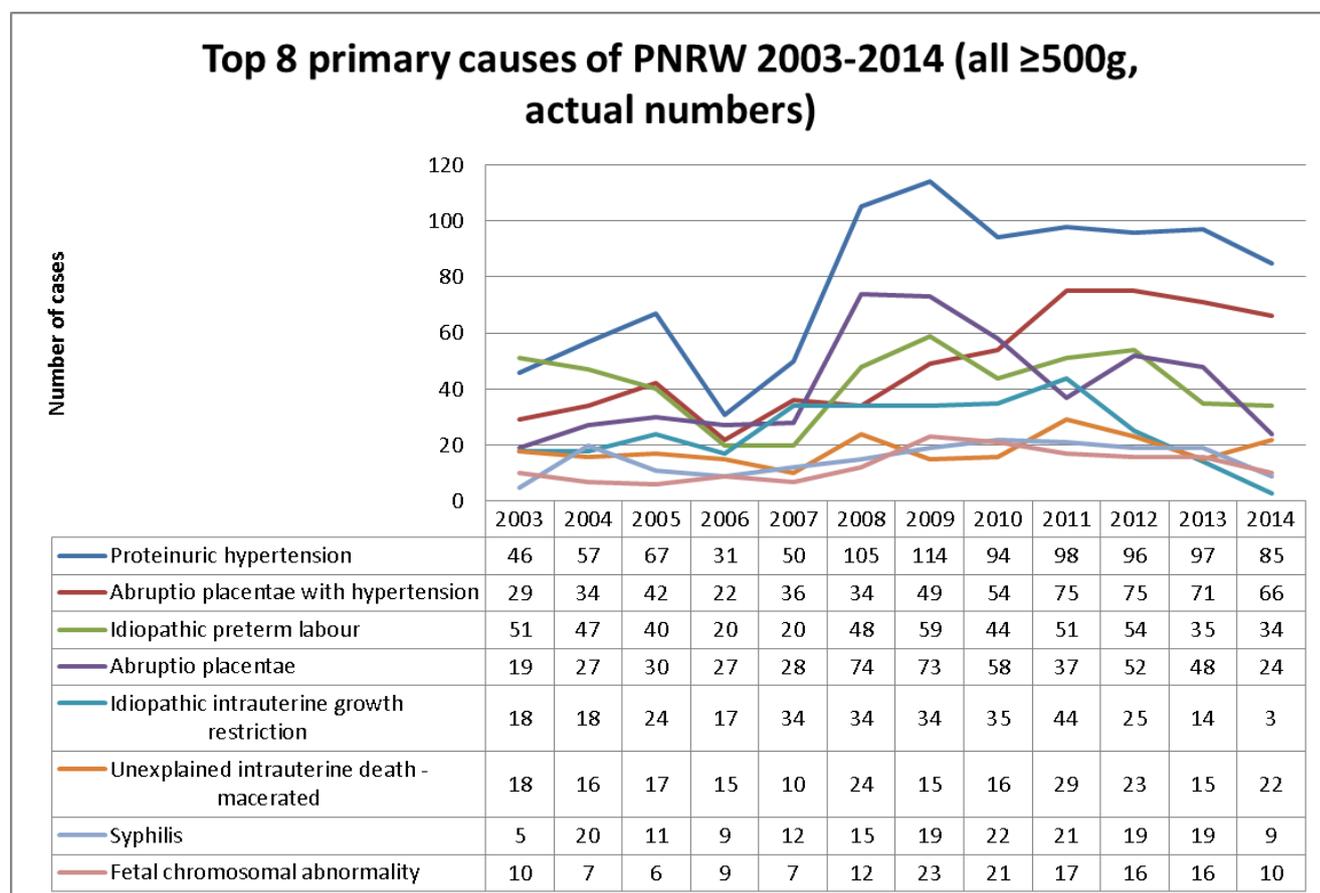
The contribution of rarer causes of death is shown in Figure 6.3.15.

Figure 6.3.15. Final cause- miscellaneous.



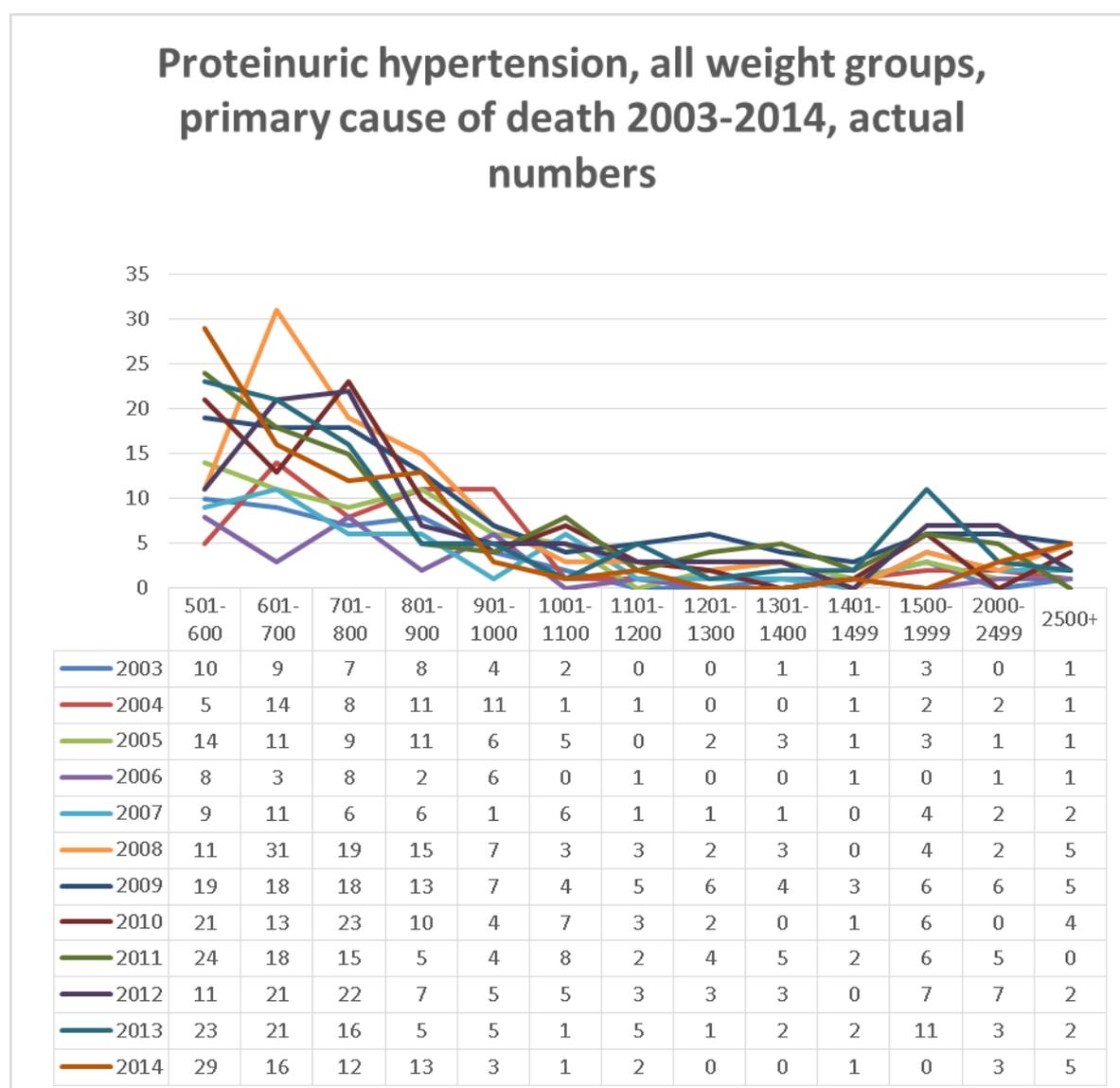
The third section of results will focus on total PNRW (all babies  $\geq 500g$ ) and will display the data over timeframes to depict trends. The first graph depicts the actual numbers of babies that died from a specific cause. The data focus on the most important individual diagnostic contributors to PNRW. The first section will depict real numbers and the later graphs will calculate the PNRW rates. Figure 6.3.16 shows the 8 most important primary causes of total PNRW. The increase in numbers of complex cases referred to Tygerberg hospital after the 2008 shifts are evident.

Figure 6.3.16. The most important obstetric causes of perinatally related wastage (actual numbers).



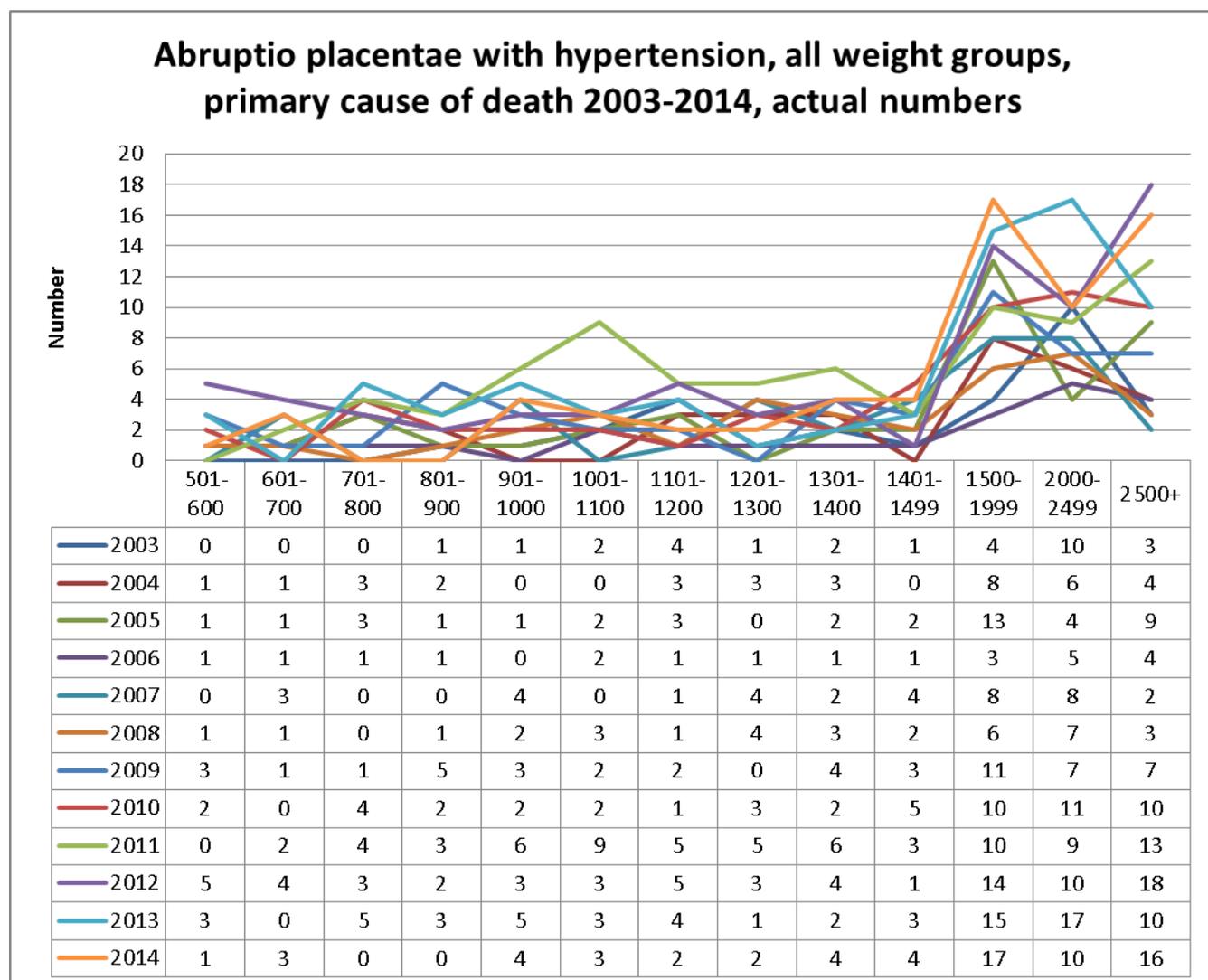
For the individual diagnostic groups, the data was further clustered into weight categories- every 100g for 500-1499g and then every 500g thereafter. The most important cause of PNRW is pre-eclampsia. This is shown in Figure 6.3.17. Most babies that die from pre-eclampsia are in the weight groups 500-800g.

Figure 6.3.17. Actual number of deaths (obstetric cause: pre-eclampsia) per weight group, 2003-2014.



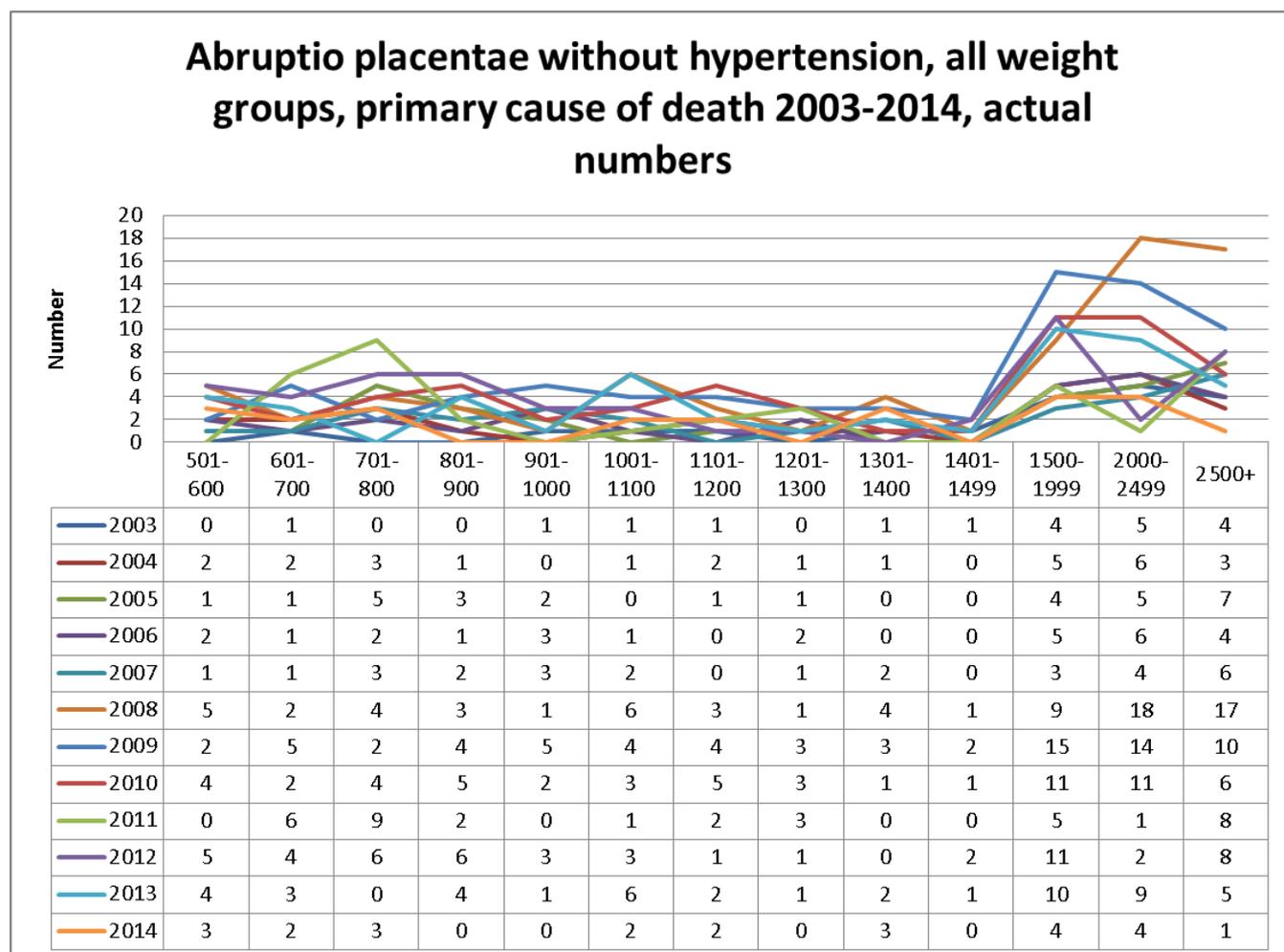
Abruptio placentae associated with hypertensive disease is the second most important cause and it kills most babies in the 1000g-2000g birth weight bracket. This is shown in Figure 6.3.18.

Figure 6.3.18. Actual number of deaths (obstetric cause: abruptio placentae with hypertension) per weight group, 2003-2014.



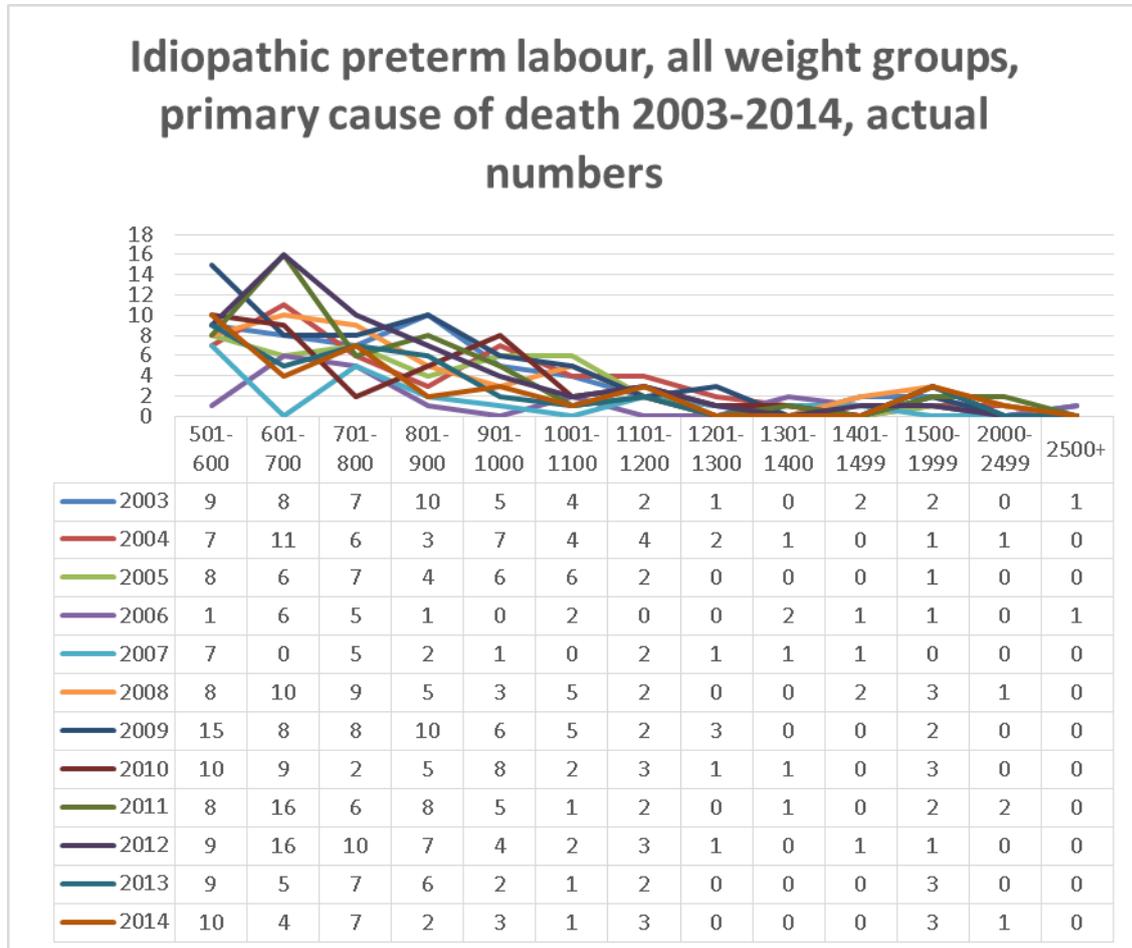
The data from abruptio placentae without hypertension is depicted in Figure 6.3.19 and follows the same pattern as abruptio with hypertension.

Figure 6.3.19. Actual number of deaths (obstetric cause: abruptio placentae without hypertension) per weight group, 2003-2014.



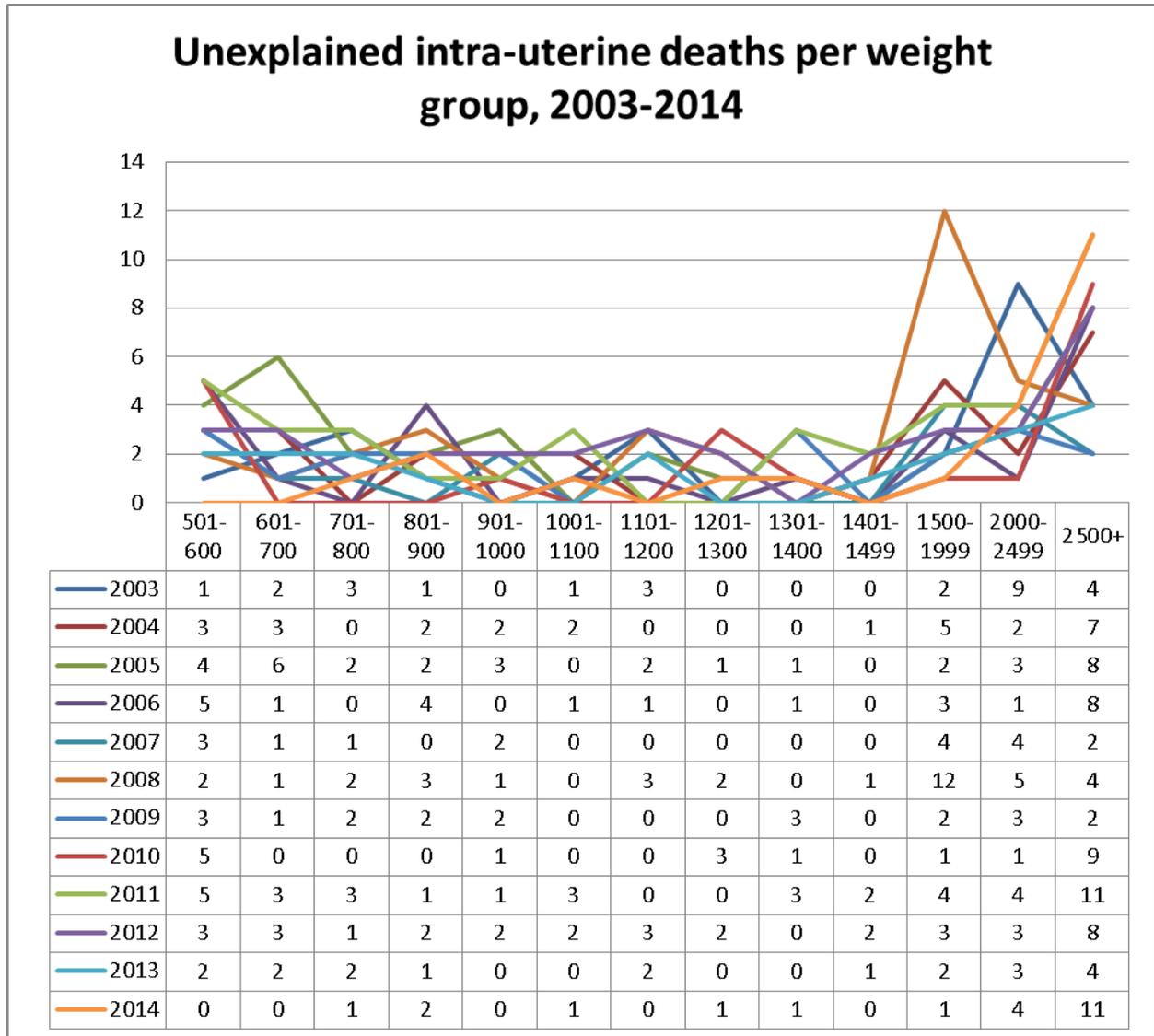
The deaths from spontaneous preterm labour are depicted in Table 3.3.20. Most babies are in the <1000g weight bracket.

Figure 6.3.20. Actual number of deaths (obstetric cause: spontaneous preterm labour) per weight group, 2003-2014.



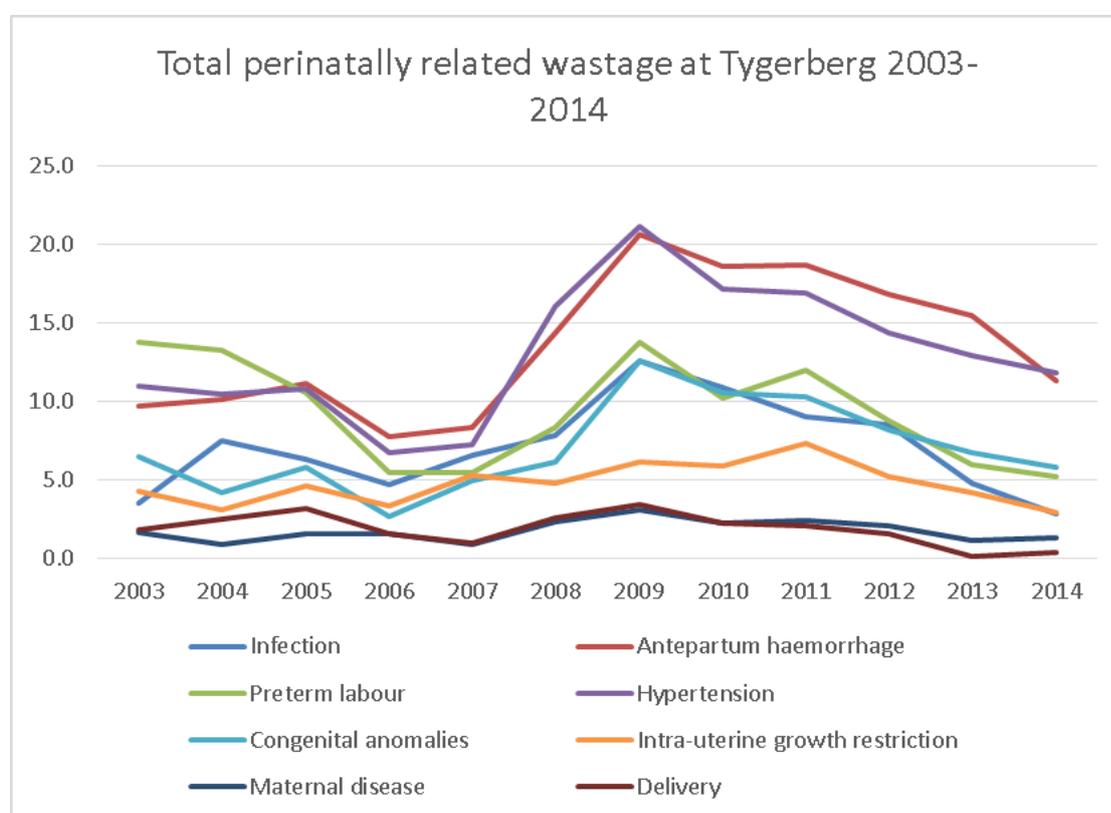
The next important group of PNRW is unexplained intra-uterine death. Most of these babies are bigger than 2000g. By 2012 the number of unexplained deaths is lower most likely due to the use of placental histology to identify the cause of death. This is shown in Figure 6.3.21.

Figure 6.3.21. Actual number of stillbirths from unexplained causes, per weight group, 2003-2014.



The following section will present the *rates* of PNRW. All of these rates are for babies  $\geq 500\text{g}$  and the delivery data of the corresponding year and weight group was used as denominator. All rates are per 1000 deliveries (dead and alive  $\geq 500\text{g}$ ). The rates for the major diagnostic groups will be presented first, followed by the individual breakdown of every group. The corresponding perinatal mortality rates will be presented after the PNRW data. The rates of the major groups are shown in Figure 6.3.22.

Figure 6.3.22. The PNRW rate at Tygerberg hospital, 2003-2014 (all groups).



The rates for the breakdown of the individual groups are shown in Figures 6.3.23 to 6.3.30. IUGR with ischaemic placental disease is a new diagnostic criterion that was added to the PPIP software during 2012. This relies on placental histology. Figure 6.3.27 shows the decrease in the number of unexplained IUDs since 2012. Although syphilis remains a major cause of death it does seem as if the rate has declined since 2010.

Figure 6.3.23. PNRW rate for the hypertension group, 2003-2014.

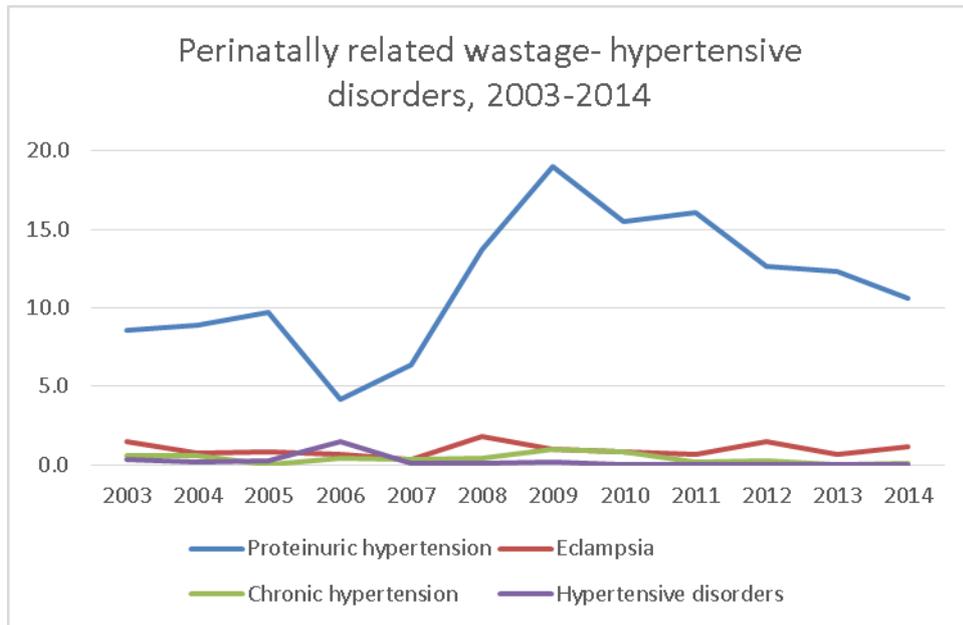


Figure 6.3.24. PNRW rate for the antepartum haemorrhage group, 2003-2014.

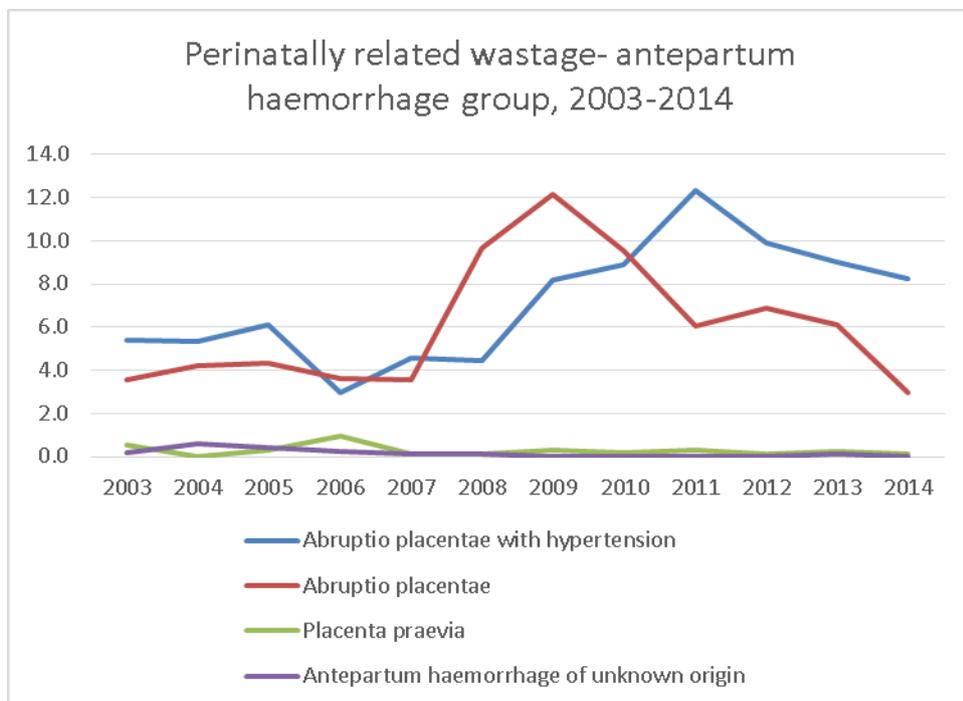


Figure 6.3.25. PNRW rate for the preterm labour group, 2003-2014.

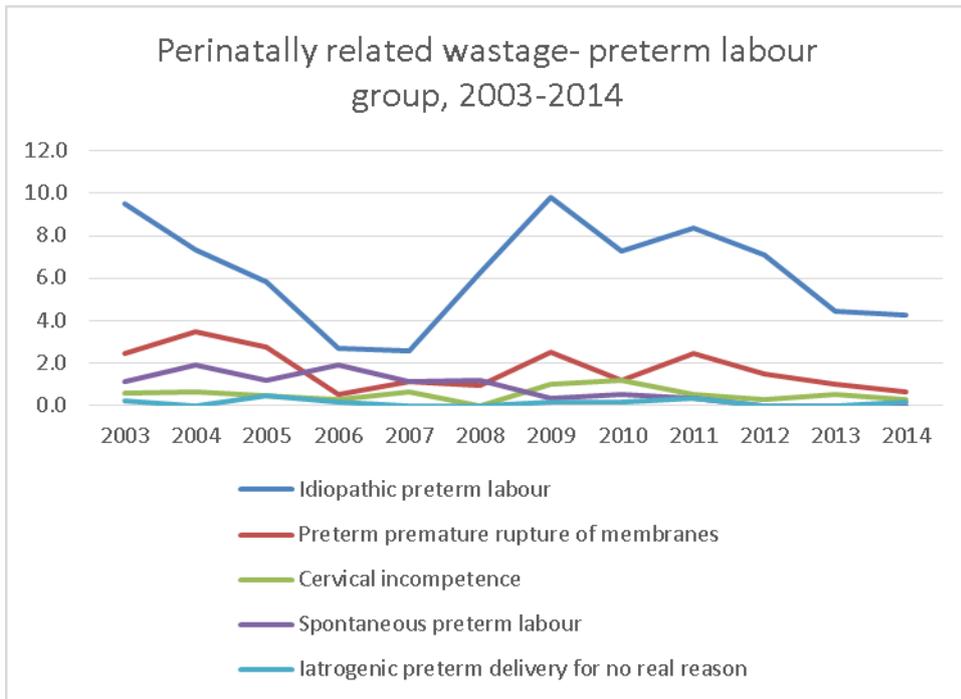


Figure 6.3.26. PNRW rate for the congenital anomaly group, 2003-2014.

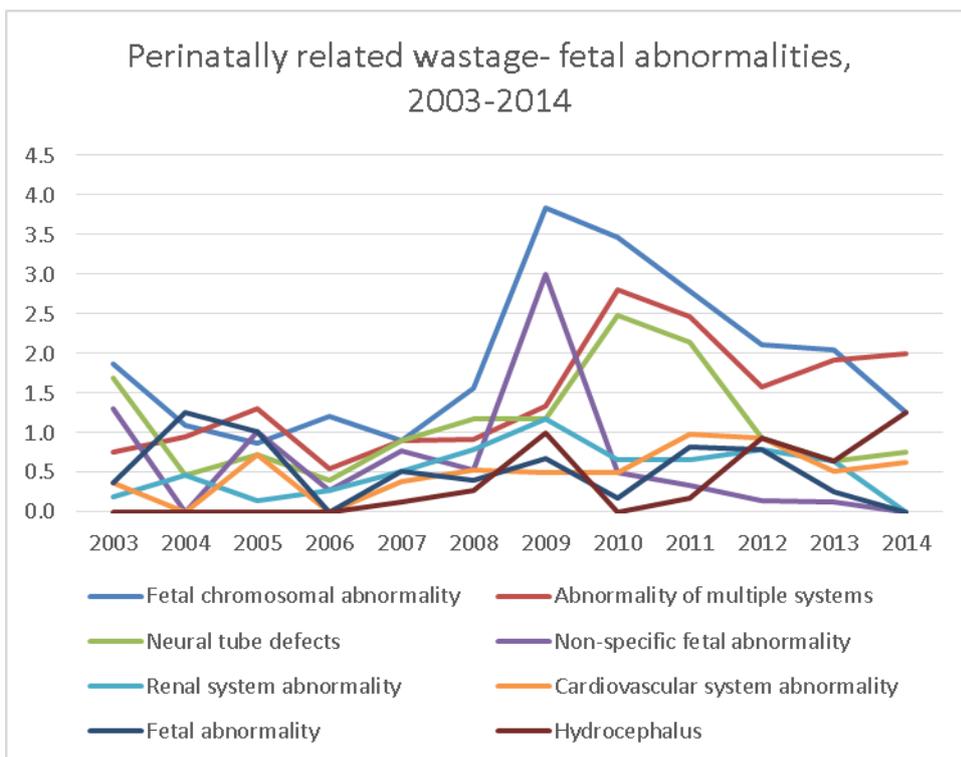


Figure 6.3.27. PNRW rate for the intra-uterine growth restriction group, 2003-2014.

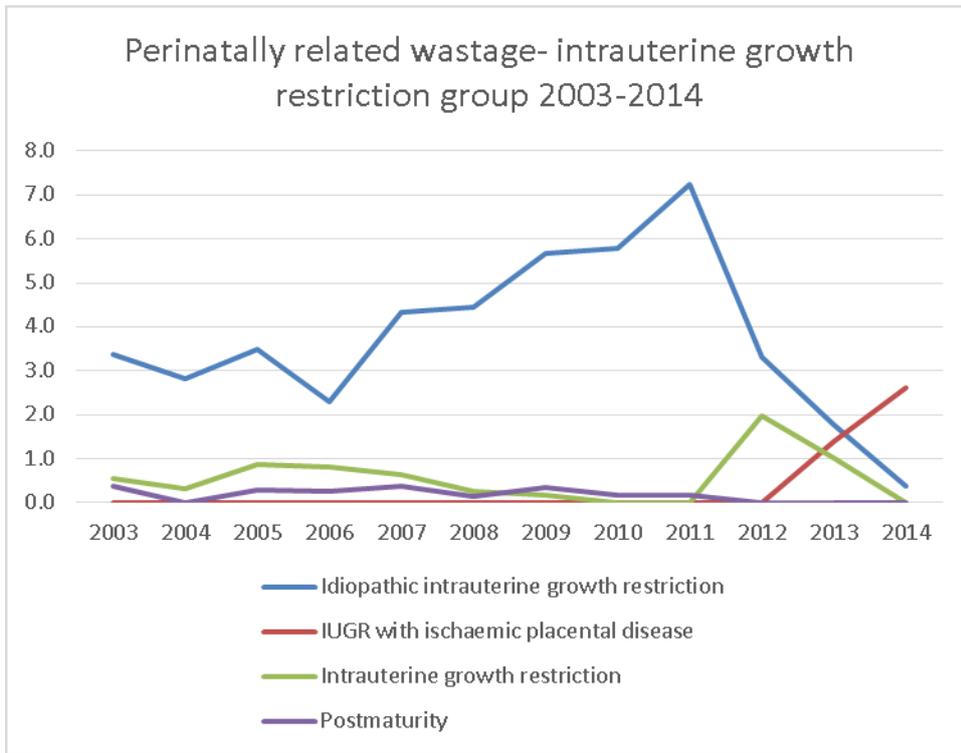


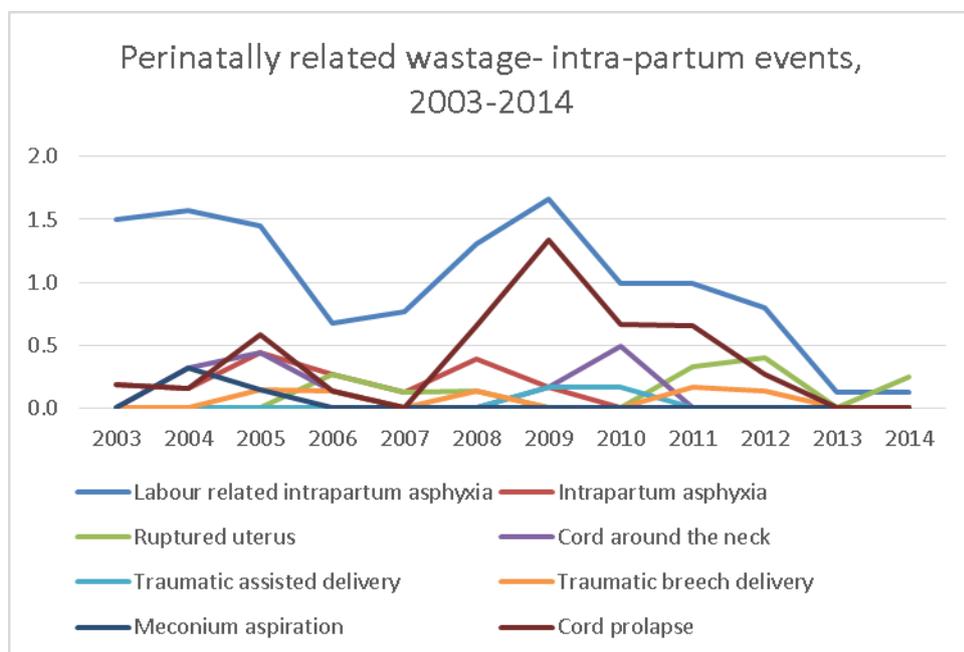
Figure 6.3.28. PNRW rate in the infection group, 2003-2014.



Figure 6.3.29. PNRW rate in the maternal disease group, 2003-2014.



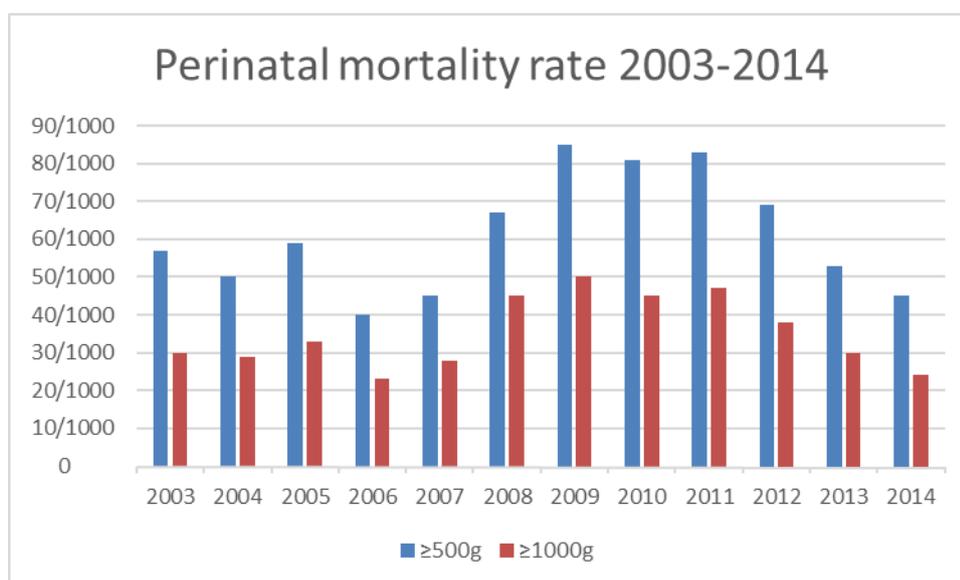
Figure 6.3.30. PNRW rate related to intra-partum events, 2003-2014.



The rate of wastage related to intra-partum events has decreased since 2009.

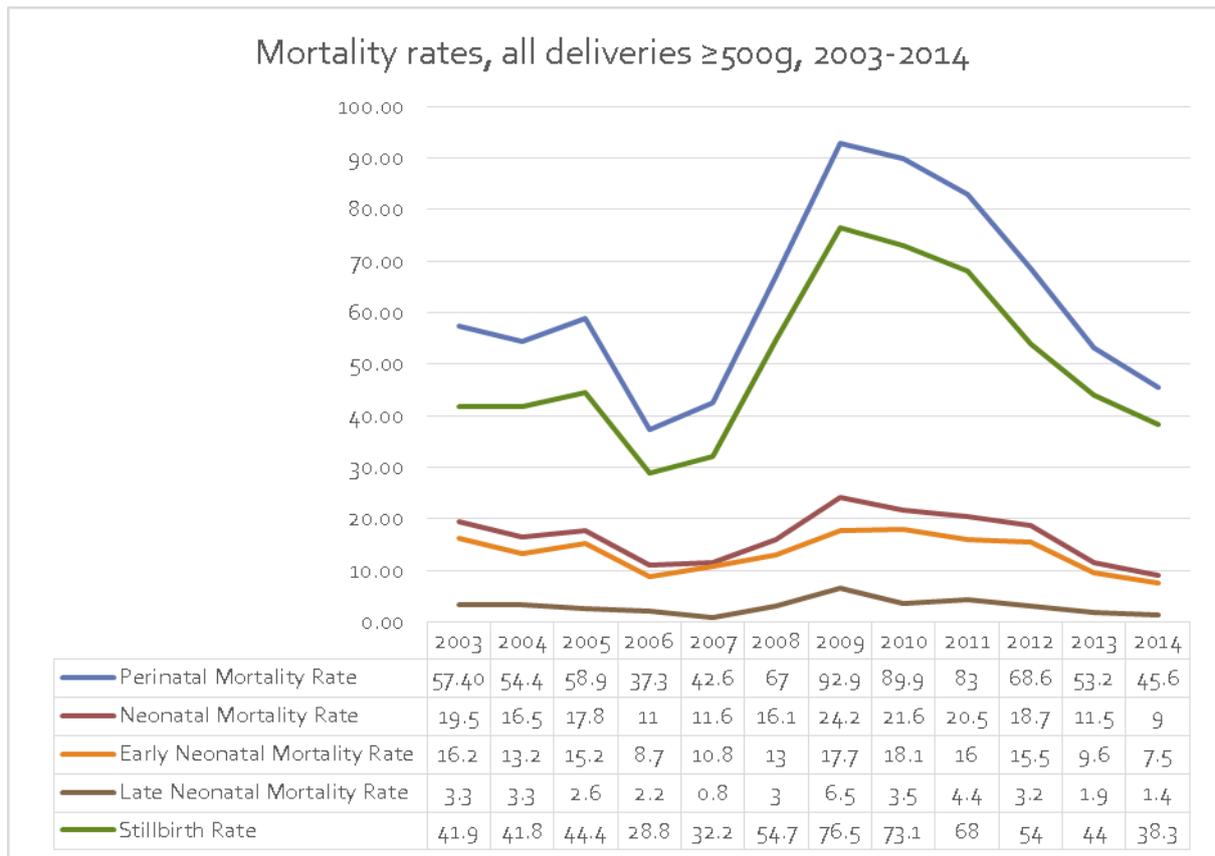
The next section of the data reports the *mortality rates*. The PNM rate for the total study period is shown in Figure 6.3.31. All rates are expressed per 1000 deliveries and the relevant weight group ( $\geq 500\text{g}$  or  $\geq 1000\text{g}$ ) is included the graphs. There was a decline in the hospital PNM rate in 2006-2007 and again from 2011-2014.

Figure 6.3.31. PNM rate for 2003-2014.



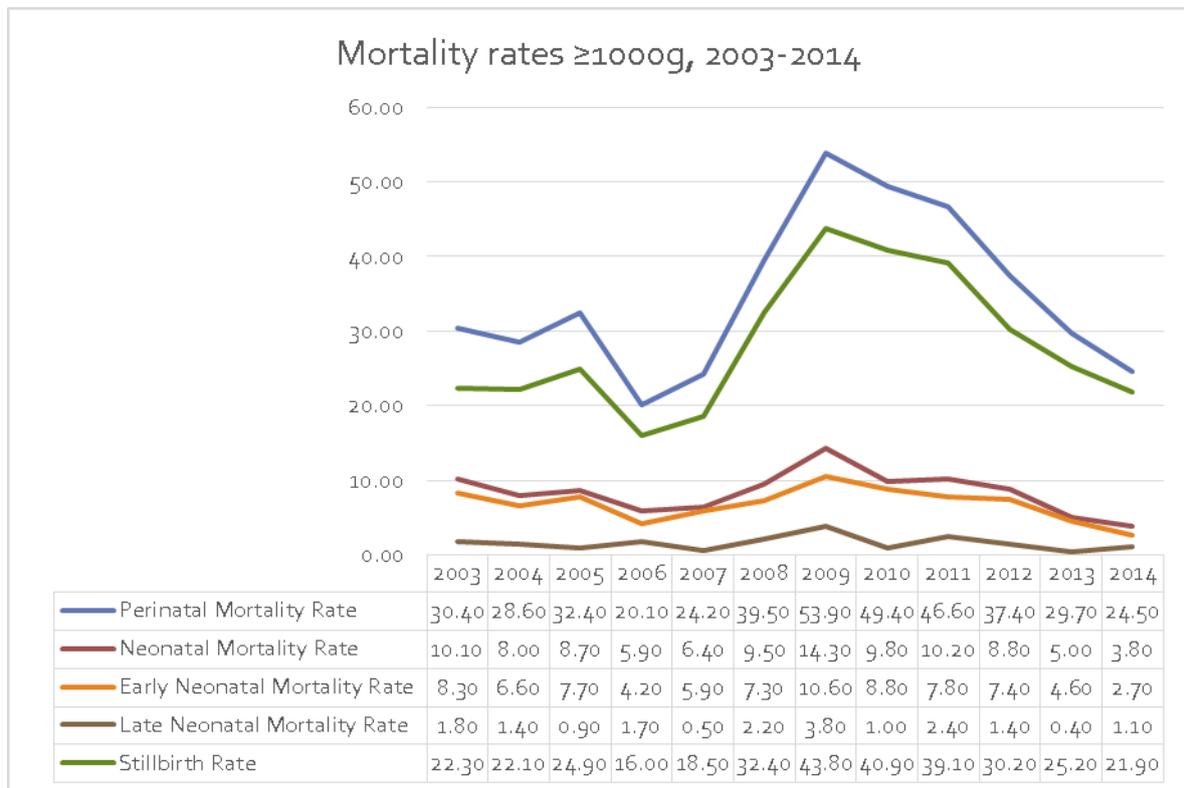
To ease understanding of the mortality rates, the following data will present yearly rates for the different weight groups. Figure 6.3.32 presents all rates for all babies  $\geq 500\text{g}$  (perinatal, neonatal, early neonatal, late neonatal and stillbirth rate).

Figure 6.3.32. Mortality rates for all babies  $\geq 500\text{g}$  at Tygerberg hospital 2003-2014.



The corresponding data for all deliveries  $\geq 1000\text{g}$  is presented in Figure 6.3.33.

Figure 6.3.33. Mortality rates for all babies ≥1000g at Tygerberg hospital 2003-2014.



The mortality rates within each birth weight group are presented in Figures 6.3.34 to 6.3.37.

Figure 6.3.34. Mortality rates for all babies 1000-1499g at Tygerberg hospital 2003-2014.

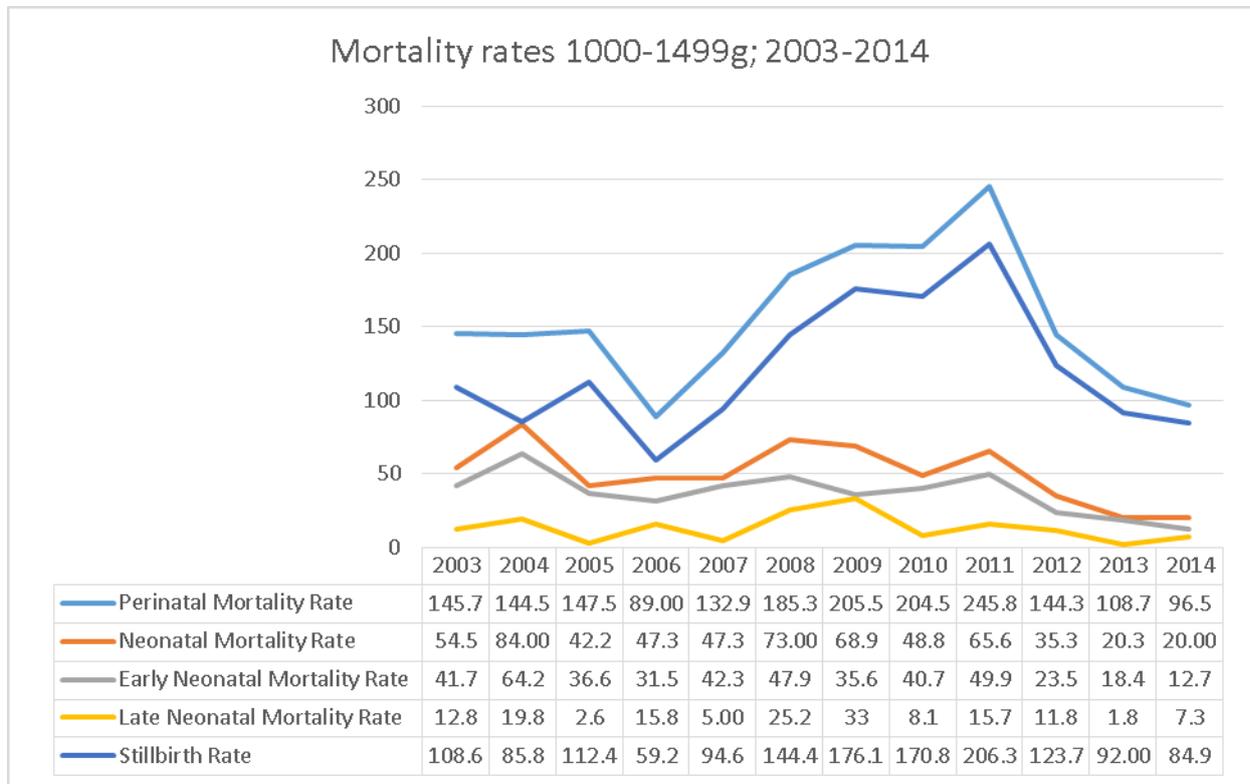


Figure 6.3.35. Mortality rates for all babies 1500-1999g at Tygerberg hospital 2003-2014.

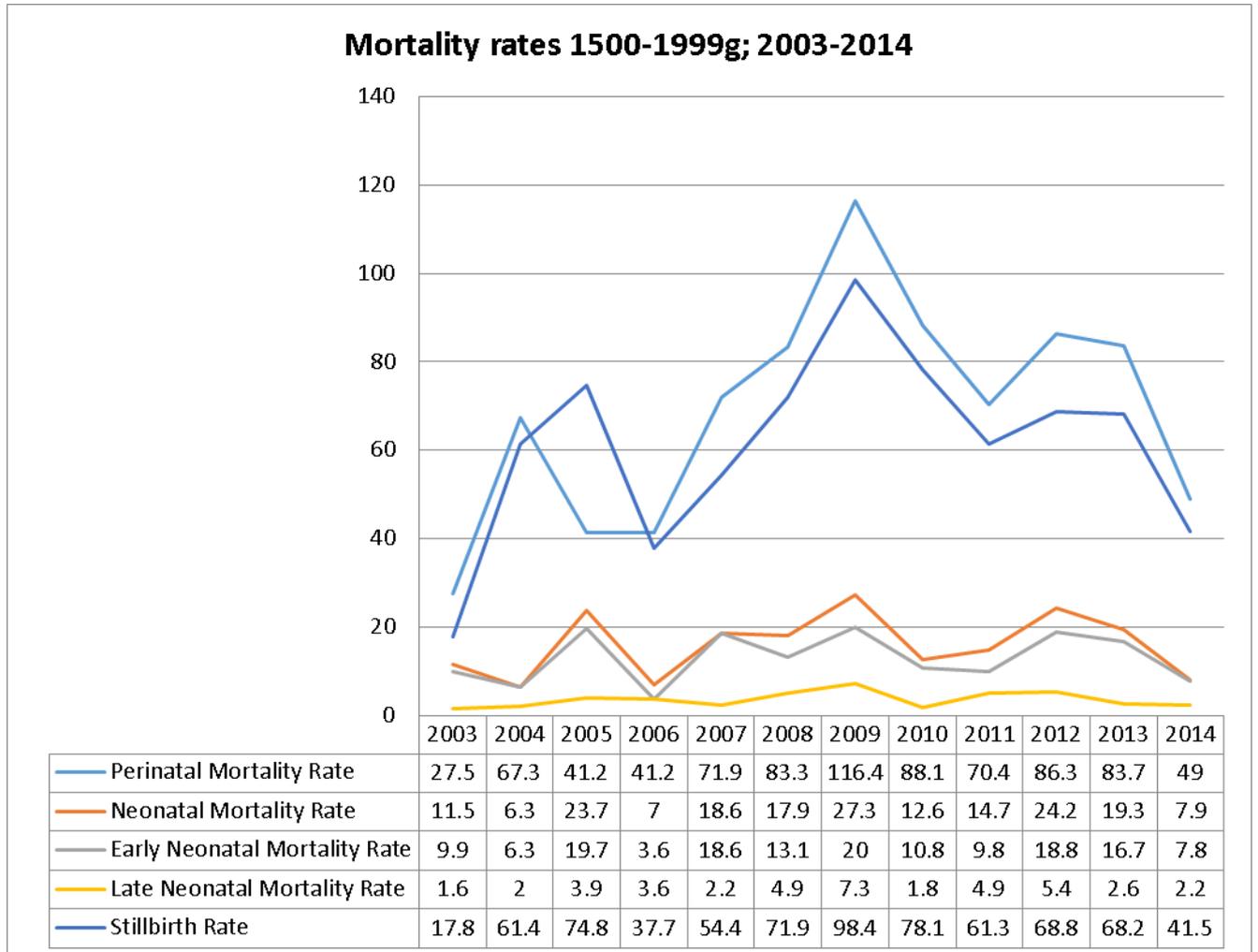


Figure 6.3.36. Mortality rates for all babies 2000g-2499g at Tygerberg hospital 2003-2014.

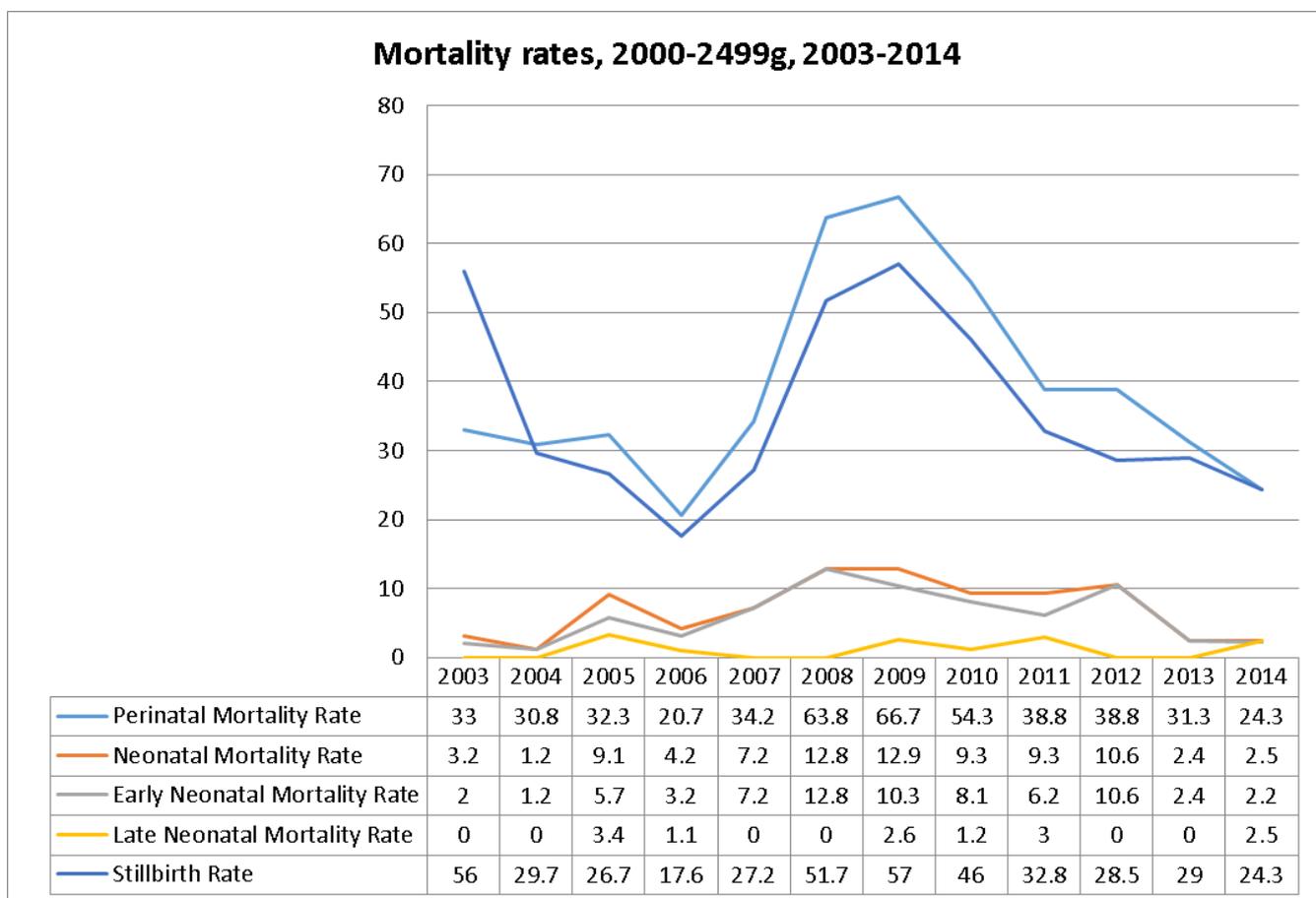
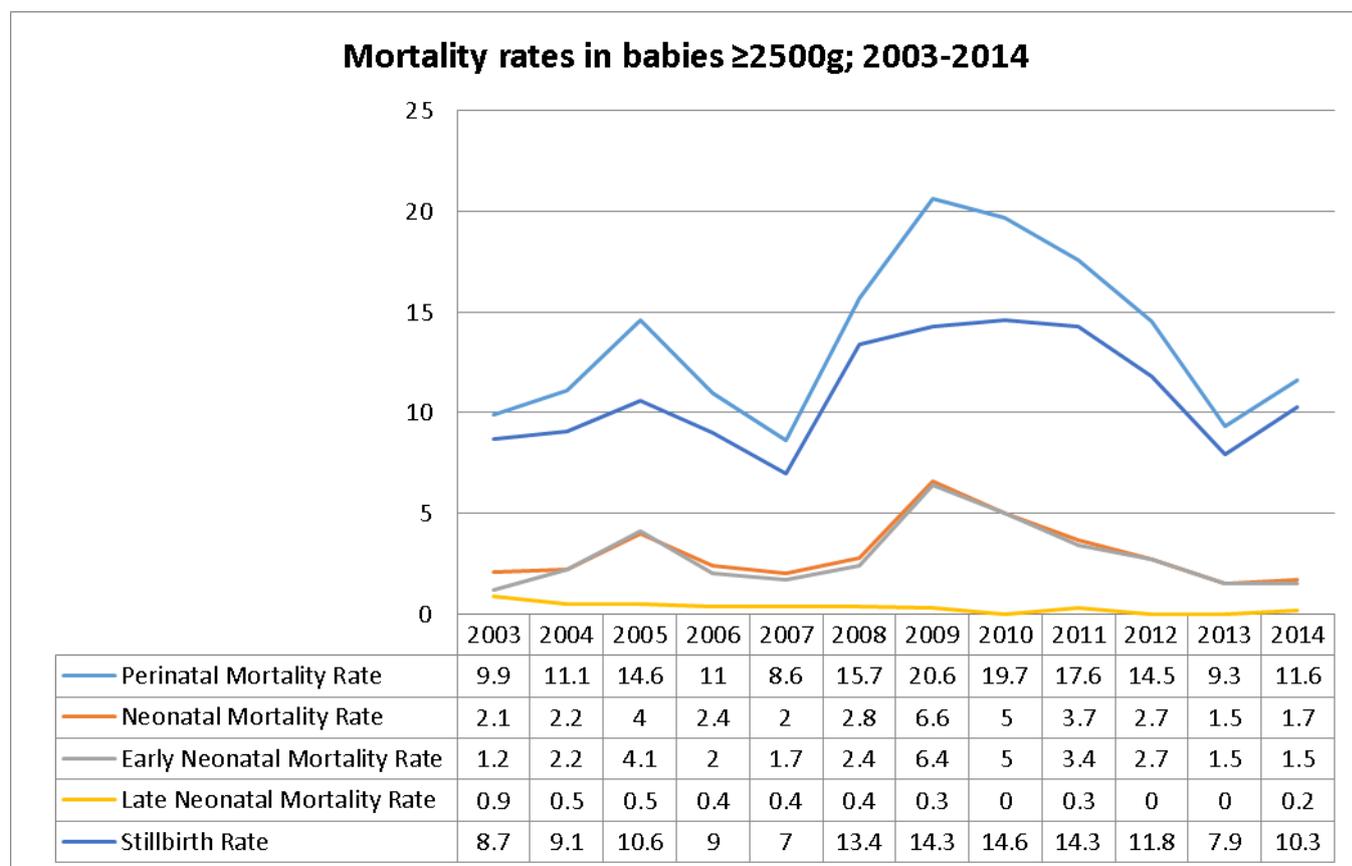


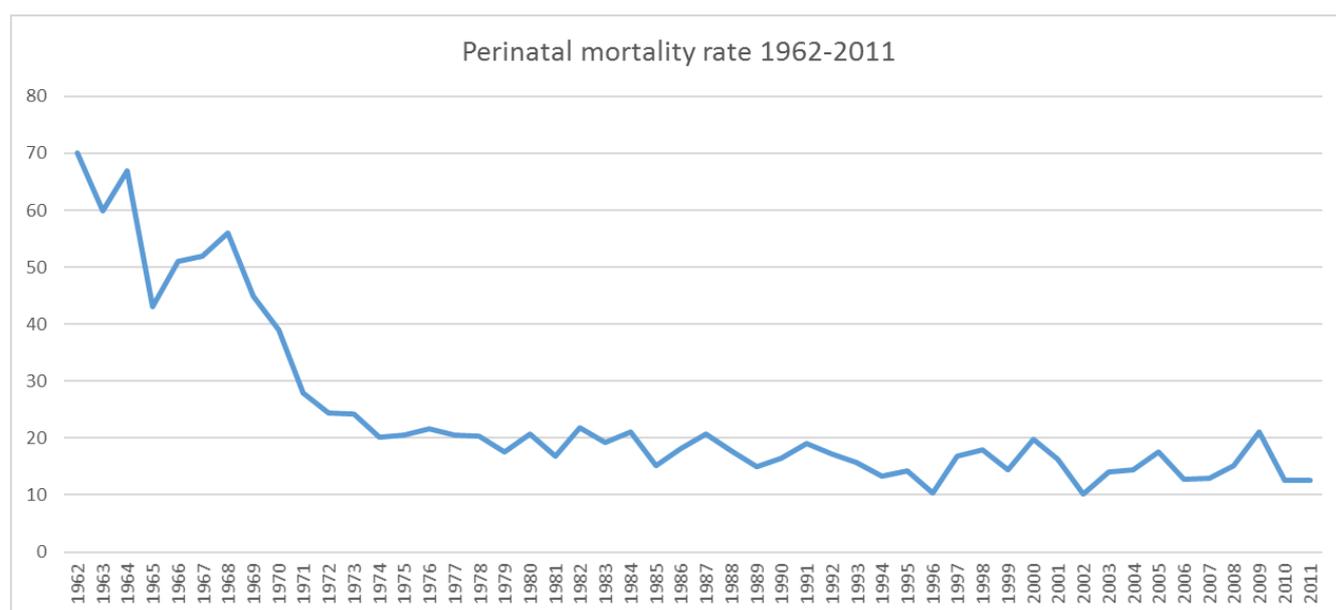
Figure 6.3.37. Mortality rates for all babies  $\geq 2500\text{g}$  at Tygerberg hospital 2003-2014.

It is clear from the data that abruptio placentae is a major killer of babies. The PNM rate for abruptio placentae was calculated for a full year (2010) based on the labour ward data for complicated admissions. This is better defined as a case fatality rate (CFR) and it was calculated as the percentage of deaths from the disease. The denominator was the number of women who delivered with abruptio and a dead baby while the numerator was women with the same pathology (baby alive or dead). There were 126 women who delivered with a clinical diagnosis of abruptio placentae and birth weight  $>500\text{g}$  (with or without associated hypertension) of which 107 babies died (101 stillbirths and 6 neonatal deaths, all within 3 days of birth). The CFR for abruptio in Tygerberg hospital during 2010 was 84.9%. Abruptio placentae is a clinical diagnosis, women where there was a histological diagnosis of abruptio

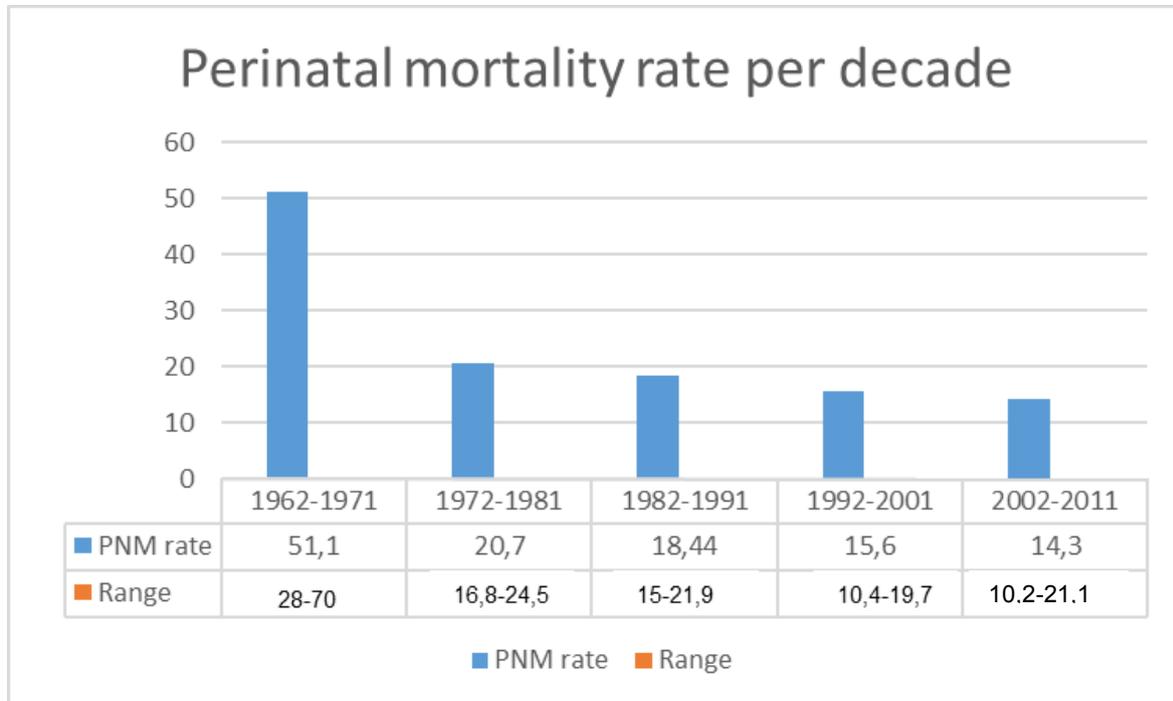
(but not clinical) was not included in the denominator. The denominator for other conditions was not available so the CFRs for those could not be determined.

The overall Tygerberg hospital stillbirth rate from 1962 to 2011 in deliveries  $\geq 1000\text{g}$  was published in 2013 (20) and that data is reproduced in Figure 6.3.38. It is included in this chapter to show the dramatic decrease in stillbirths at the end of the sixties and around the opening of the new Tygerberg hospital in 1971. For the past two decades the stillbirth rate has remained constant.

Figure 6.3.38. Perinatal mortality rate for babies  $\geq 1000\text{g}$  at Tygerberg hospital from 1962-2011 (adapted from Odendaal et al (20)).



The same data as above is given per decade in Figure 6.3.39 to show the PNM rate over 10 year periods.

Figure 6.3.39. Perinatal mortality rate  $\geq 1000g$  per decade 1962-2001.

## 6.4 Discussion

This chapter presented facility-based perinatal data for a large urban specialist (regional) and subspecialist (tertiary) hospital within a middle-income country. This local audit is a quality improvement exercise based on good-quality mortality data. The finding must be interpreted within this context. The population-based perinatal mortality rates for metro east were discussed in chapter 3.

Although the aim of this audit and analysis was not to compare inter-country data, the Saving Babies report from the corresponding time frames can be used to compare other central hospitals in South Africa. This comparison should be regarded with caution, as some central hospitals include a large number of regional and even district level patients, depending on the health care infrastructure and demography of the region. In 2003, the PNM rate for tertiary hospitals in the Western Cape was 65/1000 for babies  $\geq 500\text{g}$  (Tygerberg hospital 57.34/1000) and 35/1000 for babies  $\geq 1000\text{g}$  (Tygerberg hospital 30.4/1000) (21).

The SA national PNM rate for babies  $\geq 1000\text{g}$  in 2003 was 27.63 per 1000 live births and the neonatal death rate 9.9/1000 (Tygerberg hospital 10.10/1000). This is lower than a comparable middle-income country, namely Brazil, with a neonatal death rate of 17 per 1000 livebirths in 2002 (22). A comparison with studies performed in other middle- and low income countries (Bangladesh, Nepal, the Philippines, Pakistan and Thailand) shows SA to have a lower PNM rate than India (38/1000), Bangladesh (31/1000) and Nepal (42/1000) but higher than the Philippines (14/1000) and Thailand (5/1000) (23).

An interesting observation is the decrease in mortality rates seen in most of the graphs for the years 2006 and 2007. This was before the service shifts of 2008. Tygerberg hospital neonatology introduced the practice of administering surfactant with nasal continuous positive airway pressure in 2006 with documented improvements in survival rates (24). This can

explain the decrease in the neonatal mortality rate seen in Figure 6.3.32 for the babies  $\geq 500\text{g}$ . However, the biggest impact on the decrease in perinatal mortality rate observed in this period is due to a decrease in stillbirths. The only change in policy in 2005 was the move from laboratory testing for syphilis to a point-of-care testing at the antenatal clinics. It can be postulated that earlier diagnosis and treatment of syphilis may have contributed to a decrease in stillbirths. The infection group (Figure 6.3.28) does show a decline in syphilis deaths for 2005-2007. The 2008 National Antenatal Sentinel HIV and Syphilis Prevalence Survey showed a rise in syphilis prevalence in the Western Cape from 1.9 in 2006 to 5.1 in 2007 (25). In fact, there was an unexplained increase in syphilis prevalence in every age group in 2007 in SA. It is possible that the rise in perinatal mortality seen after 2007 could be in part attributed to more syphilis deaths. There was also the change in level of care drainage after 2008 (see chapter 3) which explains the overall rise in mortality seen after this period.

Placental histology was introduced into clinical practice at Tygerberg in 2005 but there was not a separate category in PPIP for ischaemic placental disease. This was included in 2012, with the revision of the PPIP software. Many previously unexplained cases could now be attributed to intra-uterine growth restriction or fetal infection (chorio-amnionitis or funisitis) (26). Talip has also demonstrated this in the 2006 comparisons (3). Most of the cases of IUGR up to 2012 was still classified as idiopathic and the rise in cases contributed to IUGR is shown Figure 6.3.27. It also shows the increase in cases contributed to ischemic disease since the introduction of that category to the PPIP program. The number of deaths that are truly unexplained (Figure 6.3.21) was less than 20 per year by 2014, most of them babies  $>1500\text{g}$ . This compares well to other international classification systems using placental histology, such as the 'Stockholm classification' where up to 90% of deaths have an attributable cause (27) (28).

There was an overall decline in perinatal wastage after 2009 for all the major causes of death (Figure 6.3.22). As already shown in chapter 3 (Figure 3.5.12) this decrease was population

based as well and not restricted to Tygerberg hospital. A possible assumption is that there was an overall improvement in care. The only major obstetric policy changes after 2009 was improved screening and management for diabetes and full coverage of all pregnant women with HIV disease with combined anti-retroviral drugs. The decrease in deaths seen is most pronounced in the hypertensive group and antepartum haemorrhage (Figures 6.3.23 and 6.3.24). The impact of regionalisation after 2009 and the referral of all women with pre-eclampsia for management at Tygerberg hospital may have played a role. Abruption placentae remains the major killer of babies in Tygerberg hospital and only 15% of babies will survive a clinical diagnosis of abruption. A major association in this population is with cigarette smoking and alcohol use during pregnancy (29) (30). Public education programmes should include this information.

At fetal medicine level, there was an establishment of a fetal medicine clinic at Tygerberg in 2010 as well as a provincial ultrasound policy to guide the regionalisation of ultrasound care. The large decline in deaths from fetal chromosomal abnormalities seen after 2009 could be the impact of increased detection and early abortion (Figure 6.3.26).

In conclusion, there was an overall improvement in perinatal mortality since 2009 at the same time that extensive regionalisation of care and other clinical governance endeavours were implemented. It will never be possible to attribute the overall improvement in care to any specific intervention as there are too many variables, including newer equipment and additional staff and beds. Nevertheless, the figures are re-assuring that the current practice at Tygerberg hospital, though far from developed country standards are comparable to other middle-income countries and better than most of the other health districts in SA.

The second part of this thesis (chapters 7-12) will describe the clinical governance interventions introduced at Tygerberg hospital since 2009 necessitated by the regionalisation of care described in chapters 1-6.

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## Part II (chapters 7-12).

# Clinical governance of maternity services in Tygerberg hospital and metro east.

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## Chapter 7. Quality improvement: audits of Tygerberg maternity services 2009 and 2012.

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## Chapter 7. Quality improvement: audits of Tygerberg maternity services 2009 and 2012.

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## 7.1. Introduction

This chapter reports on two audits conducted during September 2009 and December 2012. The purpose of the 2009 audit was to examine the maternity service at Tygerberg hospital in terms of bed numbers, staff satisfaction and working hours, clinic audit programmes, collection of routine indicator data, availability of guidelines and adherence to guidelines, aspects of good practice, governance and risk management strategies. The recommendations from the 2009 audit were used to transform the service in preparation for the opening of the Khayelitsha hospital and concomitant increase in case load and to re-align the regional and tertiary platforms within the infrastructure of Tygerberg hospital.

Clinical governance is defined in various ways; the RCOG defines it as *framework through which organisations are accountable for continuously improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish* (1). The Western Cape Department of Health has adopted a clinical governance framework that uses exactly the same definition and is guided by the following principles: patient centeredness, a primary care approach to service delivery, teamwork, clinical effectiveness, clinical risk management and accountability and continuous professional development (2). Quality of care can be defined in various ways, but it is usually defined in terms of standards or a list of indicators that measures performance. A more positive approach is to use indicators for self-care, health promoting behaviours, health-related quality of life and management of symptoms (3). Indicators can be used in three comprehensive ways- understanding how a system works, monitoring the performance of a system and for accountability. Without good communication, indicators cannot motivate people to change.

Quality of care is a difficult concept to measure and it can be conceptualised by examining its three components: structure, process and outcome. *Structure* indicators describe the health system (physical equipment and facilities). *Process* indicators describe how the system works (appropriateness of patient care) whilst *outcome* indicators measure the outcome of the care received (4). In perinatal care, an example of a structure indicator would be the availability of staff per shift at an MOU. A process indicator example is whether smoking cessation programs are available during antenatal care and how it is conducted while the PNM rate is an example of an outcome indicator. Qualitative research is also important when using indicators to assess quality and people trying to improve a system has to be aware of the perceptions of those working within the system (5).

In obstetric care we want to measure the quality of inpatient care and there are a multitude of indicators that can be used. Not all of them are easy to collect or relevant for a developing country. Likewise, the most commonly used indicators (e.g. CS rates, perinatal mortality rates, maternal mortality ratios) do not provide information on the patient's experience of labour. When measuring and improving quality and safety it is more important to set realistic women and infant centred goals (6).

In an ideal setting, patient-reported outcomes such as overall emotional health, confidence with breastfeeding and the role of motherhood, anal and urinary incontinence and lack of sexual desire are important indicators to measure and there is a variety of tools available for this purpose, e.g. the WHO Quality of Life-BREF (7), the PROMIS-10 (8) and the SF-12 (9). However, most of these questionnaires are administered after delivery, even up to 12 months later. This is not feasible in a setting with poor continuity of care after discharge, or where a large number of women are illiterate. In South Africa the literacy rate for women aged 15 and more is 92% but it varies between provinces and between rural and urban people (10).

As part of the comprehensive health plan described in Chapter 1 (the CSP (11)) an extensive process was undertaken to create a totally separate staff establishment for level 2 (regional) and level 3 (tertiary) services with reporting to separate line management structures within Tygerberg hospital and the Department of Health. The regional services would be responsible to the Chief Director of General Specialist and Emergency Services and the tertiary services (via the respective university dean) directly to the Deputy Director for Health. This created some complexity for hospitals such as Tygerberg which provide both these levels of care within the same infrastructure. A provincial organisational development investigation (ODI) process was undertaken to inform on the separate staff alignment within each hospital.

For Tygerberg hospital the ODI design for separate management of service in Obstetrics and Gynaecology described a general specialist platform that would include the acute labour ward, antenatal and postnatal wards, high risk clinic and general gynaecology clinic as well as colposcopy services. A separate human resource platform with registrars, specialists and medical officers reporting to a general specialist head was created by matching and placing of existing staff. The general specialist platform would be responsible to the Chief of Operations in the hospital for service delivery and to the academic head of the department for teaching and training purposes. The academic head of department ensured executive management of all academic programmes within the department and also managed the service delivery platform of all the subspecialist and special interest groups in the department (maternal-fetal medicine, reproductive medicine, gynaecological oncology and urogynaecology).

The Western Cape Department of Health also planned to decentralise financial and human resources management and performance management by establishing functional business units (FBU) for each service delivery platform (12). The complete separation of level 2 and level 3 within Tygerberg proved too complex to move beyond the service delivery platform into the management structures and separate FBUs, but by 2011 the separate general (specialised) and tertiary (highly specialised) platforms were all well established and functioning within the large discipline specific departments. A single FBU was created for each clinical department that serves both the general specialist and the highly specialised platforms. Apart from monitoring the finances of the clinical department, the FBU also serves as a monitoring body for maternity-specific targets and indicators.

The main drive behind the ODI logic was the realisation that a maternity service as envisaged for Tygerberg hospital in the departmental health plans was just too large to be managed by one person steering one department that includes:

- 187 acute beds
- 17 bed emergency labour ward
- 4 bed high care unit
- Highly specialised referral care for the Metro East, Paarl and Worcester GSAs
- Specialist referral care for half of Cape Town (Metro East including the complete Khayelitsha municipal district)
- A full academic university teaching platform

An audit was therefore done at the start of the general specialist platform organisation, to inform the way forward.

Obstetric triage is an important risk reductions strategy and improves patient flow (13). The SA triage scale (SATS) for emergency centres is a physiology and symptom based scale which prioritises acuity of care into one of four colours (14). Triage in obstetrics is slightly different than in true emergency units as there are two patients that require evaluation. Fetal heart rate tracings have to be incorporated into the observations required to work out a score of urgency and there are also past partum women with complications that may need triage but will be admitted to a postnatal ward if needed. A 5-category obstetric acuity triage scale could reduce the number of women admitted to a birthing unit from 80% to 12% and allowed for a better assessment of patient flow (15). As Tygerberg hospital is only a referral hospital for women already triaged outside of the hospital according to a regionalisation policy, there is not a need for a category of completely low risk women. The final scale (see addenda 1-3) has categories for emergency, very urgent, urgent and routine.

## 7.2 Methodology

The audit focused mainly on acute obstetrics provision within Tygerberg hospital but did touch on aspects of interaction with the referral hospitals. It based the methodology for the audit on the same model as used in the PricewaterhouseCoopers audit of acute maternity services prepared for the Department of Health, Social Services and Public Safety in the United Kingdom (16). The audit was repeated in (apart from staff interviews) in 2012 to document the progress with implementation of the action plans from the 2009 audit. The audit method included analysis of existing obstetric data, interviews with staff, review of existing departmental protocols and policies and consultation with key stakeholders within the hospital. As this audit was part of the quality improvement plans introduced by the author as part of his job description, ethical consent was not needed for the staff interviews. For the 2012 audit, ethical consent was obtained from the Stellenbosch University ethics review board which included permission to use the data from the 2009 audit (Ethics Committee reference number S12/09/240).

The terms of reference for the audit covered three comprehensive themes:

1. Activity
  - The range of maternity services on offer
  - Numbers of deliveries and caesarean sections (discussed in Chapters 3 and 3)
  - Bed management and availability of beds
  - Triage of acute maternity
  - Availability and usage of theatre time
2. Staffing
  - The views of service providers
  - Performance management and skills assessment

- Working hours and starting times
3. Governance and risk management
- Availability of guidelines and protocols
  - Risk management arrangements
  - Admission and discharge protocols

The 2009 audit started with personal (one-on-one) interviews with all the registrars and medical officers in the department as well as key nursing personnel, pharmacy, laboratory, human resources, administrative clerks, specialists and ward administrators. This was an inductive approach and interviews were transcribed by hand. Data exploration was performed by thematic content analysis. Data was collected and analysed in Excel.

### 7.3 Results

The key findings from the 2009 audit was presented to the O&G department at Tygerberg hospital at the end of 2009 and implementation of the action plans started on 1 January 2010.

The coding framework of the staff interview is depicted in Table 7.3.1. The main concerns were overcrowding in the service, burn-out amongst registrars and medical officers leading to sick leave and resignations, broken equipment, lack of clear guidance at junior doctor level, duty rosters that compel doctors to work up to 74 hours per week during their junior rotations whilst senior registrars do no calls and a lack of consultant presence in the acute service during working hours. Suggested solutions as provided by the interviewees and implemented during 2010 are also presented in the table.

Table 7.3.1. Main themes that emerged from interviews with staff, September 2009, as well as the quality improvement endeavours that followed.

Final coding framework	Initial coding framework	Quality improvement interventions (implemented 2009 onwards)
<b>Poor bed management, leading to bed occupancy rates &gt;100%.</b>	Accountable doctor not always available in wards	Re-arranged roster so that ward doctor has no other conflicting duties.
	Lack of on-site consultant presence	Arrange for consultant presence during working hours.
	Post-call doctor still has responsibilities towards their ward patients which they cannot manage. Patients are then not seen again before the next working day.	Re-arranged roster so that ward doctor has no other conflicting duties.
	Weekend ward rounds not well organised.	Re-arranged roster so weekend ward rounds are done by accountable personnel.
<b>Junior personnel poorly skilled</b>	No clear, unambiguous guidance	Provided simple protocols and guidelines.
	No elective teaching lists for CS	Negotiated elective CS lists for teaching.
	No formal structure of skills teaching or evaluation.	Implementing a formal teaching and skills training program with a logbook for junior people
	Interns and new MO's not always trained/supervised by consultant	Arranged for daytime consultant presence in the labour ward.
	Medical officers feel their skills are not utilised or developed	Upskill medical officers by giving them the same working conditions as for registrars.
<b>Registrars are overworked and under-appreciated</b>	Not dedicated time for research and study	Re-arranged call roster to allow for dedicated study hours.
	24 hour calls lead to burn-out and poor patient care with a possible medico-legal risk	Re-arranged call roster to allow for 12 hour or 16 hour shifts.
	Registrar on call for gynaecology also has to manage the obstetric critical care unit but too busy at night; resulting in poor patient management.	Re-organised duty rosters to allow for an additional registrar on call at night.
	Friday firm system unfair, registrar has to work every weekend of the 3 months' rotation	Re-organised firm system into 4 instead of 5 firms.
	No consultant on-site to teach instrumental deliveries	Arranged for consultant presence during working hours
	No formal assessment of clinical capabilities done	Introduced a three monthly evaluation of skills.
	<b>Working hours too long (&gt;56 hours per week)</b>	Clinics start too late, as doctors has to do ward rounds first; clinics not finished by closing time

	No booking system for clients	Organised a booking system at the high risk clinic.
	Theatre booking system fragmented	Investigate the possibilities of an electronic theatre booking system (ongoing).
<b>Consultants not always available for non-urgent assistance</b>	Consultants have conflicting schedules in terms of service delivery and teaching/training commitments organised at the same time	Obtained better alignment between roster and academic duties by structuring of consultant workweeks.
	No accountability for consultant presence, some consultants active in private practice while allocated to labour ward duties.	Ensured doctors are available on-site when they are rostered to do so.
<b>No compliance to protocols</b>	Not general buy-in from all staff (cleaner, porter, admin, nursing, medical, clerks) as they are not acknowledged in the process.	Allowed all staff to participate in decision making and planning by conducting two-weekly QA meetings with all relevant staff.
<b>Theatre time wasted</b>	Theatre starts late.	Ensured regular monitoring of starting times.
	No dedicated elective CS list	Negotiated a separate elective CS list.
	Procedure to book CS laborious	Streamlined the clinical governance of CS
<b>Porter services</b>	No dedicated porter in labour ward-students and doctors have to transport patients to theatre or take samples to the laboratory	Requested for a 24-hour porter in labour ward.
<b>Equipment</b>	Only 4 working fetal monitors in labour ward for 13 delivery beds.	Addressed equipment concerns urgently (see later).
	No delivery bed in working order	Addressed equipment concerns urgently (see later).
	Delivery beds cannot lift a patient >140kg	Addressed equipment concerns urgently (see later).
	No overhead lights in delivery rooms	Addressed equipment concerns urgently (see later).
	Available vacuum delivery machines not functioning well	Disposable vacuum cups better alternative, implemented since 2012.
	Poor maintenance of existing equipment	Addressed equipment concerns urgently (see later).

The rest of the 2009 audit findings are summarised in Tables 7.3.2-7.3.4. The remaining action plans following the recommendations made after the 2009 audit is presented within the table and the state of the similar audit criterion by the time of the re-audit is given in the third column. Recommendation and application of further quality improvement endeavours are listed in the last column, where applicable.

Table 7.3.2. Audit of activities

Audit criteria	2009 Audit findings	2009 action plan	2012 audit findings	2012 recommendations
<b>Bed management and availability of beds</b>	13-bed labour ward	Increase by 6 beds. Internal re-organisation to allow for single delivery rooms to ensure privacy	19 delivery beds in labour ward, arranged as 6 acute, 7 single delivery rooms and 6 less acute beds	Renovation of the labour ward will re-arrange beds into 4 semi-private acute antenatal beds, 4 acute antenatal, 7 single delivery rooms and 2 x 2-bedded rooms for less acute antenatal admissions (completed during 2013/14)
	4 step-down postnatal beds within the labour ward	Move to new space next to critical care unit after renovation	4 step-down postnatal beds within the labour ward	Completed (2014)
	22-bed antenatal ward	Add 12 antenatal beds to manage current patient load. Add 6 additional antenatal beds to accommodate Khayelitsha shift.	34-bed antenatal ward and 6 antenatal beds within ward J4.	Completed
	12-bed maternal medicine ward	Move to space vacated by the old Khayelitsha hospital to allow for more antenatal beds in current ward	12-bed maternal medicine ward plan to move after renovations	Completed (2014)
	25-bed postnatal ward (vaginal deliveries)	Add 6 postnatal beds to accommodate Khayelitsha shift	4 postnatal beds allocated (29 bed ward)	Completed
	6 acute postnatal beds within the labour ward	Assign more staff to these beds, increase to 8	Full 8 bed acute post-natal ward to be created next to critical care unit after renovations	Completed (2014)
	25-bed postnatal ward (caesarean sections)			Completed
	3-bed critical care unit	Add one more bed, allocate a registrar to work here during office hours, change the after-hours roster to allocate a registrar to night duties, allocate an additional consultant for after hour calls.	4-bed critical care unit, now with permanent registrar rotation and 24-hour registrar and consultant cover after hours.	Relocate to a separate part of the labour ward during the 2013/14 renovations.

<b>Triage of acute maternity service</b>	Makeshift labour ward triage area in converted lift lobby. No triage protocols or system in place.	Plan a new triage area with three dedicated beds. Develop guidelines and tools for obstetric triage.	Triage area built but temporarily functioning as decanting ward.	Triage area initiated as part of the renovations during January 2015. Triage tool and protocol implemented (see addenda 1-3).
<b>The range of maternity services on offer</b>	High risk referral clinic every weekday	Internal re-arrangement of allocated staff to address deficiencies in working hours	High risk referral clinic every weekday	Organised booking system for clients.
	Full range of antenatal care, intrapartum and postpartum care according to the package of care.		Full range of antenatal care, intrapartum and postpartum care according to the package of care.	
	Special care (maternal medicine) clinic once a week, one senior registrar allocated	Convert a medical officer post into a registrar post for additional help in maternal medicine	Special care (maternal medicine) and diabetic clinic once a week, two senior registrars allocated	Completed
	Fetal medicine clinic once a week, no senior registrar allocated	Allocate a 2-month registrar rotation to fetal medicine	Fetal medicine clinic twice a week, now with dedicated registrar allocated	Completed
	Full ultrasound services weekdays, office hours only	Service functions well but overburdened. All new registrars get sonar induction before they start to work.	Full ultrasound services weekdays, office hours only. Ultrasound orientation program for new doctors implemented.	Completed
<b>Availability and usage of theatre time</b>	One 24-hour emergency theatre, all elective cases are done in between emergency cases.	Additional elective theatre to decrease the burden on emergency list, decrease waiting times for elective lists and to allow for training	One 24-hour emergency theatre and an additional two-and-a-half-week day list for elective cases. Training program in place for interns.	Plan to extend working hours of Tuesday and Thursday lists to 19h00 at night (realised in March 2014).
	No dedicated recovery room	Open 2 bed recovery area for uncomplicated CS next to theatre.	Recovery area functioning, using agency nursing personnel.	Appoint permanent nursing personnel. (ongoing).

Table 7.3.3. Audit of staffing at Tygerberg 2009 and 2012.

Audit criteria	2009 Audit findings	2009 action plan	2012 audit findings	2012 recommendations
<b>Staffing norms</b>	Labour ward- 5 midwives per shift for 13 beds	Increase staffing to 1 midwife for every 2 beds	7 midwives per shift	Increase to 9 midwives per shift (ongoing planning)
	No existing staffing norms. Resource limitations on creating new posts. Re-alignment of existing staff done to improve efficiencies.	Still no provincial or hospital staffing norms, but re-alignment of staff completed and service delivery platforms functioning well.	Await provincial debate on staffing norms in maternity services.	
<b>Views of staff</b>	See Table 7.3.1			
<b>Performance management</b>	No performance management of medical officers in place.	General specialist head to do performance management of all medical officers and registrars on obstetric rotations	Every medical officer and obstetric registrar received formal staff performance management at least 3 times per year.	Ongoing
<b>Skills assessment</b>	No induction program for new staff.	Induction program for all new staff developed	All new staff gets an induction program	Ongoing
		All interns have to do the Essential Skills in the Management of Obstetric Emergencies (ESMOE)	ESMOE presented every 4 months to all new interns.	Ongoing
		All medical officers and registrars working in obstetrics have to complete a log book with a certain number of consultant-observed skills.	Logbooks are completed.	Ongoing
	Working hours and starting times	Inefficiencies in current firm system detected- re-organise complete maternity service platform into a shift system that allows for a maximum of 56 hours per week and includes study days and rest days. No 24 hour calls- only 16 hour or 12 hour shifts.	Shift system implemented.	Completed

Table 7.3.4. Audit of clinical governance and risk management at Tygerberg hospital maternity, 2009 and 2012.

Audit criteria	2009 Audit findings	2009 action plan	2012 audit findings	2012 recommendations	
<b>Standard operating procedures (SOP), guidelines and protocols</b>	No recently updated protocols on management of common obstetric conditions	Establish a protocol group and develop protocols for the most common obstetric procedures and complications.	20 protocols already in place; evidence based, signed and with the planned date of revision.	Create an electronic repository for all departmental protocols, SOPs, policies and related documents. (Available since 2014 at <a href="http://www.obsttyger.co.za">www.obsttyger.co.za</a> )	
	Some SOPs in place, but mostly outdated.	Develop relevant SOPs for notification of deaths, cord clamping, drug administration, obtaining consent, etc.	7 SOPs in place.		
	Only a single printed version of all departmental policies and SOPs available in a folder in labour ward; no electronic versions or other paper-based versions.	Distribute all new protocols electronically via email and have printed versions available in all wards and on all hospital computers.	Protocols freely available. Paper-based versions tend to disappear from wards.		
	No audits of compliance to protocols conducted.	Develop audit tools and conduct protocol adherence compliance.	2 audit tools developed (see chapter 6).		Add to dashboard (see chapter 12).
	No SOP to guide CS booking.	Develop SOP.	SOP in place.		
	No written escalation plans.	Develop and workshop a maternity ward escalation plan.	Escalation plan in place.		
	No maternity ward operational plan in existence.	Develop and workshop a maternity ward operational plan.	Maternity ward operational plan in place.		
	No admission and discharge plan for maternity.	Ensure morning and afternoon consultant-led ward rounds in antenatal and labour ward. Develop an admission and discharge SOP.	Consultant ward rounds establish. SOP for doctors working in the wards developed.		Expand afternoon rounds in labour ward to weekends as well (implemented in 2014).
<b>Risk management arrangements</b>	No formal system of adverse incident reporting- left to registrars to comply weekly activity sheets.	Develop an anonymous, web-based reporting and complaint line.	Formal adverse incident reporting instituted by hospital policy.	Anonymous reporting functioning since 2014.	
	No formal system of maternal death notification other than reporting by staff.	Develop a system to ensure all maternal deaths in the hospital are reported.	See Chapter 5.		
	No regular quality review of clinical notes available	Develop a policy and audit tool for quality of case note review.	Policy and audit tool ready for use.	Regular audits started during 2014.	

	Adverse incidents discussed at a weekly academic meeting but with very little feedback to nursing staff.	Meetings to be minuted and minutes sent to all relevant staff, with feedback to management or nursing of applicable cases.	Minutes of meeting circulated.	Plan a monthly morbidity review with all relevant personnel and provide the minutes as scenarios of the care pathway (started in 2015).
	No safety representative for the maternity ward.	Appoint a safety representative on the hospital safety committee.	Representative attends monthly meetings with feedback to relevant staff.	Ongoing
	No guidance on handover of accountability available.	Develop a SOP on continuity of care and handover of responsibility.	SOP in place; compliance monitored at regular intervals.	Ongoing
	No obstetric clinician involved in regular, scheduled quality assurance meetings where minutes are kept.	Establish a quality assurance forum within the maternity service.	Regular QA meetings (twice a month) in place with minutes taken.	Ongoing
<b>Audits</b>	Regular perinatal mortality review in place (weekly meetings).			
	Perinatal mortality data entered into PPIP database, but database not up to date.	Aim to update database retrospectively as well as ensure good quality of the ongoing data. See Chapter 8.	Database up to date	Ongoing
	Folder review of perinatal deaths left to registrars, with no input from trained staff.	Allocate a dedicated medical officer and consultant to do the death reviews and oversee the PPIP program and meetings. Develop formal terms of reference and distribute minutes of the meetings.	Formal system in place. PPIP statistics up to date and reliable.	Ongoing
	No regular review of CS rates available, apart from academic meetings with registrars.	Monitor CS rates at monthly FBU meetings.	See Chapter 7.	
	Maternal mortality database kept up to date but notification forms not completed for all cases.	Ensure notification of all deaths within 6 weeks.	See Chapter 5.	
	A good system of teaching and training visits to MOUs within the Tygerberg catchment area in place.		Outreach to MOUs now the responsibility of their respective district hospitals.	Need to develop mechanisms to ensure regular outreach of high quality takes place.
<b>Outreach</b>	No formal outreach agreement or activity to any of the district	Sign outreach agreements with all district hospitals and	Agreements with three district hospitals in place,	Ongoing.

	hospitals within Metro East.	start outreach based on their needs.	with a range of activities that include labour ward skills training and ward rounds.	
	Oncology outreach to Paarl and Worcester hospitals in place.			Ongoing.

## 7.5 Discussion

This chapter described two audits conducted at the obstetric service of Tygerberg hospital while undergoing two major changes: a change in regionalisation of perinatal care and expansion of the catchment area with almost half a million people. The service was evaluated with structural, process and qualitative audits. The process component of quality of care is more difficult to measure and criterion-based clinical audits are a useful method to do this. The audit on patient notes (described in this chapter) and on protocol adherence (chapter 10) are both criterion-based audits. Pirkle et al report that criterion-based clinical audits are feasible in sub-Saharan countries but that its measurement properties need to be rigorously evaluated (17).

The criteria for the audit of patient notes are included in the addenda. It could be done by a non-clinician with minimal training. When measuring quality of patient notes a criterion-based audit in England fared better than a holistic approach using patient notes audit (18). This small but important aspect of patient safety will form part of ongoing quality assurance in the maternity dashboard for Tygerberg hospital (see chapter 12). The importance of good clinical notes will also be discussed in the medico-legal chapter (chapter 11).

It was possible to change from a system of personal continuity with groups taking responsibility for a specific days of the week (a firm-based system) to a shift system where a team rather than an individual look after a patient. This required extensive change management and it will be important to continue to measure patient satisfaction as well as the safety of transfer of accountability between shifts (19). Clinicians may lack a clear consensus about when responsibility is transferred at handover (20) and this was clearly defined in a handover SOP (see addendum 6).

Skills training was aided by the Essential Steps in the Management of Obstetric Emergencies (ESMOE) program of the national department of health (21). Completion of this training package can result in a significant improvement in knowledge and skills of interns (22).

The introduction of triage into a system of first-come-first-served required many hours of teaching and continuous audit. Patients as well as health care workers were used to the system of queuing for service and a late arrival that triggers an 'urgent' triage score and is seen first was perceived as jumping the line or receiving special favours.

## 7.6 Conclusion

Quality of care is an ongoing process and the large scale audit of the complete service will be repeated at regular intervals as new service delivery challenges emerge. The audit tools are now developed and ongoing results can be included in a maternity dashboard that will inform on the day to day aspects of quality and service provision (see chapter 12). The following is available as addendums at the end of the chapter: triage tool (adapted for maternity care from the South African Triage Scale, Addendums 1-3), standard operating procedure (SOP) and audit tool for patient note keeping (Addendum 4-5) as well the guide to handover of patients (Addendum 6).

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## 7.7 Addendums

### Addendum 1

#### Obstetric adult triage score



Name .....  
 Folder Number.....  
 Date of Birth.....

TYGERBERG HOSPITAL  
 DEPARTMENT OF OBSTETRICS AND GYNAECOLOGY

**OBSTETRIC TRIAGE RECORD**

Date:  Time that patient presented to TRIAGE:

Brought in by

Main complaint

**OBSTETRIC ADULT TRIAGE SCORE**

	3	2	1	0	1	2	3
Mobility				Walking	With help	Stretcher/ immobile	
Respiratory rate		≤10		11-20	21-24	25-29	≥30
Maternal heart rate		≤40	41-50	51-100	101-110	111-129	≥130
Systolic BP		<90	90-99	90-139		140-159	≥160
Diastolic BP		≤60		60-89		90-109	≥110
Temperature		≤35		35.1-37.4	37.5-38.4	≥38.5	
Urine protein				Nil, trace	1+		2+ or more

TEWS (COLOUR CODED SCORE)	RED	ORANGE	YELLOW	GREEN
	9 OR MORE	6-8	3-5	0-2

Triage CTG (only viable fetus)	Normal	Suspicious, or not sure of interpretation	Pathological, or struggling to find fetal heart rate
	Continue with triage	Alert doctor- must review within 30 minutes	Alert doctor- must review immediately

HB:  HGT:

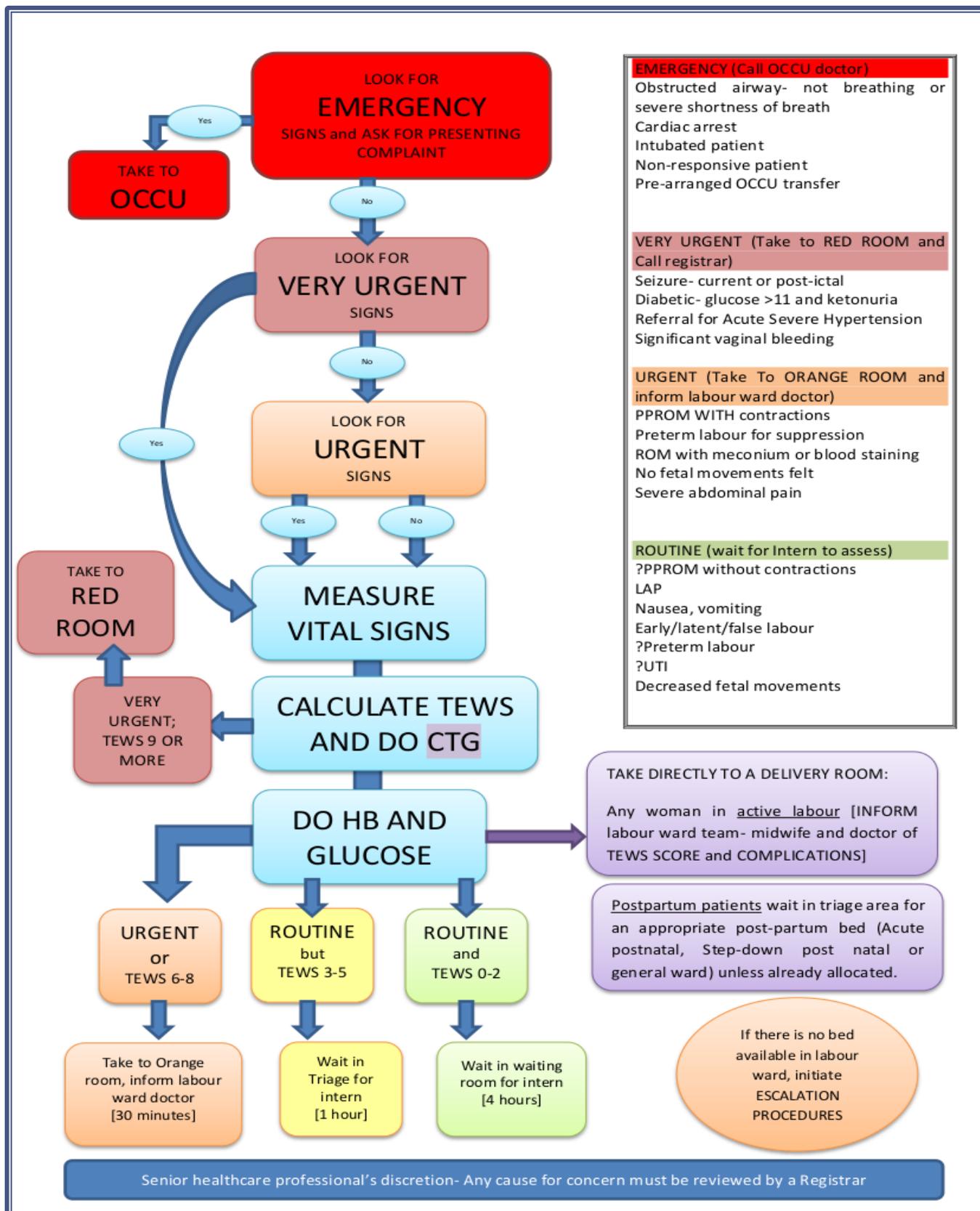
OUTCOME:

DOCTOR INFORMED:

SIGNATURE: \_\_\_\_\_ TIME OUT:

## Addendum 2

Adult maternity triage pathway (adapted from the South African Triage System (14))



## Addendum 3

Guideline to triage in Tygerberg hospital maternity services.



### TYGERBERG HOSPITAL Department of Obstetrics and Gynaecology



#### A guide to obstetric triage for Tygerberg Hospital

This guidance does not override the individual responsibility of health professionals to make appropriate decision according to the circumstances of the individual patient in consultation with the patient and /or carer. Health care professionals must be prepared to justify any deviation from this guidance.

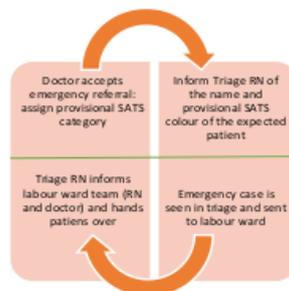
Adapted from, and based on the principles of the South African Triage Scale (SATS)<sup>1</sup>

The benefits of implementing SATS

1. Expedite the delivery of time-critical treatment for patients with life-threatening conditions.
2. Ensure that all patients are appropriately prioritised according to their medical urgency.
3. Improve patient flow.
4. Improve patient satisfaction.
5. Decrease the patient's overall length of stay.
6. Facilitate streaming of less urgent patients.
7. Provide a user-friendly tool for all levels of health care professionals.

#### Introduction

Triage can only be successful if there is continuous two-way communication between the TRIAGE person (RN-registered nurse or doctor) and the maternity ward team (registered nurse or doctor).



Women presenting at triage will be either unbooked emergencies or referrals from peripheral units. As soon as an emergency referral is accepted (telephonically), the labour ward doctor must inform the TRIAGE RN of the name of the expected arrival, and the diagnosis and provisional colour coding.

For any patient that presents to triage:

- The process of triage starts with a question to the patient or family as to the reason for coming to the emergency centre. As this question is being asked and answered the triage process already commences with the triage practitioner rapidly assessing the patient for any Emergency clinical

<sup>1</sup> South African Triage Group under the auspices of the Emergency Medicine Society of South Africa, used under a Creative Commons Attribution-NonCommercial-ShareAlike license: <http://creativecommons.org/licenses/by-nc-sa/3.0/>

signs. If emergency clinical signs are found, the patient is assigned a Red priority level and taken straight to the resuscitation area (OCCU) without delay OR resuscitation is immediately commenced and the OCCU team called to assist in triage.

→ It is important to note that if a patient has any emergency signs then a TEWS does NOT need to be calculated at triage. There should be no delay in taking the patient to the resuscitation area/OCCU.

- If no Emergency clinical signs are present then check for any Very Urgent or Urgent clinical signs.
- Whether these are present or not, vital signs are measured, a TEWS<sup>2</sup> is calculated, key additional investigations are checked (10 minutes triage CTG, Hb and Hgt; where indicated) and the triage priority adjusted.
- **RED patients** must be admitted to the RED ROOM and THE REGISTRAR INFORMED that the patient is admitted, for clerking and management. This handover must be documented in the OBSTETRIC TRIAGE RECORD (name of doctor informed, signature of RN, and time patient left triage).
- **ORANGE patients** must be admitted to the ORANGE ROOM and THE LABOUR WARD DOCTOR INFORMED that the patient is admitted, for clerking and management. This handover must be documented in the OBSTETRIC TRIAGE RECORD (name of doctor informed, signature of RN, and time patient left triage).
- **YELLOW patients** must remain in TRIAGE, and the intern called for clerking and management. Patients must be seen within one hour. After assessment, the intern must discuss the further management with a LABOUR WARD DOCTOR and a joint management plan must be documented.
- **GREEN patients** can wait in the waiting room, and the intern called for clerking and management. Patients must be seen within four hours. After assessment, the intern must discuss the further management with a LABOUR WARD DOCTOR and a joint management plan must be documented.
- **ANY WOMEN in established or advanced labour** must be admitted to a delivery room AND the LABOUR WARD MIDWIFE as well as DOCTOR informed of the admission and the urgency (RED/ORANGE/YELLOW/GREEN). This handover must be documented in the OBSTETRIC TRIAGE RECORD (name of doctor informed, signature of RN, and time patient left triage).
- **A suspicious or pathological TRIAGE CTG must be shown to the labour ward registrar without delay.**

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<b>DATE REVISED</b>	
<b>DATE EFFECTIVE</b>	1 Feb 2015
<b>REVIEW DATE</b>	31 Jan 2016

<sup>2</sup> **TEWS: Triage Early Warning Score.** This is a composite score of the patient's physiology. The score is derived by assigning a number between 0 and 3 for each of the patient's vital signs. The higher the score the greater the urgency

## Addendum 4

### Audit tool for patient notes.

#### Folder Audit:

Facility: \_\_\_\_\_

Month: \_\_\_\_\_

The audit is an assessment of the ADMISSION NOTES for the FIRST admission to the triage area of the hospital; regardless of whether the patient was admitted or not. This part of the audit is on the physical presence and content of the actual written notes, NOT on the quality of the notes. A standardised format of notes was used when notes contain in (some) order the history, physical findings, investigations, diagnosis, treatment and outcome. If any entry is only partial (e.g. syphilis status recorded but not Rhesus) or incomplete it is scored as "No (=0)".

No.	INPATIENTS	X	OUTPATIENTS	Folder	Yes = 1 No = 0 N/A = not applicable										Comments		
Question / Aspect																	
1	Admission notes signed and initials & surname written/printed in block letters (student/intern)																
2	Admission notes countersigned and initials & surname written/printed in block letters by a registered doctor																
3	The time and date when the notes were made are present																
4	A standardised format was used to record notes (see instructions)																
5	The bio-psychosocial history of the patient, including allergies and idiosyncrasies are clearly documented																
6	A brief obstetric history is documented.																
7	The patient's HIV status including CD 4 count, Viral Load and current medication is clearly stated																
8	Syphilis and Rhesus status is documented																
9	The current medication is correctly documented. (Not taking any medication = 1; On medication and documented = 1; Notes on meds omitted but patient on medication = 0)																
10	The observations (Blood pressure, pulse rate, respiratory rate and temperature) is documented.																
11	The clinical examination is documented.																
12	The abdominal examination is documented fully.																
13	An assessment of the patient's condition was made.																
14	The condition of the fetus was documented, including CTG where appropriate.																
15	A clinical risk assessment was done that included thrombo-embolic risk assessment.																
16	A proposed clinical management plan was formulated.																
17	Medicine administration chart in file																
18	Medications administered signed, dated & time recorded																
19	Dosage reflected																
20	Only authorized abbreviations used																
21	All records are legible																
Actual Score																	
Maximum possible score (Sum of all questions minus the not applicable responses)																	
<b>Sum of actual score/Sum of possible score X 100</b>																	

Audit performed by: \_\_\_\_\_ Signature \_\_\_\_\_ Date: 

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## Addendum 5

Standards for obstetric note keeping (extract of admission note criteria).

Contents of Admission Notes should include:

- Age, gravidity and parity, gestational age (and how it was calculated), or number of post-partum days (if applicable)
- Immediate problem statement
- Patient history; previous medical history, previous obstetric history, known allergies, social context; delivery history if post-partum
- HIV status
  - If negative, date of last retest
  - If positive, latest CD 4 count, latest viral load, current medication, date of inception of medication
- Rhesus status
- Syphilis status
- Details of any current medication and allergy status
- Observations (minimum requirement blood pressure, heart rate, temperature, respiratory rate, urinary dipsticks)
- Details of general examination
- Detail of abdominal examination (minimum requirement when antenatal: height of fundus, number of fetuses, lie, side of the baby's back, presentation, head-above-brim, clinical weight estimation). Height of fundus if post-partum.
- Detail of speculum examination (when indicated)
- Detail of vaginal examination (if indicated)
- If membranes ruptured, the time of rupture as well as the status of the draining amniotic fluid.
- If fetal monitoring is indicated; the status of the latest CTG must be documented.
- Clinical risk assessment for specific risk assessments required/undertaken, including thromboembolic risk assessment
- A working diagnosis and care /treatment plan signed and dated. Clear nursing instructions, dated and signed, must be made on the prescription chart in all cases and include as minimum
- Intended ward for admission
- General observations required and frequency thereof (according to standard nursing care plan, or more frequently if clinically indicated)
- The action to take if any observation(s) are abnormal
- Diet/fluid requirements as well as IV fluid requirements if indicated; NPO if indicated
- Whether CTG is indicated or not; the frequency thereof and whether it must be signed off by a clinician when performed after hours.
- All medication (current and new)
- All single dose/ stat drugs including prophylactic antibiotics, pre-op medication and steroids where appropriate

## Addendum 6

### SOP for handover

	<b>TYGERBERG HOSPITAL</b> <b>Department of Obstetrics and Gynaecology: General Specialist Services</b>	
Standard operating procedure: <b>Continuity of care and Transfer of Accountability</b>		
<b>Introduction</b>		
<ul style="list-style-type: none"> <li>• At Tygerberg O&amp;G multiple health professionals and teams contribute to the care of a single patient within a shift system. While patients value personal continuity, it does not necessarily ensure quality of treatment. It may also legitimise the idea that there are patients for whom an individual is not responsible and this threatens organisational responsibility.</li> <li>• This shift system allows for the management of large numbers of patients in different areas (that is not always under the direct care of a registrar; e.g. elective Caesarean section lists done by medical officers); better patient flow, and more agreeable working conditions.</li> <li>• Any shift system have challenges with continuity of information- namely large numbers of patients under the care of a single team; a doctor may have no day-to-day contact with the patients they are responsible for in the out-of-hours period; frequency with which the team changes, frequent movement of patients between wards and departments sometimes without the doctors' knowledge and the involvement of multiple specialist teams in the management of a single patient.</li> <li>• To ensure continuity of care, the most important feature of the shift system is a safe handover system (Transfer of Accountability) during which sufficient and relevant information should be exchanged to ensure patient safety; and for which very specific criteria and responsibilities have been set within the department. Each area within the service has a dedicated team looking after the patients within that area.</li> <li>• Continuity of care must involve some way of assuming personal responsibility for certain subsets of patients: ICU patients, complications from surgery, patient care involving morbidity or mortality reports; death certificates and medico-legal summaries and also following on the progress of complicated patients.</li> </ul>		
<b>Implementation of the above principles is as follows:</b>		
<b>1. Obstetrics:</b>		
<ol style="list-style-type: none"> <li>i) <u>During office hours</u>, the obstetric team (led by the registrar) takes full responsibility for every patient in the acute labour ward, including <u>any cases done in the two labour ward (C2A) theatres</u>.             <ul style="list-style-type: none"> <li>• The labour ward consultant assumes overall daytime responsibility.</li> <li>• The care of specific complicated patients managed by the day consultant (e.g. post-partum hysterectomy) will <u>remain within the group (group 1-4) that was on call the when the complication was first managed</u>, for further continuity; and care must be handed over to the night consultant personally.</li> </ul> </li> <li>ii) <u>After hours</u>, the on-call obstetric team (led by the registrar) takes over that responsibility and the consultant on call for the labour ward assumes overall responsibility; the care of any specific complicated patient after hours will remain within the group (1-4) that the on-call labour ward consultant is assigned to.</li> <li>iii) If an obstetric patient is discharged and <u>re-admitted with an acute problem directly related to the delivery</u> (e.g. postpartum haemorrhage) or the medical condition in pregnancy (e.g. pulmonary edema following pre-eclampsia; eclampsia etc) she will be admitted to the labour ward or OCCU and managed further by the emergency team.</li> </ol>		
<b>2. Gynaecology</b>		
<ol style="list-style-type: none"> <li>i) The registrar on call takes responsibility for all acute gynaecology emergencies admitted and evaluated during the 24 hour call period (08h00-08h00). The consultant in labour ward can be approached for advice and help with emergencies or ultrasound in the admissions area during office hours.</li> <li>ii) The <u>consultant on call for gynaecology</u> takes overall responsibility for gynaecology admissions and must be aware of every admission, major theatre booking or complication; and be informed of these patients on the 16h00 handover round as well as see them on the post-intake ward round the next morning.</li> <li>iii) The consultant on call for gynaecology for a night takes day-time (office hours) responsibilities for cases done in the <u>main hospital emergency theatre</u>. These cases will either be originating from that day's call or be personally handed over from the previous day's call (see later).</li> </ol>		

- iv) Once any gynaecology patient in the ward has an unexpected complication (e.g. admission to an ICU or complications during surgery), the registrar and group first involved in managing that complication must remain involved in the further management of the patient, especially if there are re-look laparotomies etc.
- v) If an obstetric patient is discharged and re-admitted with a new problem (e.g. wound sepsis, pneumonia, breakdown of episiotomy, breast abscess, wound dehiscence, etc.) she is now the responsibility of the gynaecology registrar who admits her with the complication; as she will be admitted into a gynaecology ward and operated (if needed) on the main theatre slate.
- vi) The gynaecology registrar who admits and books an emergency patient on the main theatre list remains responsible for the surgery and post-op care of that case; with the consultant who was on call with him/her, even on a post-call day; especially if it is a complicated/critically ill patient or difficult surgery is expected.
  - If for some reason any one of them cannot do the case themselves after their call, they can hand it over to the next day's team, but it must be a documented (in the notes) registrar to registrar AND/OR consultant to consultant handover.
  - The **admitting team** remains responsible for the further care of the patient when they return from their post-call day. If the patient was still not operated, **they** need to expedite the surgery and either operate themselves or hand over to the team on call for that day.
  - When the team that operates on the patient is not the team that admitted the patient, and they experience surgical complications, it will be in the best interest of the patient if the operating team continue with the further care, especially if a re-look procedure will become necessary. There must be a clear (documented; consultant informed) decision on whether care will be continued or whether it is handed back to the initial admitting team.
- vii) All gynaecology ICU patients, day 1 post routine gynaecology surgery and complicated/ill gynaecology patients must be managed/seen by the responsible registrar and not an intern (also over weekends; the registrar can designate this task to another registrar, who accepts this responsibility in documented notes).
- viii) After discharge, a patient should be referred to primary care for follow up. If she is re-admitted with the same problem within 6 weeks, she can be handed back to the team that managed her problem initially. After 6 weeks, if she is seen as an emergency with any problem; the care will remain with the group that manages her as an emergency case on that day (except if it is clearly related to her previous surgery, e.g. bladder/bowel/ureter injury etc).

### 3. OCCU

A patient in OCCU/ICU that needs surgery (and who is not already linked to a registrar/consultant group according to the points above) presents a specific challenge, as the OCCU team cannot take her to theatre; and she may have been there for several days without "belonging" to a specific person/group, and the complications she was admitted for (e.g. severe pre-eclampsia)- may not be the reason why she is going to theatre (e.g. acute abdomen/wound sepsis etc).

- i) For this reason, the group (1-4) on call (and specifically the consultant on call for OCCU/gynaecology that evening) takes responsibility and the patient should be referred to the registrar on call for that day to discuss with his/her gynaecology consultant.
- ii) If it is obstetric-related surgery (e.g. Caesarean section or postpartum bleeding); and it will be done in the labour ward theatre, the labour ward/OCCU consultant and labour ward/OCCU team takes responsibility.

GS Gebhardt  
26 August 2013



Signed: GS Gebhardt  
Head: General Specialist Services; Obstetrics and Gynaecology  
Date effective 12 September 2013

## Chapter 8

In-hospital mortality of women in their reproductive age- determining the burden of disease in women at Tygerberg hospital, South Africa 2011-2014.

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## **Chapter 8. In-hospital mortality of women in their reproductive age- determining the burden of disease in women at Tygerberg hospital, South Africa 2011-2014.**

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## 8.1 Introduction.

The millennium development goals (MDG) 4 and 5 have placed a lot of focus on the reduction of the number of women dying from complications of pregnancy (1). Yet in most of the hospitals in South Africa there are many more women in their reproductive years dying from complications not related to pregnancy. The life expectancy at birth of women in the Western Cape (WC) is currently the highest of any in the country, estimated at 67.9 years (2). This is still lower than the global figure. Female life expectancy world-wide increased from 61.2 years (in 1970) to 73.3 years in 2010 (3).

The official mortality statistics produced by Statistics South Africa are not regarded as good enough quality for complete mortality reporting as up to 93% of deaths are coded to ill-defined injuries (4). The burden of disease study from the WC used more accurate data from the health district, supported by the Medical Research Council (MRC) (5). Their age-standardised mortality rates (MR) per 100 000 for non-communicable conditions showed that the top 6 killers of Cape Town women were stroke (MR 76/100 000), diabetes (MR 70/100 000), ischaemic heart disease (MR 64/100 000), hypertension (MR 40.8/100 000), chronic obstructive pulmonary disease (MR 24.8/100 000) and lung cancer.

These are mostly conditions that will increase in incidence with advancing age. The age-standardised causes of death in the age group 15-45 years in women were HIV disease, tuberculosis and other communicable diseases and trauma. Breast cancer accounts for 3%, cervical cancer for 1% and maternal deaths for less than 1% of all female deaths in the reproductive age group. The major causes of death are conditions that affect both sexes (6).

In South Africa, maternal deaths are a notifiable condition in pregnancy and every death is analysed for cause of death and avoidable factors. Maternal deaths are reported to the National Confidential Enquiry into Maternal Deaths (NCCEMD). It is modelled on the United

Kingdom (UK) confidential enquiry process and UK advisors assisted SA in developing its own enquiry. The triennial data has been published since 1998 (7). The reports also have information on deaths related to early pregnancy. Deaths occurring outside of a hospital is not easy to detect and including them may bias the report. The NCCEMD therefore focus on the institutional (hospital only) maternal mortality ratio (iMMR), reported per 100 000 live births (8). It includes all reported deaths from the public as well as private sector hospitals. The iMMR for South Africa was 154.06 per 100 000 live births in the 2011-2013 report (9). This was a decrease of 12.6% from the previous triennium (176.22 per 100 000 live births) (10). The WC has the lowest iMMR (75.99 per 100 000 live births) and Limpopo province the highest (196.38 per 100 000 live births).

Maternal death reviews only include deaths up to 6 weeks after delivery. Complications related to the pregnancy can still cause death at a later stage. An underlying medical condition that was intensified during pregnancy could also cause death at a later stage. Maternity health care workers may not always be aware of the burden of disease in non-pregnant women in the age group that they only manage for antenatal care. This review was done to put maternal deaths at Tygerberg hospital into perspective with other leading causes of death of women in the reproductive age group dying in the same hospital.

## 8.8 Methods.

This was a retrospective case file review of all women who died in Tygerberg hospital from 1 January 2011 to 31 December 2014. Routine hospital data was obtained from the Clinicom™ patient administration system and was filtered to include all women between the ages of 14 and 45 years with the method of discharge coded as 'death'. Files were then inspected to determine the main disease and the cause of death, as the available international classification of disease (ICD-10) coding was not detailed enough or reliable to use. In addition, the database of all deliveries from 2007-2014 (described in Chapter 3) was used to control the hospital number of any mother that delivered against that of the deaths from 2011-2014, to obtain the folders of female deaths with a prior delivery that may not have been notified.

The main objective was to determine the burden of in-hospital disease in Tygerberg hospital in women of reproductive age. A secondary aim was to test the reliability of the existing system of maternal deaths notification as there may be deaths in pregnant women in other wards not referred to the attention of the maternity teams.

### 8.3 Results.

The first finding was that there were 6 additional maternal deaths for 2011 and 2012 identified by comparing the hospital numbers in the delivery and mortality databases. These were not detected by the system existing up to then (self-reporting by clinicians) and were too late to notify for inclusion in the NCCEMD report. From 2013 onwards this comparative analysis was added as part of the routine identification of maternal deaths. The clinical detail of the 6 unreported deaths is given in Table 8.3.1. Only one of the women was not managed by the maternity team and it is surprising that the other 5 was never notified to the NCCEMD in time for inclusion in the triennial reports.

Table 8.3.1. Clinical detail of 6 maternal deaths not notified to the NCCEMD.

Age and gravidity	Summary of case notes (2011, 2012)
36 G2P2	Patient did not book for antenatal care. She had hypothyroidism and was admitted with severe shortness of breath at 27 weeks of pregnancy. She was intubated in the labour ward but arrested during the intubation. She transferred to the ICU but died 19 days later. No clinical diagnosis was made and cause of death is uncertain. No post mortem was requested.
21 G2P1	Delivered 2009 at Tygerberg hospital with known HIV disease. This was detected by the comparison of folder numbers. The case notes indicate that she was admitted during 2011 with disseminated tuberculosis and died at 20 weeks gestation. She was never referred to the maternity team.
31 G2P2	Was known at Tygerberg hospital with disseminated tuberculosis. She had a caesarean section for breech presentation with a massive cerebral bleed during the procedure and an unsuccessful resuscitation.
29 G1P0	Patient did not book for antenatal care. Referred from Worcester hospital at 31 weeks of pregnancy with fulminant liver failure of unknown cause, most likely acute fatty liver. She was intubated in the maternity critical care unit and transferred to ICU but died three days later.
25 G1P1	Known HIV disease with low CD4 count and tuberculosis. She developed respiratory distress after delivery and died 5 days later in ICU. Pulmonary embolus was suspected.
28 G2P1	Admitted with disseminated tuberculosis, respiratory distress and an intra-uterine death. She needed intubation in the labour ward and died two days later in ICU.

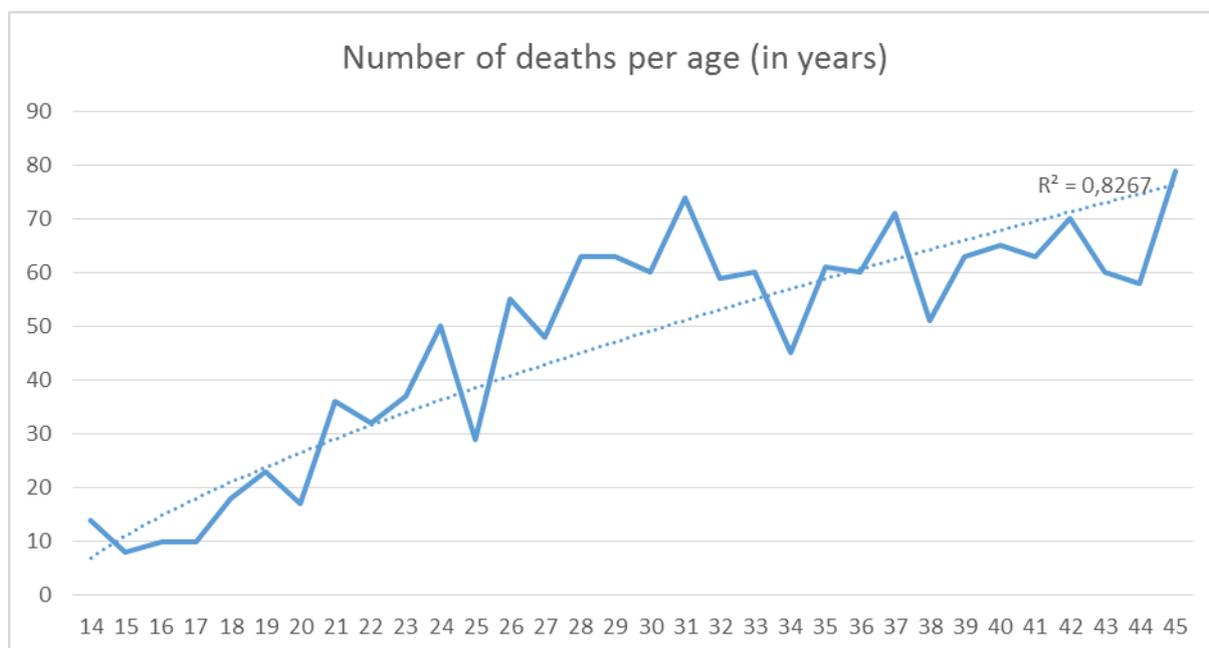
The total number of women in their reproductive life dying at Tygerberg hospital (including all the maternal deaths) is shown in Table 8.3.2. Five percent of all deaths were directly or indirectly related to pregnancy or within 6 weeks of delivery.

Table 8.3.2. Number of female deaths age 14-45 years at Tygerberg hospital, 2011-2014

Year	Number of deaths	Notified number of maternal deaths at Tygerberg with the NCCEMD (percentage of total number of deaths)	Corrected number of maternal deaths (percentage of total number of deaths)
2011	332	16 (4.8%)	19 (5.7%)
2012	398	16 (4%)	19 (4.8%)
2013	460	24 (5.2%)	24 (5.2%)
2014	322	14 (4.3%)	14 (4.3%)
<b>Total</b>	<b>1512</b>	<b>70 (4.6%)</b>	<b>76 (5%)</b>

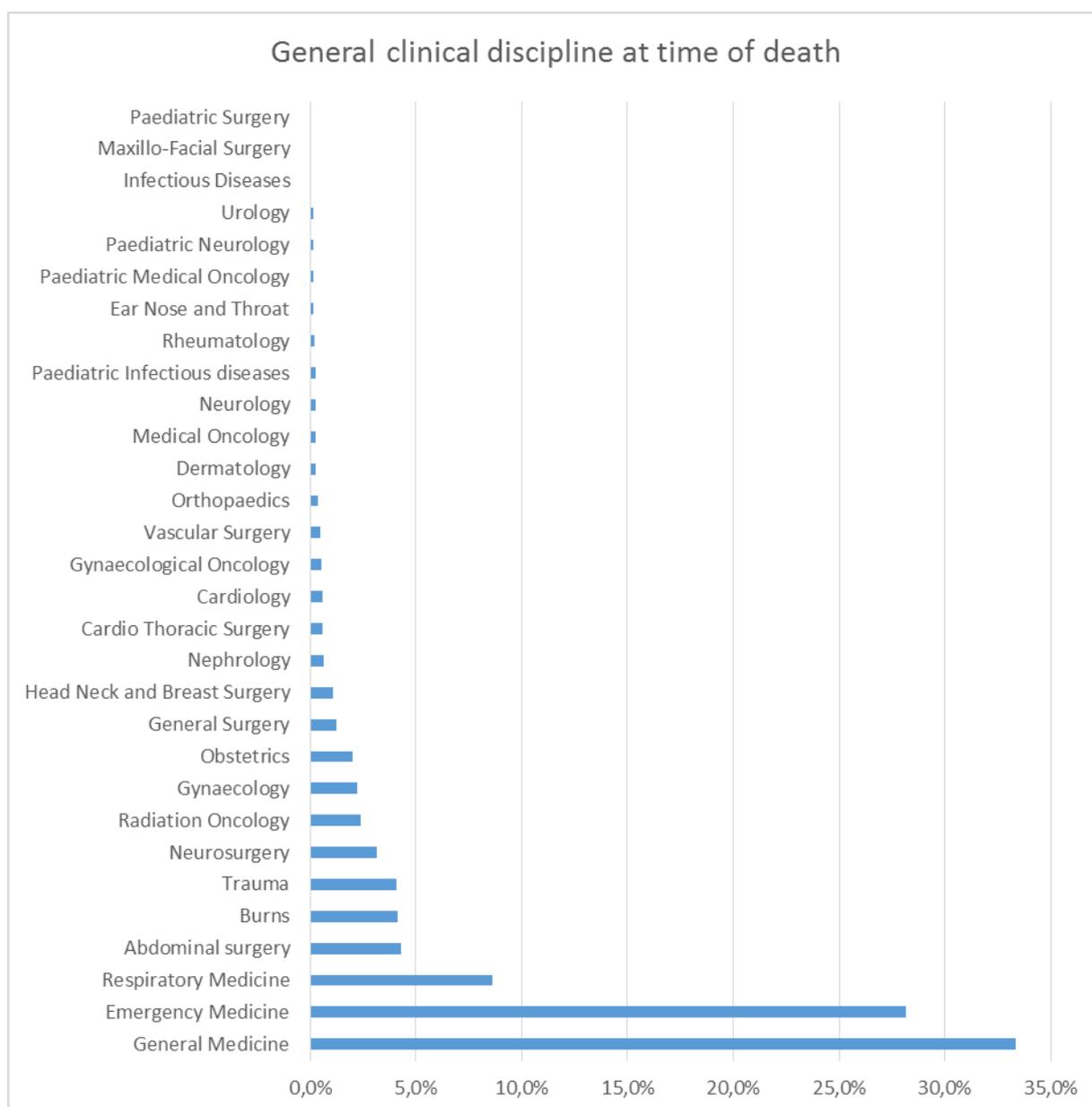
The age distribution of the female deaths is presented graphically in Figure 8.3.1. The information from Table 8.3.2 was used to plot the age distribution of all female deaths. There is an almost linear increase in deaths from the age of 15 to 45.

Figure 8.3.1. Number of deaths per age group.



The general clinical discipline responsible for the management of a woman at the time of her death is shown in Figure 8.3.2. Although paediatric patients are classified as adult patients after the age of 12, some children with chronic conditions and all paediatric oncology patients continue with treatment at paediatrics after that, well into their reproductive years. The majority of women died in the medicine wards.

Figure 8.3.2. Clinical discipline at time of death at Tygerberg hospital, age group 14-45.



The linkage of deliveries in the labour ward to death in other wards will not detect deaths were the pregnancy ended in miscarriage or was still ongoing by the time of death. Although laborious, since 2013 the electronic case notes of every woman who died outside of obstetrics or gynaecology ward between the ages of 14 and 45 is scrutinised to detect any

notes relating to a possible pregnancy. Two extra deaths were detected this way for 2013 and 2014. They were notified to the NCCEMD after detection and are already included in the number of notified maternal deaths as summarised in Table 8.3.1. These additional cases detected through case note review is summarised in Table 8.3.3.

Table 8.3.3. Additional maternal deaths identified through case note review.

Age and gravidity	Summary of case notes (2013, 2014)
24 year G1P0	Newly diagnosed pregnancy, unbooked, known HIV disease, CD 4 count 9 cells/mm <sup>3</sup> , started on antiretroviral therapy but defaulted for 12 weeks. Admitted with acute kidney failure and pneumocystis pneumonia, died in the medical ward before referral to obstetrics.
27 years, G3P2	Managed at 9 weeks of pregnancy with uncontrolled diabetes and hypertension. Termination of pregnancy performed and discharged. Admitted 3 weeks later after severe domestic assault and died from brain injuries (co-incidental death).

Deaths within 6 weeks of a pregnancy failure or delivery is most likely related to the pregnancy itself and therefore part of the definition of a maternal death. However, a number of women die just after this arbitrary cut-off to complications that arose during the pregnancy or delivery. Four deaths were detected with case note reviews. They were not under the care of the maternity team anymore, who was unaware of their deaths (according to the clinical notes). These cases are summarised in Table 8.3.4.

Table 8.3.4. Deaths occurring just more than 6 weeks after pregnancy

Age and gravidity	Summary of case notes
28 year G3P3	Elective caesarean section for diabetes and big baby, also on antiretroviral therapy for more than 6 months. Postoperative stay uncomplicated and discharged from hospital. Presented one month later at Internal Medicine with jaundice and a diagnosis of fulminant hepatic failure with encephalopathy was made; she needed continuous dextrose infusion. Hepatitis studies were negative and ultrasound findings in keeping with cholecystitis and she was referred to surgery. No definitive diagnosis was made and she deteriorated over the next few weeks of supportive management and demised 10 weeks after delivery. It may have been due to hepatotoxicity of her anti-retroviral drugs.
28 years G1P1	Died 60 days after delivery from hepatic failure due to efavirenz toxicity; antiretroviral therapy was started in pregnancy.

21 Years G1P1	Known with systemic lupus since the age of 16 years. Pregnancy complicated by severe pre-eclampsia and intra-uterine growth restriction. The baby was stillborn. She died 2 months later from neurological complications of lupus in a medicine ward.
24 G2P2	Delivered May 2011 with preterm labour and severe pre-eclampsia at 32 weeks. On arrival her cervix was fully dilated. There were no complications during delivery and she was discharged on enalapril. She was admitted to a medicine ward in August 2011 with massive right heart failure. A diagnosis of peripartum cardiomyopathy was made. She was started on warfarin. She was re-admitted October 2011 with a thrombus in the left ventricle and acute arterial occlusion of her arm. She went into massive heart failure and died in the ward.

There were also four deaths in women who were recently pregnant and managed by an obstetrics and gynaecology (O&G) team, but where an underlying medical condition was either not detected or satisfactorily managed, and they later died from these conditions. This is summarised in Table 8.3.5. All these deaths occurred outside of the 6 weeks postpartum period and NCCEMD notification was not required.

Table 8.3.5. Deaths in women after recent treatment in an O&G ward.

Age and gravidity	Summary of case notes
37 G5P4M1	Managed for a spontaneous miscarriage and discharged without complications. Died 8 weeks later from metastatic liver carcinoma.
21 G1P1	Delivered in February 2011. Was known then with hypothyroidism that was difficult to treat and it was suspected that the patient was non-compliant. She remained weak and tired after delivery but was not followed up at the maternity ward. By September the weakness was diagnosed as myotonic dystrophy. She deteriorated and aspirated and developed pneumonia. She developed an iatrogenic pneumothorax after placement of a central venous line and died in the medical ward.
27 year G2P1	Caesarean section for fetal distress, also on antiretroviral drugs but with poor compliance. No abnormalities noted during CS and post-operative course uncomplicated. Admitted 9 weeks later with disseminated tuberculosis and ascites (abdominal tuberculosis) and died a few days later.
26 years G1P1	She did not attend antenatal clinic and arrived in labour with twins and a caesarean section was performed. She was then newly diagnosed as HIV positive with a CD4 count of 56 cells/mm <sup>3</sup> but discharged herself without that knowledge and was not contacted for follow up. She died 10 weeks later from <i>Cryptococcus meningitis</i> .

Two deaths were identified following pregnancy but unlikely attributed to the pregnancy itself and after the 6 weeks cut off for maternal death notification. This is shown in Table 8.3.6.

Table 8.3.6. Deaths from folder review most likely not related to the pregnancy.

Age and gravidity	Summary of case notes
PR 34 years G2P2	Developed a skin rash and progressive weakness 8 weeks after normal vaginal delivery. Not on any medication and no diagnosis made before her death. Post mortem diagnosis most likely Guillain–Barré syndrome.
32 year G1P1	Vaginal delivery for pre-eclampsia and HELLP syndrome. Admitted 7 weeks after delivery with sudden onset right sided hemi-paresis, neck stiffness and aphasia, computed tomography (CT) of the brain showed a massive sub-arachnoid bleed. She died on return from CT scan.

Women with known severe underlying medical conditions are managed to the best of the obstetrician's abilities in consultation with the appropriate discipline, but some of them do not survive for long after the pregnancy and succumb to complications of their condition. There were two women in this group with severe mitral valve disease that survived pregnancy but died a few months later from the cardiac complications. A number of deaths following months to years after delivery was not associated to the pregnancy in any way- these were mostly deaths from haematological cancers.

Deliveries of women outside of Tygerberg hospital, but who died in the tertiary hospital will not be detected this way. The database of all deliveries in the province will have to be checked against the database of all deaths, but the provincial delivery data is not currently linked to personal identifiers. The Burden of Disease (BoD) study group reports on deaths associated with pregnancy as reported by the department of Home Affairs. The following datasheet with patient information was kindly supplied by Dr. Andrew Boule, a public health specialist associated with the BoD study, after a search on the hospital information system. The unique identifiers (folder number and where available identity document number) of

deaths during 2012 were linked to a recent discharge (within 6 weeks) from a maternity ward somewhere in the province, or to laboratory blood tests performed for antenatal screening (syphilis, rhesus and blood group). This identified 6 women who died in Tygerberg hospital after a delivery taking place somewhere else. Analysis of these folders are summarised in Table 8.3.7.

Table 8.3.7. Additional deaths identified at Tygerberg where the place of birth was elsewhere.

Age and gravidity	Summary of case notes
34 G2P2	Uneventful normal vaginal delivery as low risk patient. Developed fulminant hepatic failure after delivery presumably due to herbal remedies taken to induce labour. Managed in ICU at Tygerberg. Died nine weeks after delivery.
31 G3P3	Delivered at MOU and had maternal collapse shortly thereafter, presumably due to eclampsia. Intubated at MOU and transferred to Tygerberg (October 2011). Managed in ICU but severe hypoxic brain damage was present and patient did not recover. Was extubated and eventually transferred to a hospice, where she died in May 2012.
35 G2P2	Discharged from maternity ward at a district hospital, referred to Tygerberg for stage 4 cervical carcinoma where she died. She was never pregnant but managed in a maternity ward as there was no vacant bed in the gynaecology ward.
36 G5P2M3	Died from chorio-carcinoma with severe bleeding and metastases 9 weeks after a miscarriage.
The following 2 patients identified this way was already reported to the NCCEMD:	
21 G1P1	Intracranial bleeding following eclampsia.
28 G2P2	Known HIV disease, died from lower respiratory tract infection.

No maternal death that was not already accounted for in the hospital database was identified this way.

## 8.4 Discussion.

This chapter only investigated female deaths within Tygerberg hospital. It can be assumed that a certain number of terminally ill women with malignancy will die in a hospice or at home and not in the hospital. It also did not investigate deaths of women treated in the hospital but dying at referral hospitals or at home. According to Statistics South Africa about 30% of deaths occur at home (2). The mortuaries are sensitised to the NCCEMD notification procedure and women referred for post-mortem where there are signs of recent pregnancy are notified to the provincial NCCEMD coordinator. However, it is of concern that a small portion of women managed in a tertiary labour ward that died shortly thereafter were not notified to the NCCEDM.

The adjusted number of maternal deaths for the WC for 2011-2013 including the deaths reported here would now be 220 instead of 214. A modified iMMR (there were 281 602 live births during this period) for the WC will be 78.12 per 100 000 live births.

Other ways of obtaining maternal deaths are the use of data from the national birth and death registry. Bomela, using the vital registration database of Statistics South Africa calculate the proportion of maternal deaths in the WC as about 5% of all maternal deaths in SA. The same data estimates the MMR for the WC as 87 per 100 000 live births which is close to the NCCEMD (11). Udjo and Lalthapersad-Pillay used the same vital registration data as well as the 2011 household survey data and adjusted it with a method that correct for incomplete or over reporting of deaths in households during a census or survey (12). They report a MMR of 102 per 100 000 live births in the WC. Both of these estimates are higher than the NCCEMD data, which only counts institutional deaths. They may be closer to the true MMR and obstetricians should continue to ensure all deaths are accounted for.

## 8.5 Conclusion.

The method used in this chapter relies on the electronic availability of case notes at Tygerberg hospital, making it easier to peruse a few hundred deaths per month to ensure all deaths are accounted for. There are currently pilot studies underway in the KwaZulu Natal province investigating the feasibility of household surveys and community reporting to detect maternal deaths. It is possible that even the rigorous system of detecting maternal deaths at Tygerberg hospital described here may miss some maternal deaths. ICD-10 coding (13) is done by clerks and not clinicians and it is possible that they can misinterpret clinical notes, enter the wrong code by mistake or a file may not be entered at all. The magnitude of these human errors are most likely small.

Maternal deaths account for less than 1% of deaths of women in the reproductive age group. Tuberculosis and HIV disease remain the main killers of woman in this age group (14) and there is a substantial chance that any healthy woman who attends antenatal care at a low risk clinic may be infected. All women are screened for HIV disease during antenatal care. The diagnosis of pulmonary and non-pulmonary tuberculosis should be emphasised in training and awareness programs for maternal deaths.

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## Chapter 9

Maternal mortality in metro east and trends in maternal mortality in the Western Cape 1999-2014.

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## **Chapter 9. Maternal mortality in Metro East and trends in maternal mortality in the Western Cape 1999-2014.**

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## 9.1 Introduction

This short chapter aims to re-align the Western Cape (WC) data from all the published Saving Mothers reports (1) (2) (3) (4) (5) as well as the provincial database on maternal deaths to get a GSA specific demographic view of the data. This way the mortality ratio from Metro East can be compared with the other GSAs. Maternal mortality remains a relatively rare event and a combination of the available triennial data may give a more comprehensive overview of maternal mortality ratios. As discussed in chapter 8, the NCCEMD uses the institutional MMR (iMMR) to calculate mortality ratios.

Audits of maternal mortality was periodically conducted in Cape Town in (what it was called then) the Peninsula Maternal and Neonatal Service (PMNS) in the region of Cape Town that closely correspond to the Metro West of today. Van Coeverden de Groot reported on the maternal mortality ratio (MMR) in the PMNS for 1953 to 1977 (6) and again for 1978-1983 (7). Fawcus gave a 50 year overview of the PMNS deaths (from 1952-2002) in 2005 (8). During these years the PMNS included the Site B Khayelitsha MOU and its corresponding catchment area. The MMR declined significantly over the years (the MMR was 301/100 000 in 1952) and only started to rise again after 1999 due to the HIV pandemic. There is not a similar historical report for Metro East as the of the fledgling Karl Bremer and Tygerberg hospitals were built later and the drainage areas changed as human settlement in the area progressed.

South Africa has not reached its target for the millennium development goals (9) but the National Department of Health has adopted 15 interventions that can bring the iMMR in South Africa down to 153 deaths per 100 000 deliveries (10). The iMMR in the WC is already well below this (65/100 000 in 2011-2013) (3) and comparable to the rate in Brazil (69/100 000 in 2013) (11). It is still higher than China (32/100 000 in 2013) (11). Data from the vital

registration database of Statistics South Africa (using death registration rather than hospital notification as the source) calculates the WC MMR at 87/100 000 (for 2002-2006) (12).

## 9.2 Methods

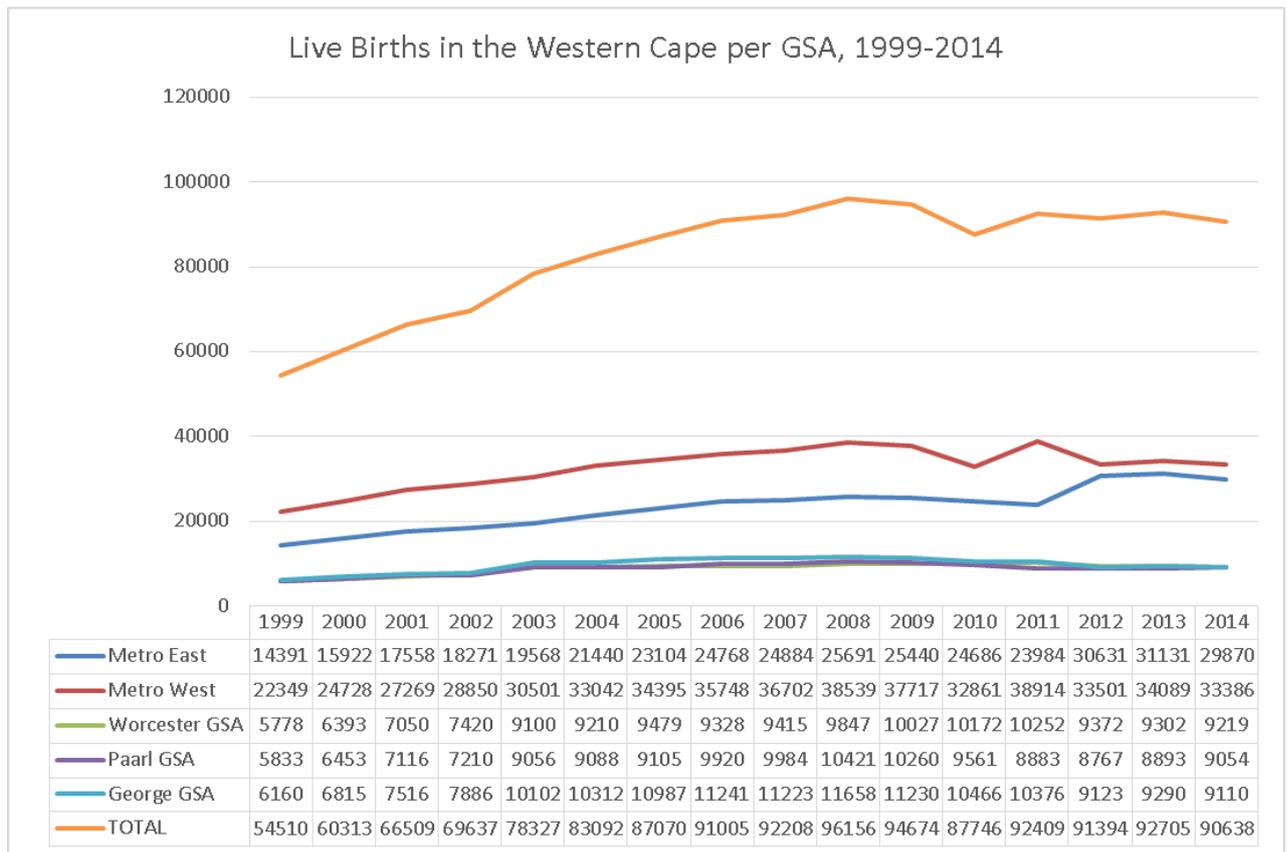
Data was obtained from the Saving Mothers reports and provincial delivery and mortality databases. Permission to use the data already published in the triennial Saving Mothers reports was obtained from the chairperson of the National Committee for Confidential Enquiries into Maternal deaths (NCCEMD). Only data already in the public domain was used. In addition, the database of maternal deaths maintained within the province for clinical governance purposes was used to obtain delivery dates and home addresses to calculate the geographical origin of patients. This database is maintained by the author as chapter head of the provincial Saving Mothers chapters (2009-2011, 2011-2013) and permission to use it was obtained from the chairperson of the Western Cape CCEMD. Data was entered into Microsoft Excel™ spreadsheets and basic descriptive statistical analysis was performed.

The GSA concept did not exist prior to 2002, although there were only small changes to the drainage areas from 2002 onwards. The delivery and mortality data for 1999-2001 was re-aligned to correspond to the GSA setup after 2002 for easier comparison. The drainage shifts after 2009 and 2012 were taken into account when aligning patients to their respective GSA. Delivery data was obtained from the provincial office. The denominator used in the calculation of the institutional maternal mortality ratio was live births and not total deliveries. The additional maternal deaths in Metro East for 2011 and 2012 (described in Chapter 8) that was not included in the Saving Mothers report are included in the numbers for this chapter.

### 9.3 Results

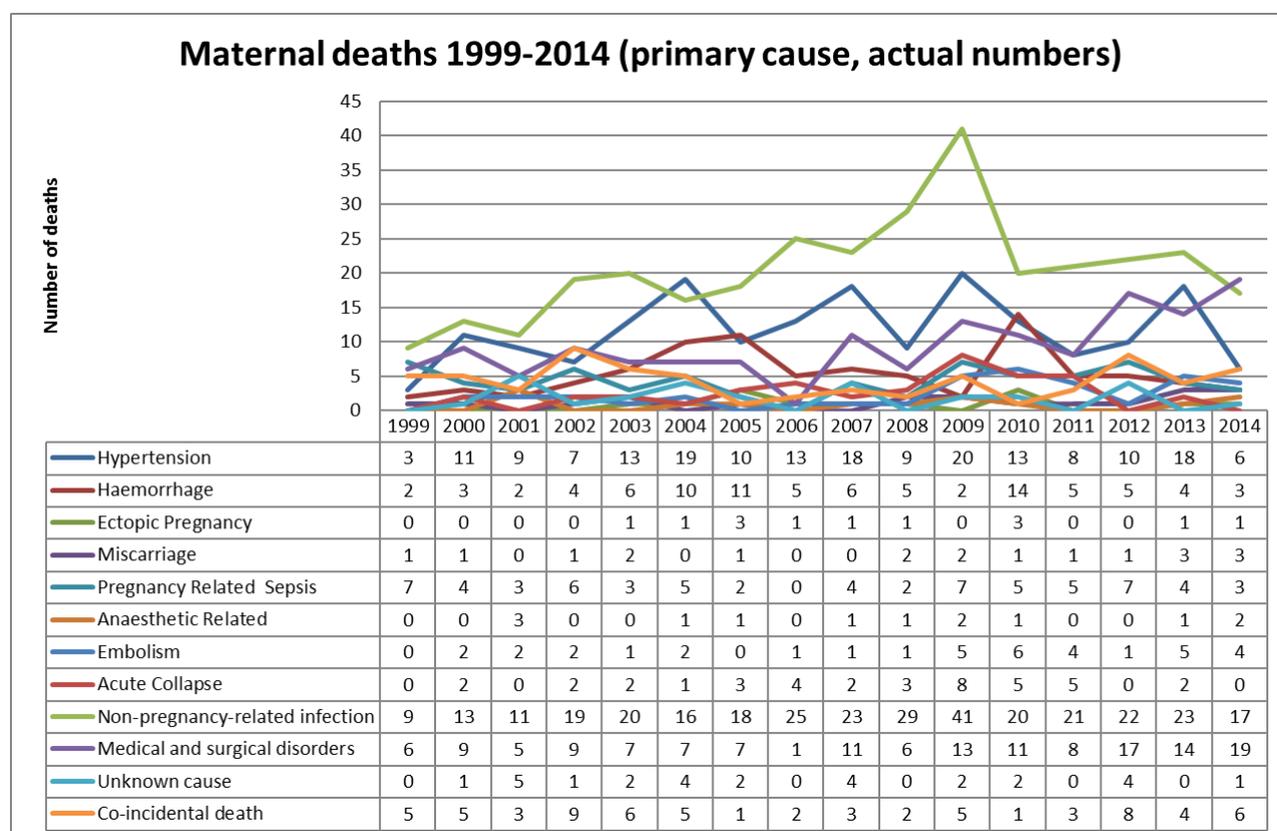
The number of public sector deliveries increased from 1999 until 2008 and then stabilised. The number of live births is depicted in Figure 9.3.1. The change in drainage for Khayelitsha Site B from Metro West to Metro East in 2012 explains the changes seen on the graph. After 2012 there is almost the same number of deliveries in Metro East and West.

Figure 9.3.1 Live births in the Western Cape per geographical service delivery area, 1999-2014.



The primary causes of maternal deaths for the province are shown in Figure 9.3.2. Non-pregnancy related infections dominate the numbers after 2005. Deaths due to medical disorders remained constant until 2006 and subsequently increased steadily to the second most common cause in 2012 and 2104.

Figure 9.3.2. Primary causes of maternal deaths 1999-2014; actual numbers.



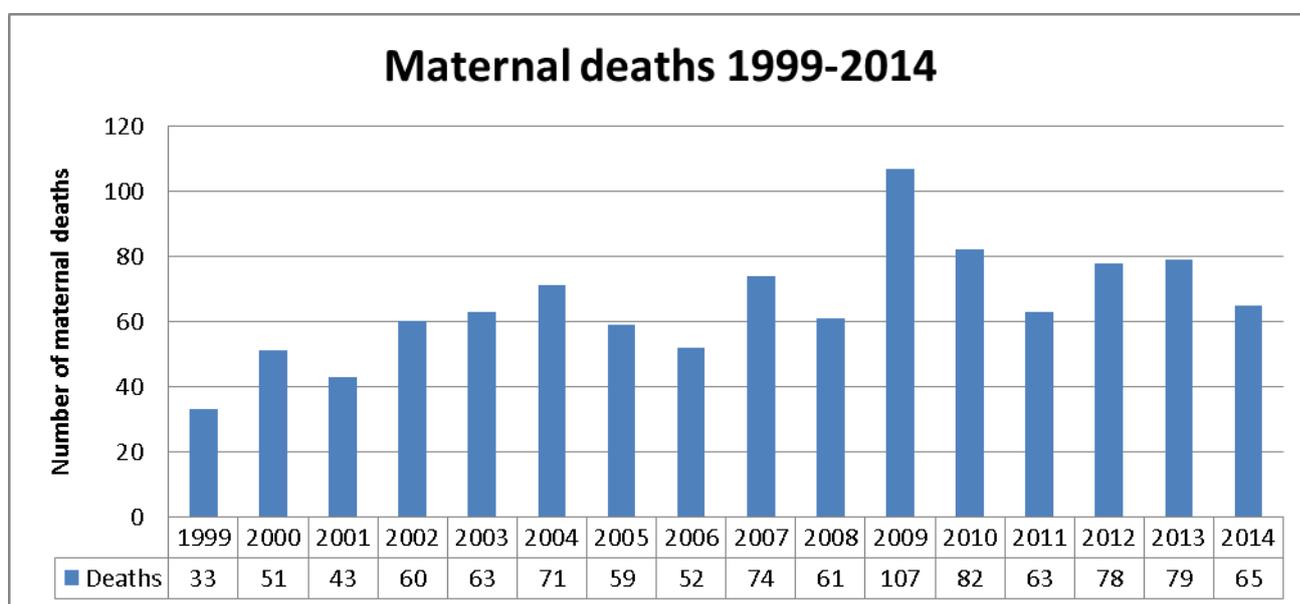
The total number of maternal deaths in the WC is about 5% of the deaths in South Africa. This is shown in Table 9.3.1 and a graphic representation of the actual number of reported deaths is shown in Figure 9.3.3. The peak in deaths seen in 2009 and to a lesser extent in

2010 was attributed to an H1N1 influenza epidemic and 36 maternal deaths in the non-pregnancy related infections group were due to pneumonia.

Table 9.3.1. Number of maternal deaths in the Western Cape (including cases not reported to the NCCEMD) and percentage of total deaths in South Africa.

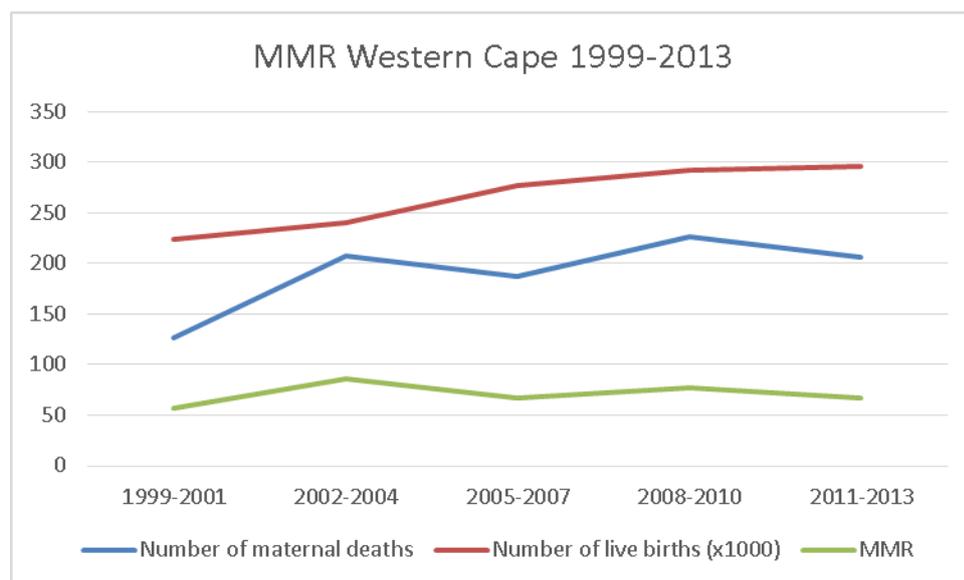
Year	Number reported	% of deaths in SA	Triennial percentage
1999	34	4.2	4.4
2000	50	4.8	
2001	42	4.2	
2002	60	5.9	6.1
2003	67	5.5	
2004	80	6.8	
2005	61	4.8	4.6
2006	53	3.7	
2007	73	5.3	
2008	60	3.9	5
2009	110	6.2	
2010	82	5.0	
2011	63	3.8	4.7
2012	77	4.8	
2013	79	5.7	
2014	65	Not known	

Figure 9.3.3. Actual number of maternal deaths 1999-2014.



The WC iMMR per triennia is shown in Figure 9.3.3. The iMMR for 2014 (not included in the graph) was 71/100 000. The iMMR increased until 2004 and then stabilised.

Figure 9.3.3. Institutional maternal mortality ratio: comparison of triennia 1999-2013.

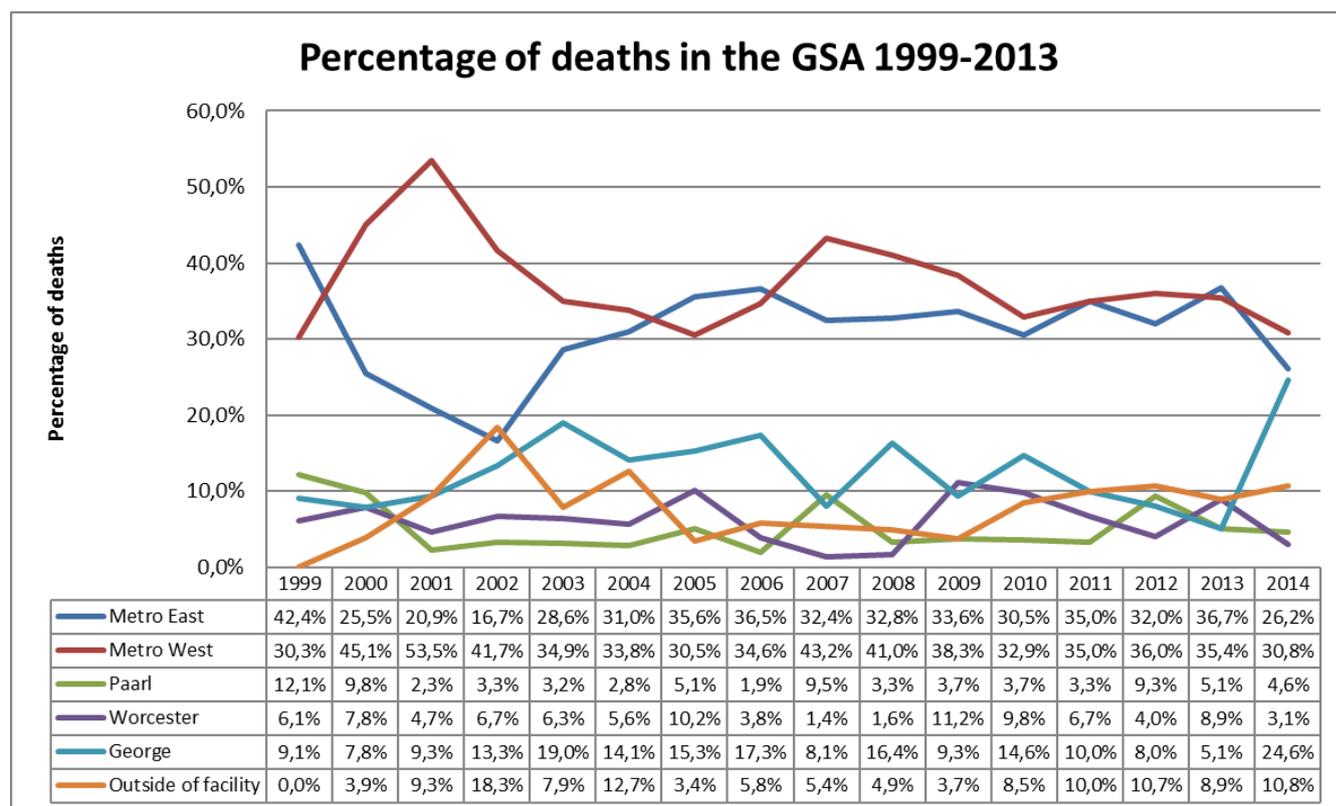


The deaths according to the women's home address were aligned to the GSA where the death occurred. Figure 9.3.4 first shows the GSA where the patient died (the percentage of deaths per year for each GSA). This is a year by year comparison and not triennia. Most deaths occur in the Metro and after 2010 the iMMR in Metro West and East is almost similar.

There were 61 deaths in Metro East in clinics and district hospitals and 57 in Metro West for the 1999 to 2014 period. The iMMR for deaths in clinics and district hospitals in Metro East was 16 and for Metro West 11. This is not a reliable comparison to make at district level, as most women who would have received district care in Metro West are managed in Mowbray and Somerset hospitals that are regional hospitals. Both these hospitals have a large district

component but for mortality calculations they are regarded as regional hospitals. Before 2009 Tygerberg hospital also received district level referrals.

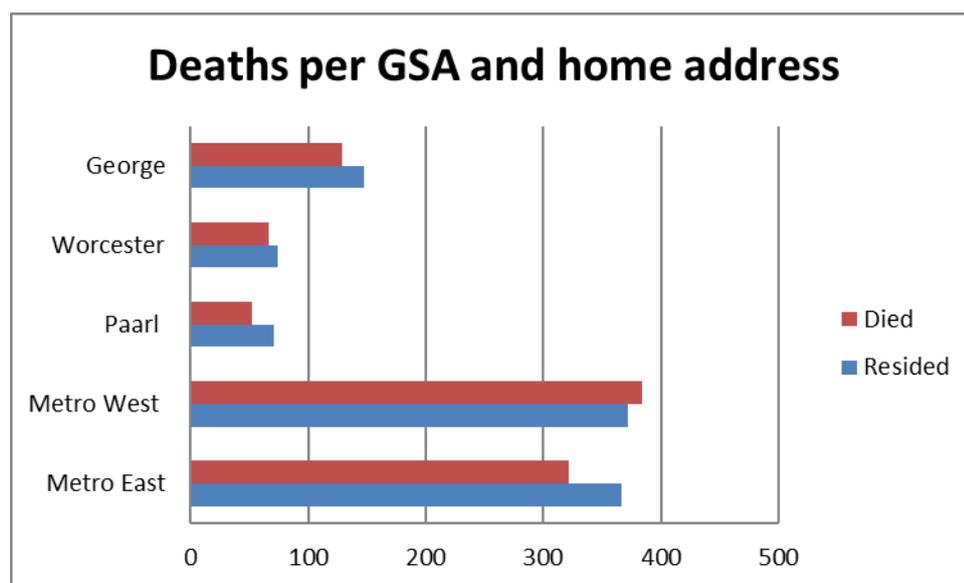
Figure 9.3.4. Percentage of deaths per area where a woman died, 1999-2014.



The number of deaths per home address was next compared to the deaths per GSA for the total time period. The number of women who died outside of a hospital is excluded. This is shown in Figure 9.3.5. It is surprising that most women died within the GSA that she resided which reflects few referrals to the central hospitals in the metro. For all three rural regions there is just slightly less deaths than the number of women residing there at the time of the catastrophic event that led to their deaths. During these years, only 11 deaths were from women who were referred from Paarl or Worcester GSA. An interesting observation is that

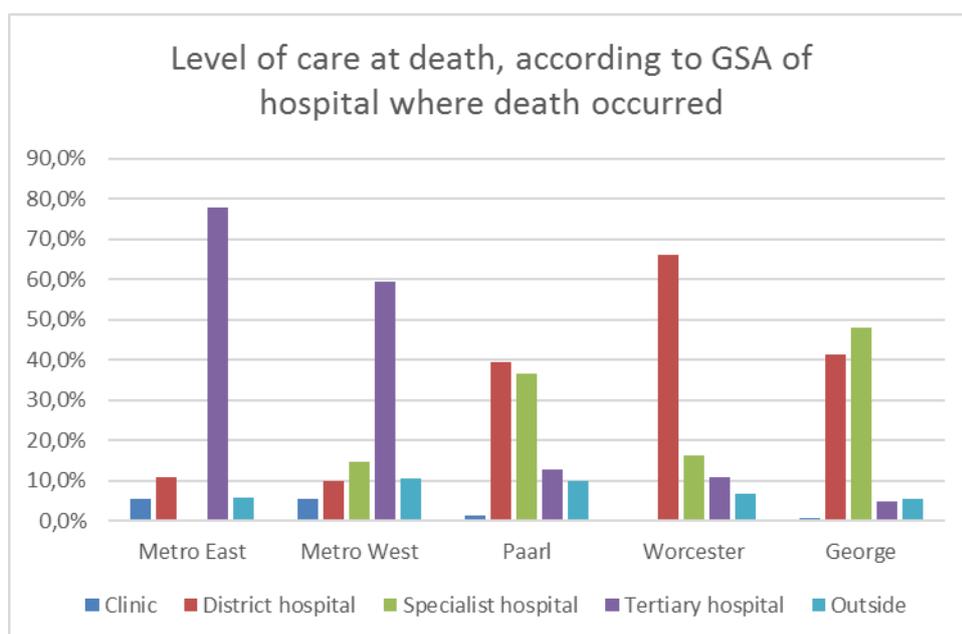
there were women who resided in metro east but did not demise there. Closer inspection shows that most of these deaths are from women living in the Khayelitsha (metro east) area but who died in Groote Schuur (metro west) hospital.

Figure 9.3.5. Deaths per area and home address per area; total numbers 1999-2014.



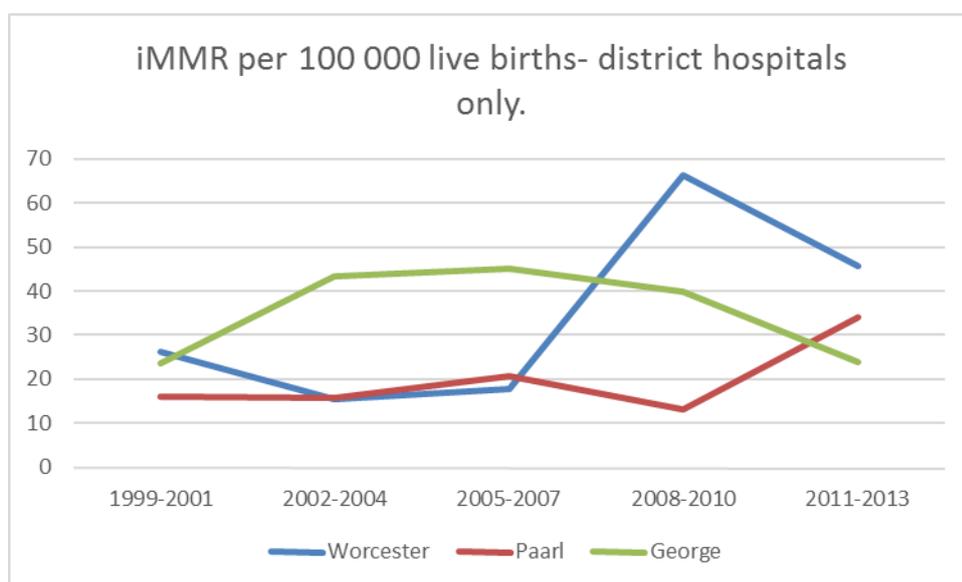
If most women die within her GSA, it means there is little referral from rural GSAs to Metro GSAs. To investigate this, the level of care for the hospital where a woman died within the GSA was examined. This is shown in Figure 9.3.6. Less than 12% of all women from the rural GSAs died in the metropolitan central hospitals. A large percentage of rural deaths occurred in district hospitals and more so in the Worcester GSA. This is the GSA with large district hospitals that are geographically isolated from their regional hospital and transport may play a role. Most of the deaths were in Hermanus hospital which has no major route linking it to Worcester and no easily assessable public transport to Worcester. The deaths at Tygerberg hospital are not aligned to the regional or tertiary part of the hospital as both are in the same structure. All deaths are reported as tertiary hospital deaths.

Figure 9.3.6. Level of care at death, according to geographical service delivery area of hospital where death occurred.



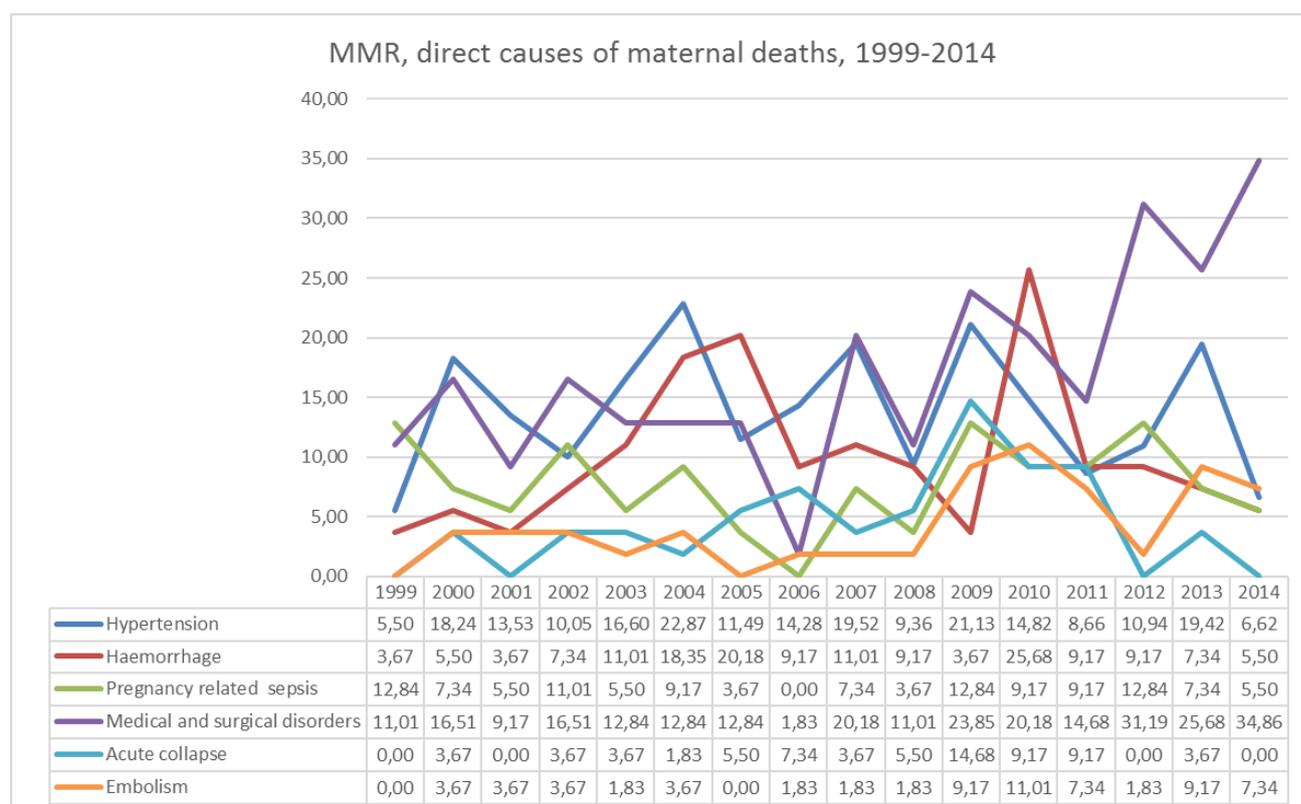
To investigate the rural deaths over the time period, the iMMR for district hospitals deaths only within the rural GSAs were plotted over time and is depicted in Figure 9.3.7. The peak in Worcester GSA deaths in 2009 was the impact of the H1N1 epidemic and was discussed in the comprehensive fifth Saving Mothers report (13). As there is large fluctuation in year to year data, the triennial periods as used for the NCCEMD reports were used.

Figure 9.3.7. Institutional maternal mortality ratio per 100 000 live births in district hospitals in the rural areas.



The provincial iMMR for direct obstetric causes of death is shown in Figure 9.3.8. This is a yearly (not triennial) plotting of data so there will be variation between years. Deaths due to medical disorders have increased since 2007 and there was a gradual decline in deaths from hypertensive conditions. The biggest contributor to the deaths from pre-existing medical conditions was cardiac lesions.

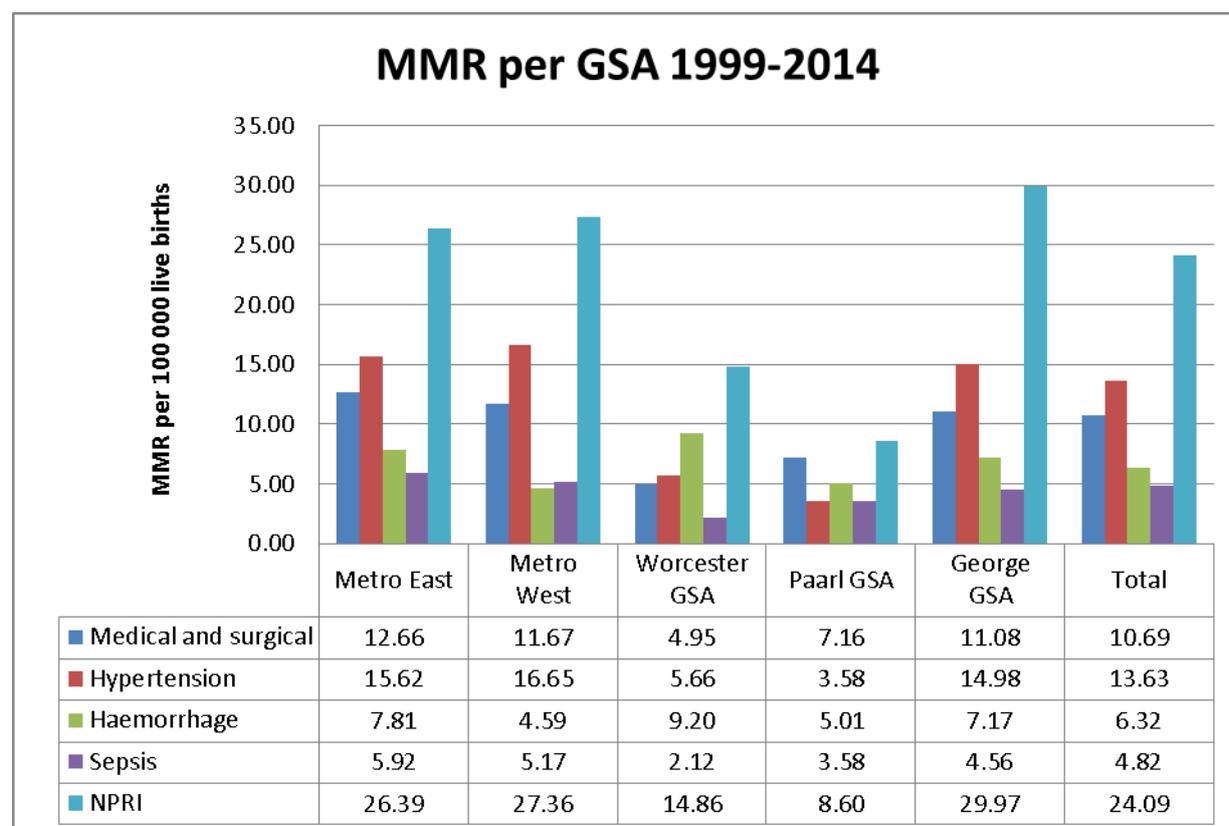
Figure 9.3.8. Institutional maternal mortality ratio for direct obstetric causes of death, 1999-2014.



The iMMR for the direct obstetric causes of death for each GSA during the complete time period is shown in Figure 9.3.9. This is the iMMR specific for each GSA and the live births per GSA was used as denominator. Compared to Worcester and Paarl GSAs, non-pregnancy related infections (NPRI) have the biggest impact on the George GSA. Most of the NPRI deaths however, are in the metro. The distribution seen in George GSA is therefore similar as the regions with tertiary hospitals.

Metro East and Worcester are the two GSAs that have a higher iMMR from haemorrhage than the provincial average. Detailed analysis of the haemorrhage group (n=26) in Metro East showed 3 deaths from ruptured uterus, 3 from bleeding during caesarean section (CS) and 2 from bleeding after CS. The rest was related to antepartum bleeding (mostly due to abruption) and postpartum haemorrhage (mostly due to uterine atony). This is not different than the distribution of cases in Metro West (n=23). For the other causes Metro West and East is remarkably similar. George GSA has a high iMMR for hypertensive deaths which could be due to the long distance from its referral hospital (Groote Schuur) resulting in fewer referrals.

Figure 9.3.9. Institutional maternal mortality ratio per geographical service delivery area, 1999-2014.



## 9.4 Discussion

This brief re-analysis of the mortality data demonstrates that Tygerberg hospital within its GSA has comparable mortality ratios to Metro West and that most women who die, do so in the central hospital.

The number of women who died in a metro west hospital but who resided in the metro east region could be the tail-end of the metro shifts. For this chapter the home address was aligned to the GSA at the time of the service shifts described in chapter 3. A community that is used to taking their critically sick to Groote Schuur hospital may not be aware of the change in drainage route for several months after the change. It is mainly the ambulance referral routes that changed immediately. Most likely women still found their way to the metro west GSA with other means of transport.

The finding that very few women die outside of their GSA may be a tribute to the care provided at the more specialised levels of care. As seen in chapter 3, about 5% of women will be referred for tertiary care within their pregnancy or the postpartum period, with few of the complicated patients referred resulting in a death.

A confidential enquiry into maternal deaths is more than a community-based or facility based audits and death reviews. It has a commitment from designated individuals and is overseen by bodies involved in high-level planning and policy (14) and has the potential to make a bigger impact. The United Kingdom, France and the Netherlands has the longest running confidential enquiry processes. Few other developing countries has a full confidential enquiry and comparison between countries will not be valid regarding the mortality ratios. There is large variation in iMMRs even within the provinces of South Africa. It will be more interesting to determine what the WC, a province with a robust enquiry process can learn from the enquiry process from other countries and how the main causes of death compare.

Modifications of the process has been tested with various success in Ghana and Indonesia (15). A similar process was introduced in 12 Eastern European countries in transition, including Moldova (16). The Moldova review showed that social determinants (especially poverty and migration) played a part in more than half of the deaths (17). The NCCEMD has not included social determinants into its analysis yet, but it is planned for the 2014-2016 triennium.

The confidential enquiry from the Netherlands showed an increase in maternal mortality ratio in the years 1993-2005 (18). The most important direct cause was hypertensive conditions and embolism, the same as for the WC. Similar to the WC, there was also a rise in the indirect causes of death with medical conditions and cardiac lesions in particular a shared finding (19). France has had a confidential process since 1995 and the leading cause of death is obstetric haemorrhage (20). Deaths due to haemorrhage is increasing in the WC while deaths due to hypertensive conditions are decreasing. In the UK, the major causes of maternal deaths are indirect, with infection and cardiac lesions at the top of the list (21). The causes of death for the WC is more comparable to these countries than to the rest of SA, although the iMMR are much higher.

The challenges of the process include incomplete or missing case notes, inadequate death reporting and poor quality of the health information and data. This is highlighted in the Moroccan mortality surveillance process and is more of an issue in the rural provinces in South Africa such as Limpopo and KwaZulu Natal (22). The confidential process in Indonesia was limited to two rural districts in Java which highlighted the high mortality rates for disadvantaged women (23). South Africa is leading the way with the process in sub-Saharan Africa and with the help of the United Nations Population Fund at least 15 countries in this region has introduced maternal death reviews (24). Once this process is reporting good quality data it will be useful for comparing South Africa with its neighbours.

The research agenda for the WC in terms of mortality should be twofold- lessons learned that can be applicable to the rest of the country, and ways to reduce deaths to at least the level of other middle-income countries like China. The main killer of pregnant women in the WC is the same as that of women dying outside of pregnancy (see Chapter 8), namely HIV, tuberculosis and medical disorders rather than direct obstetric conditions. HIV is also an independent contributor to blood transfusion for obstetric haemorrhage in South Africa (25) and it is essential that the HIV epidemic in the WC is managed well. This would have the biggest impact on further reduction of maternal deaths and also deaths occurring after the pregnancy.

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## Chapter 10

Clinical governance in a changing obstetric service- assessing patient safety by monitoring adherence to a new protocol for induction of labour.

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## **Chapter 10. Clinical governance in a changing obstetric service- assessing patient safety by monitoring adherence to a new protocol for induction of labour.**

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## 10.1 Introduction

Induction of labour (IOL) is a method where the onset of labour is stimulated artificially, prior to the onset of spontaneous labour. The indications, mechanisms and methods are well described (e.g. McCarthy and Kenny) (1). The audit of Tygerberg hospital maternity services during 2009 (reported in Chapter 7) identified a lack of written protocols to guide junior doctors. A new protocol for IOL at Tygerberg hospital was implemented on 1 August 2010, after a thorough review of the literature. This was partly based on the existing Western Cape guideline for induction of labour, the National Institute for Health and Care Excellence (NICE) guideline on IOL (2), relevant literature up to that date as well as practical aspects specific to the Tygerberg hospital labour ward (organisational aspects, availability of drugs and methods). An IOL safety check list was introduced at the same time at the high risk clinic, where women who need elective induction of labour are counselled and booked.

A safety check list is a low-technology physical reminder of all the relevant steps in a specific protocol to ensure that no important detail is overlooked. It is one of the important tools of an obstetric patient safety programme (3). It is not the purpose of this short audit report to scrutinise the existing literature on IOL, nor to describe the process that lead to the development of the hospital-based IOL protocol and safety check list, as this was part of the routine clinical governance initiatives in the department. The complete protocol and check list are attached as Addendum 1 and 2 for reference.

The protocol stated that every induction must have a safety checklist completed to ensure the decision for induction is made at specialist level and that basic safety aspects are checked prior to admission for induction. Table 10.1.1 list all the aspects that need a safety check prior to admission for IOL. The safety check list was adapted from the American College of Obstetricians and Gynecologists (ACOG) patient safety checklist (4).

Table 10.1.1. Aspects that must be checked prior to admission for elective induction of labour.

<b>Clinical detail</b>		
	<b>Aspect</b>	<b>Comment</b>
<b>Maternal detail</b>	Gravidity	
	Parity	
	Syphilis	
	Rhesus	
	HIV status	
<b>History</b>	Previous uterine scars	
<b>Cervical evaluation</b>	Bishop score	
<b>Gestational age on the day of booking</b>	How it was calculated	Stated whether it was certain or unsure, and re-checked personally
<b>Fetal lie</b>	Longitudinal lie	Re-checked personally
<b>Fetal presentation</b>	Cephalic lie	Re-checked personally
<b>Estimated fetal weight</b>		Clinically or by ultrasound
<b>Indication for IOL</b>		Selected from list of acceptable indications
<b>Organisational detail</b>		
	<b>Aspect</b>	<b>Comment</b>
	Induction of labour method chosen	
	Place of induction	Stratified by risk- either to antenatal ward, labour ward or critical care unit
	Discussion with specialist	Name to be provided
	Doctor making the booking	Name to be provided

## 10.2 Methods.

This was a retrospective review of 150 consecutive women who delivered after being booked for elective IOL at Tygerberg hospital, from 1 September 2012 to 31 December 2012. A copy of the booking form was kept at the clinic to ensure all patients were entered into the database. The clinical criteria informing the audit tool was obtained from the protocol and is attached as Addendum 3. Data was entered into a Microsoft Excel 2013™ spreadsheet directly after discharge from the delivery unit to ensure completeness of data. The audit was stopped after the 150<sup>th</sup> patient delivered, towards the end of December 2012.

This was a specific audit of elective inductions, i.e. women who were evaluated for the induction days or even weeks before the admission for induction. It did not include IOL where the decision was made in the acute labour ward (e.g. eclampsia, prolonged rupture of membranes, severe pre-eclampsia etc.) or in the antenatal ward (e.g. preterm rupture of membranes remote from term and now reaching 34 weeks).

This was cross-sectional collection of data to audit changes to clinical practice after the introduction of an evidence-based protocol. The main purpose of the audit was to:

- Determine the key characteristics related to elective (outpatient booked) IOL at Tygerberg hospital
- Analyse the waiting times from admission to start of induction and between transfer to the labour ward and delivery (workload).
- To audit adherence to the patient safety checklist.
- To audit adherence to the protocol.

The secondary aims were to see which aspects of the protocol or safety checklist could be improved or deleted, and to propose a standardised classification system for future audits of

IOL. The audit tool developed for this purpose will serve as a model for ongoing audits in the labour ward, which will be added to the maternity dashboard (see Chapter 12).

## 10.3 Results.

The folders of all 150 patients were available for review. Patients were admitted on average 9.5 days after the completion of the safety checklist; the minimum was 1 day and the maximum 32 days. The maternal demographic data is given in Table 10.3.1.

Table 10.3.1. Demographic characteristics of the audit group.

Characteristic	Median	Minimum	Maximum
Age (years)	31	18	48
Gravidity	3	1	7
Parity	2	0	6

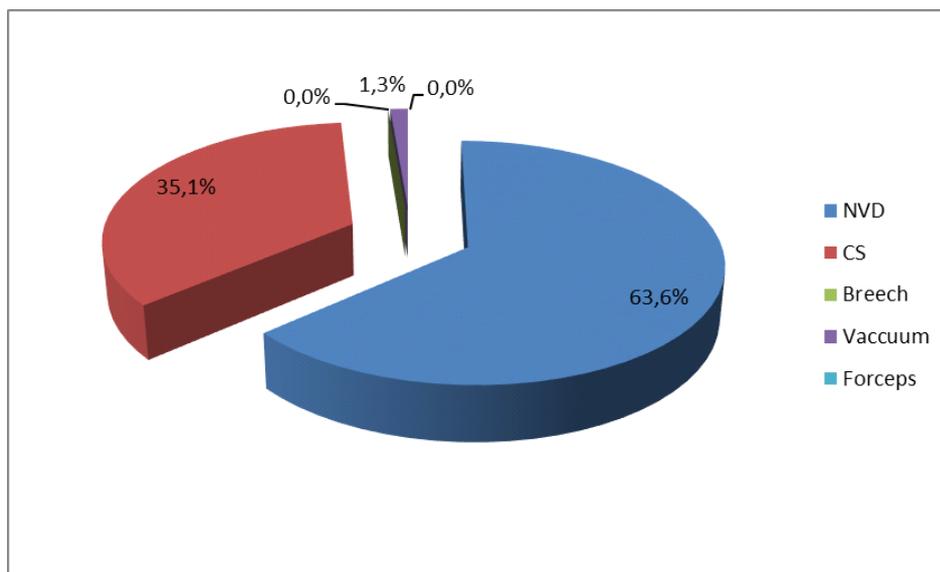
The actual gestation at the time of delivery for the different indications is presented in Table 10.3.2. This was re-calculated using the early ultrasound to ensure the IOL occurred at the correct time. It is an important safety check as inductions of labour before term could lead to unneeded neonatal morbidity. There was one case of gestational hypertension where the dates were miscalculated and she delivered at 34 weeks and 2 days. There was no super-imposed pre-eclampsia. The other inductions were all admitted and performed at the correct gestational age according to the protocol.

Table 10.3.2. Gestation at delivery.

	Median		Minimum		Maximum	
	Weeks	Days	Weeks	Days	Weeks	Days
<b>Chronic hypertension</b>	39	1	35	1	41	0
<b>Dichorionic twins</b>	38	6	38	1	39	0
<b>Diabetes Mellitus type 1</b>	38	5	38	2	39	1
<b>Diabetes Mellitus Type 2</b>	38	2	38	0	38	5
<b>Gestational diabetes</b>	39	1	37	6	42	2
<b>Fetal anomaly</b>	40	0	37	4	42	3
<b>Gestational hypertension</b>	38	5	34	2	41	2
<b>Maternal disease</b>	39	3	39	0	40	0
<b>Previous intra-uterine death</b>	39	1	37	3	40	6
<b>Post dates</b>	41	5	40	6	43	3

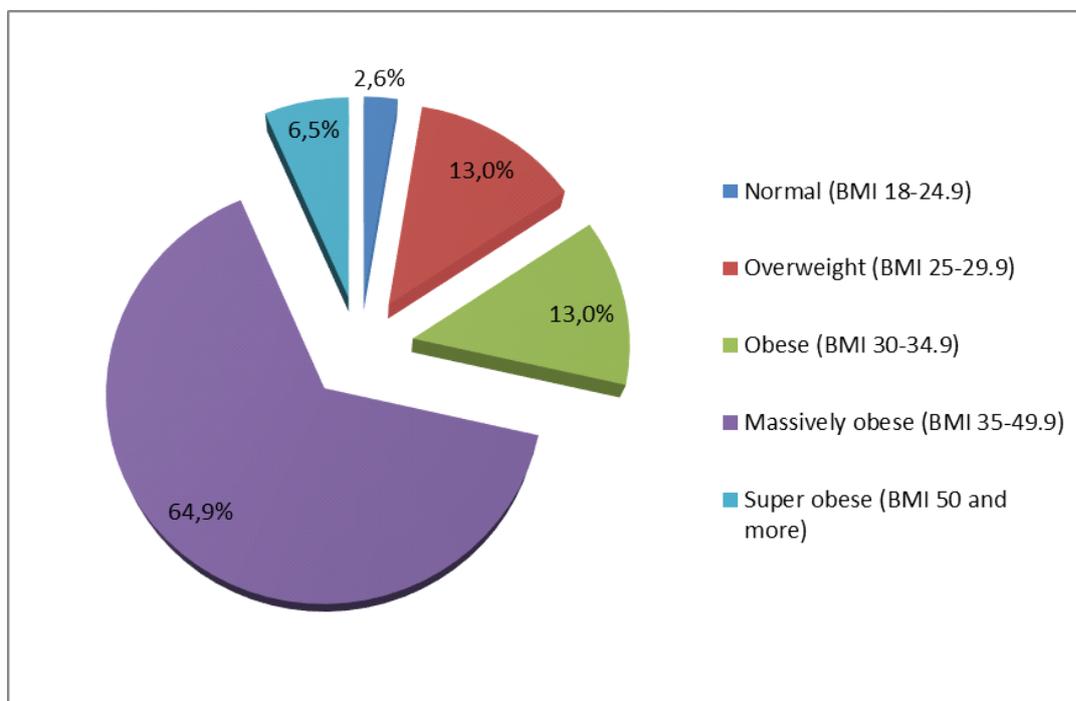
The method of delivery is given in Figure 10.3.1. The CS rate for the IOL group (35%) was lower than the average CS rate in Tygerberg hospital for the corresponding time (43%; see Chapter 5). The most likely reason is that women needing elective delivery and not deemed suitable for vaginal delivery were booked for elective CS instead.

Figure 10.3.1 Method of delivery.



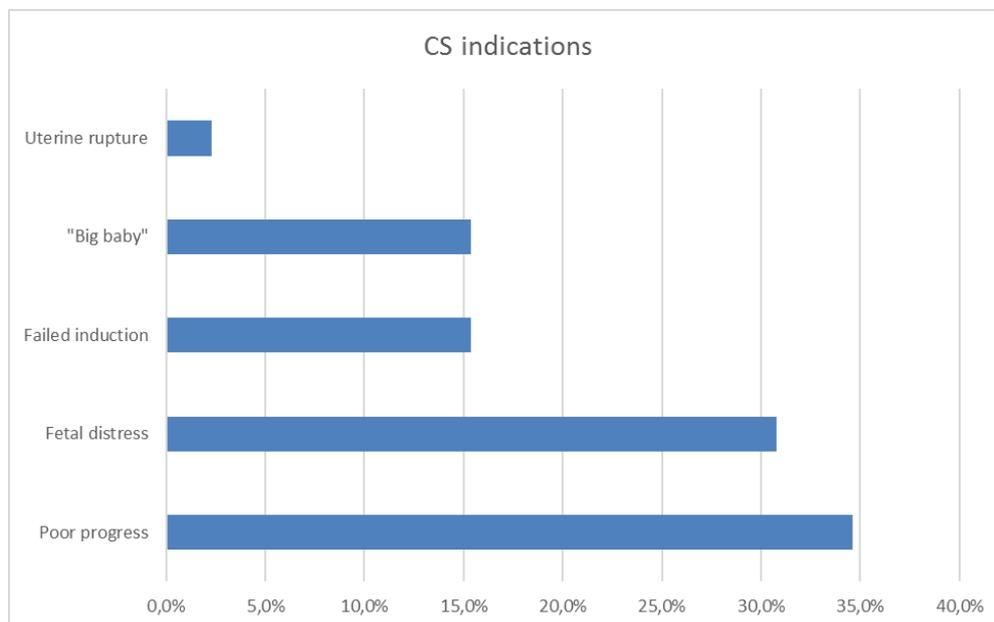
The body mass distribution of participants in the IOL is represented in Figure 10.3.2. Almost two thirds of the women were massively obese and only 2.6% had a normal body mass index (BMI). Body mass index of 40kg/m<sup>2</sup> or more is a referral criterion for a specialist hospital level of care.

Figure 10.3.2 Body mass index in the audit group.



A previous CS was present in 27 (18.5%) of inductions. All of these women consented to an induction and a trial of labour after a previous CS (vaginal birth after previous CS or VBAC). The method of induction in these women was either prostaglandin cervical gel (54%) or bulb induction (46%). The indications for a caesarean delivery following a patient that was selected for IOL is given in Figure 10.3.3.

Figure 10.3.3. Indications for caesarean section (total group).



CS for a 'big baby' was when the induction process was halted or interrupted due to clinical concerns that the baby weighed more than 4500g and will not be able to deliver vaginally (or >4000g in a diabetic woman). The median birth weight in this group was 3995g (range 3250g-4790g). Analysis of the safety checklist for this groups shows a median estimated birth weight of 3600g (3500g-3700g); done on average 3 days before admission.

The indication as selected by the clinician during the initial visit at the clinic is given in Figure 10.3.4. Most of the indications for elective delivery at term were for gestational diabetes or a previous intra-uterine death. The tick sheet has a check block for maternal condition as a broad category. The detail (final indication) was obtained from the notes and are given in Figure 10.3.5. Most inductions were for gestational diabetes, which is not surprising for this group of women with a high BMI.

Figure 10.3.4. Indication for induction of labour as selected at the antenatal clinic

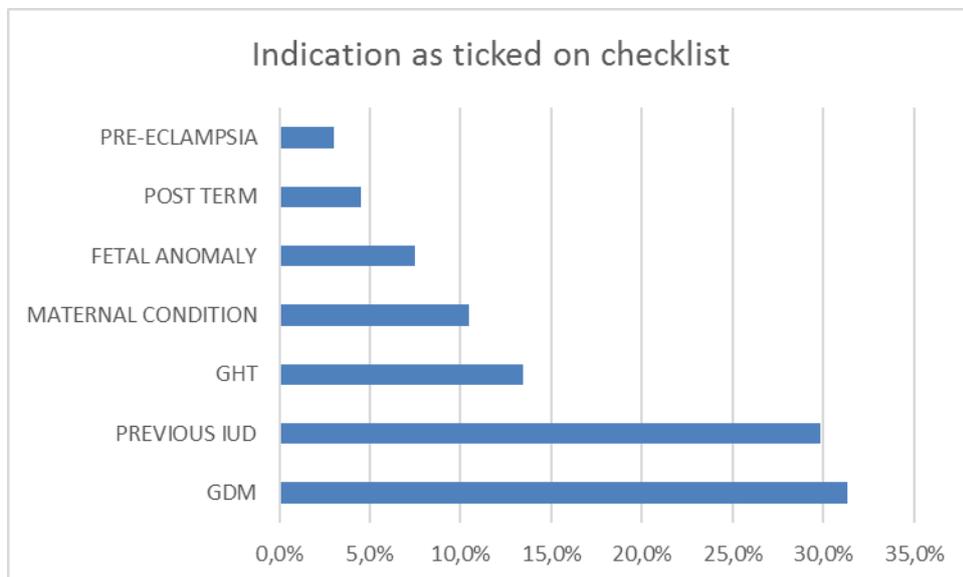
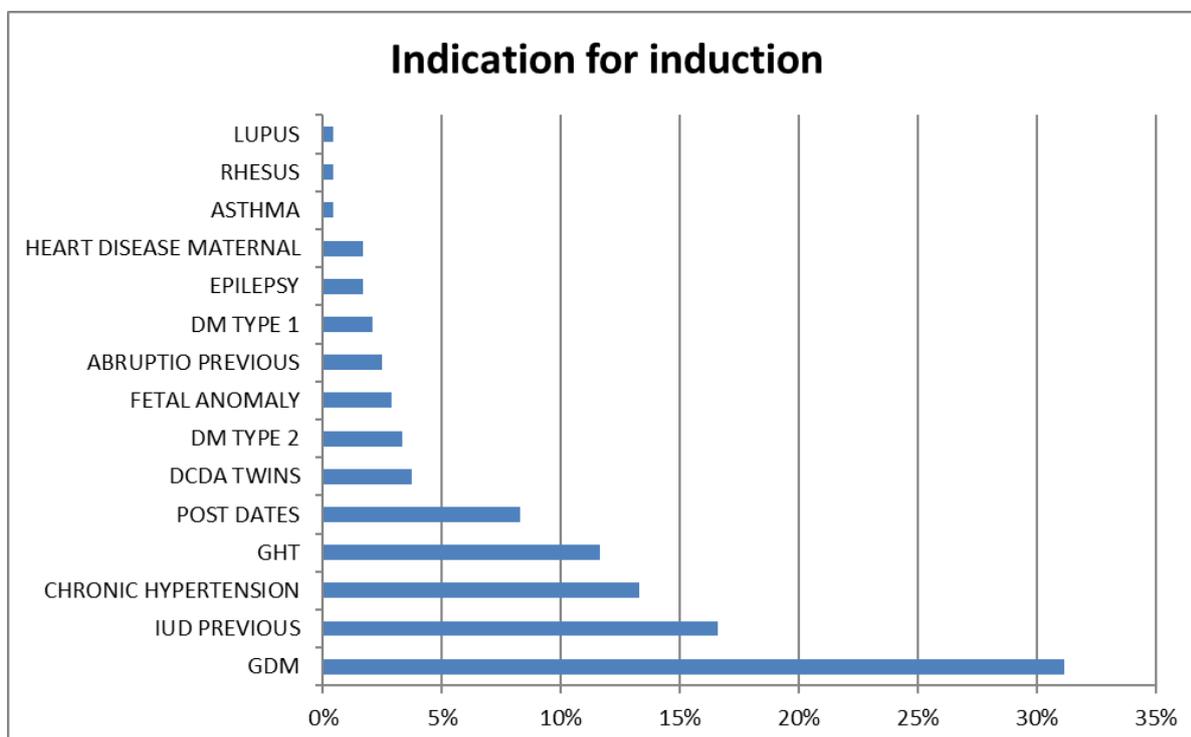


Figure 10.3.5. Indications for induction of labour (final indication).



DM = diabetes mellitus  
 DCDA = dichorionic, diamniotic

GHT = gestational hypertension

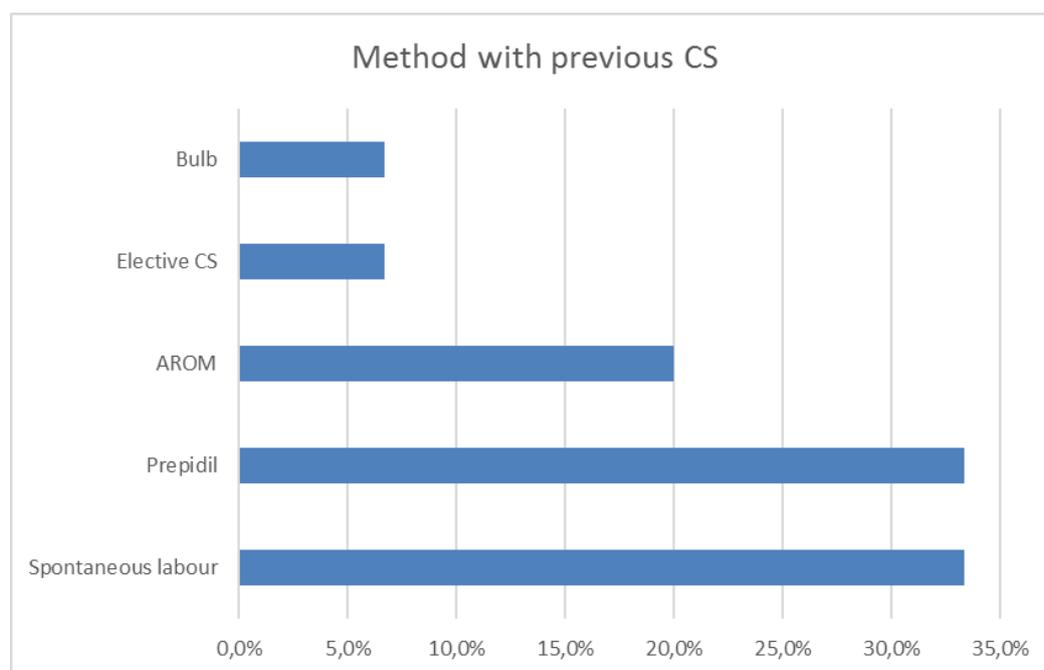
IUD = intra-uterine death

GDM = gestational diabetes mellitus

The method of induction chosen for women with a previous CS (n=29) is shown in Figure

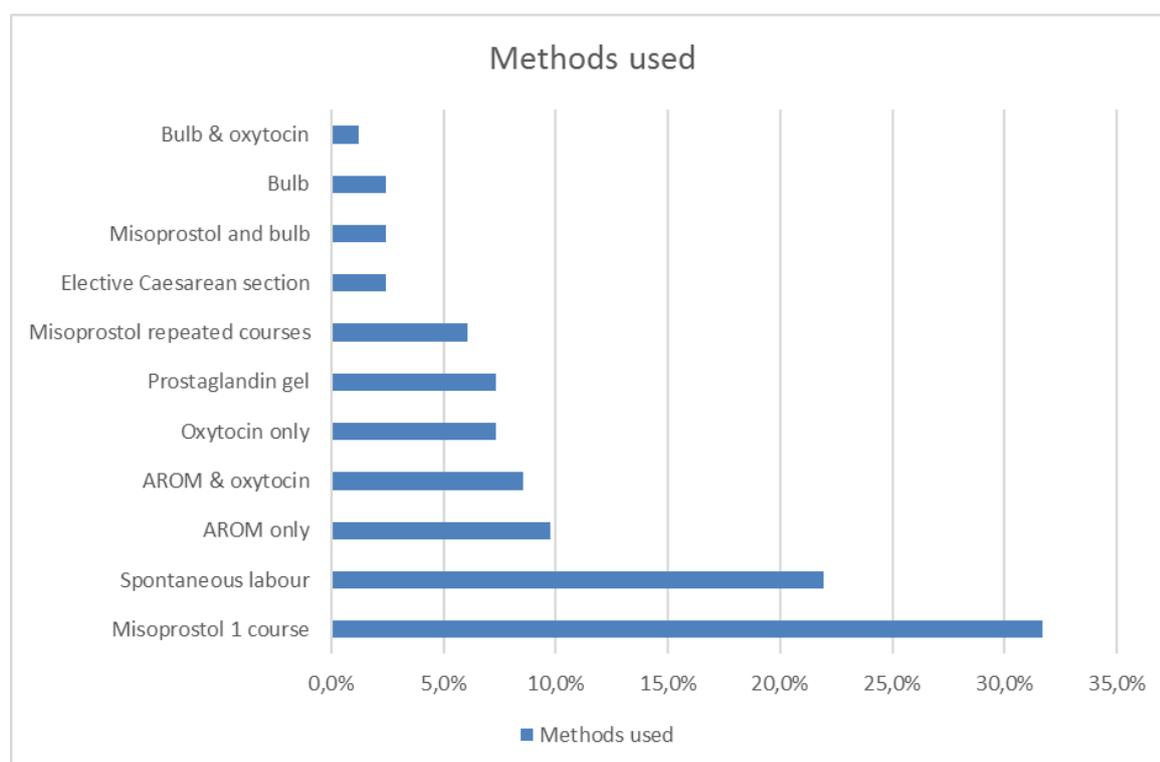
10.3.6. In 2 cases the indication for elective vaginal delivery changed to elective CS. This was mostly due to women who now declined a VBAC. Ten women with a previous CS went into labour before their scheduled induction date.

Figure 10.3.6. Method of induction of labour used in women with a previous caesarean section.



Of the 10 women with a previous uterine scar who went into spontaneous labour, 8 delivered vaginally and of the 6 induced with AROM, 5 delivered vaginally. All the women who needed cervical priming with a bulb or prostaglandin gel ended with a repeat section; they were mostly IOL for gestational diabetes. The different methods used in the total group are shown in Figure 10.3.7.

Figure 10.3.7. Methods used for induction of labour.



A safety checklist was completed in 60% of women. The adherence to the safety check list and compliance with the protocol was measured using a tool developed from the protocol. It has 11 criteria and is depicted in Table 10.3.3. Each criterion has a standard for achievement set at 100% out of the total number of women who qualifies for that specific criterion of the audit.

Table 10.3.3 Adherence to an induction of labour protocol and policy

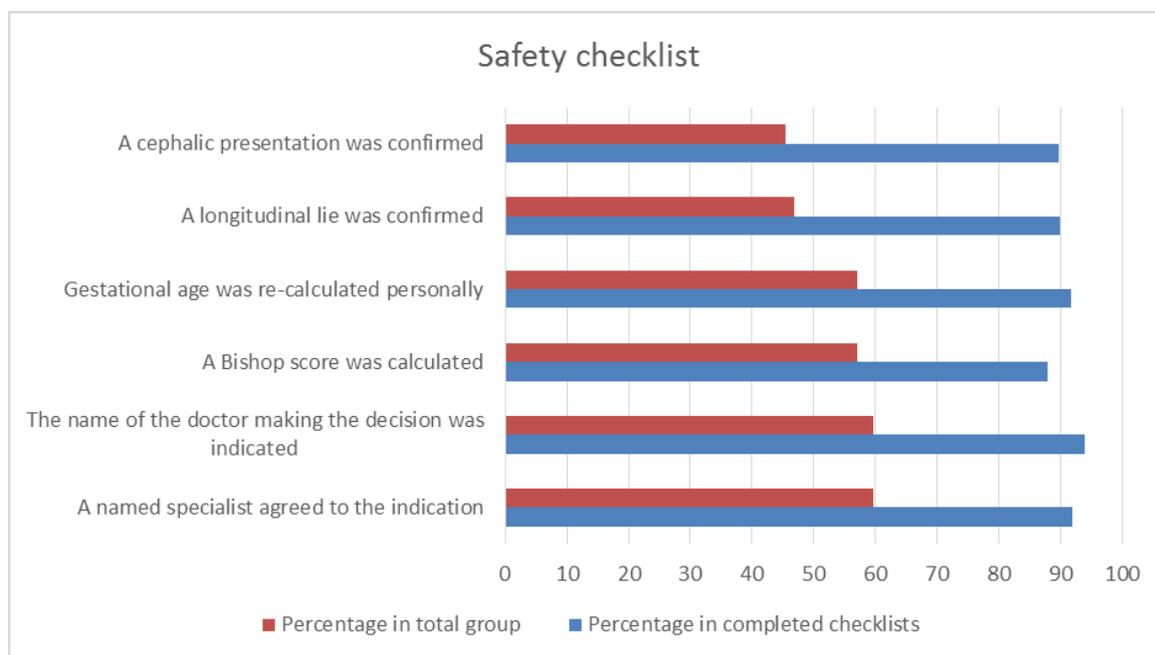
Induction of labour – outpatient appointment evaluation	
<b>Criterion 1</b>	Do a full maternal and fetal assessment with emphasis on the 6 critical safety aspects: Abdominal examination ( <u>Lie</u> , <u>presentation</u> , estimated fetal weight) Cervical assessment ( <u>Bishop score</u> ) Complete an Induction of labour safety checklist including <u>name of doctor</u> and <u>name of specialist</u> <u>Recalculate the gestational age</u> personally.
<b>Exceptions</b>	None

<b>Standard</b>	100%
<b>Result</b>	Only 95 of the 150 patients (63.6%) of patients had completed safety checklists.
<b>Induction of labour – admission to hospital</b>	
<b>Criterion 2</b>	Check that the indication for IOL is valid Repeat the cervical assessment (Bishop score) Do a 10 minute fetal heart rate monitor to ensure a normal pattern
<b>Exceptions</b>	When a cervical assessment was performed within the last 24 hours, omit Bishop score
<b>Standard</b>	100%
<b>Result</b>	98.6% (n=113/115). A Repeat Bishop score was not deemed necessary in n=35 (23.3%) of cases (see exceptions).
<b>Criterion 3</b>	Artificial rupture of the membranes (AROM, amniotomy) should be performed in all HIV negative* women where the Bishop Score is 8 or more (after transfer to the labour ward).
<b>Exceptions</b>	<ul style="list-style-type: none"> <li>•HIV positive (*unless viral load is known to be non-detectable; or &gt;4 weeks compliant on highly active anti-retroviral therapy)</li> <li>•Breech</li> <li>•Intra-uterine fetal death</li> <li>•Unengaged presenting part (except in controlled AROM with severe polyhydramnios)</li> </ul>
<b>Standard</b>	100%
<b>Result</b>	100%. Of the 37 women, 30 (81%) delivered vaginally.
<b>Criterion 4</b>	An Oxytocin infusion should be started after one hour of AROM, if there are no uterine contractions present, to stimulate contractions, using a standard oxytocin regimen.
<b>Exceptions</b>	<p>Not to be used within 6 hours of any prostaglandin administration</p> <p>Cannot be used without continuous cardiotocographic (CTG) monitoring.</p> <p>Can only be used in the Labour Ward</p>
<b>Standard</b>	100%
<b>Result</b>	76%. For 9 women there was a delay in starting after one hour due to lack of infusion pumps.
<b>Criterion 5</b>	If oxytocin was used, was a standard oxytocin regimen followed?
<b>Exceptions</b>	None
<b>Standard</b>	100%
<b>Result</b>	100% (n=29/29)
<b>Criterion 6</b>	If the cervix is unfavourable (Bishop score <8), prostaglandin E <sub>1</sub> (PGE <sub>1</sub> ) should be used for the induction of labour in the form of misoprostol tablets (oral dose of 50 microgram 4 hourly for 6 doses)
<b>Exceptions</b>	<p>Previous uterine surgery [open uterine surgery / when the uterine cavity was entered]</p> <p>Previous caesarean section</p> <p>Grande multiparity (parity 5 or more)</p> <p>Severe intra-uterine growth restriction (Absent End Diastolic Flow on Umbilical Artery Doppler)</p> <p>Placental insufficiency (strongly suspected or proven)</p> <p>Severe pre-eclampsia (consultant decision needed)</p>
<b>Standard</b>	100% (either prostaglandin or bulb, see criterion 7)
<b>Result</b>	100% (n=95).
<b>Criterion 7</b>	If the cervix is still unfavourable (Bishop score <8), after the first course of misoprostol, a consultant decision is needed before a repeat dose can be offered.
<b>Exceptions</b>	If there is a complication or clinical reason

<b>Standard</b>	100%
<b>Result</b>	100% (only 9 women needed a repeat dose)
<b>Criterion 8</b>	Mechanical dilatation of an unfavourable cervix using a Foley catheter bulb is an alternative to prostaglandin ripening of the cervix
<b>Exceptions</b>	If there is a complication or clinical reason
<b>Standard</b>	100% (either prostaglandin or bulb, see criterion 5)
<b>Result</b>	100% This method was only used in 7 women with an unfavourable cervix as the primary method.
<b>Fetal monitoring</b>	
<b>Criterion 9</b>	As soon as contractions start, fetal wellbeing should be assessed with electronic fetal monitoring
<b>Exceptions</b>	None
<b>Standard</b>	100%
<b>Result</b>	100% (n=150)
<b>Criterion 10</b>	If oxytocin is used continuous fetal monitoring with CTG must be documented.
<b>Exceptions</b>	None
<b>Standard</b>	100%
<b>Result</b>	81% In 25 of the 31 women audited for this component, continuous fetal monitoring was documented.
<b>Criterion 11</b>	Fetal viability must be checked with CTG prior to the start of the induction.
<b>Exceptions</b>	None
<b>Standard</b>	100%
<b>Result</b>	100% (n=150)

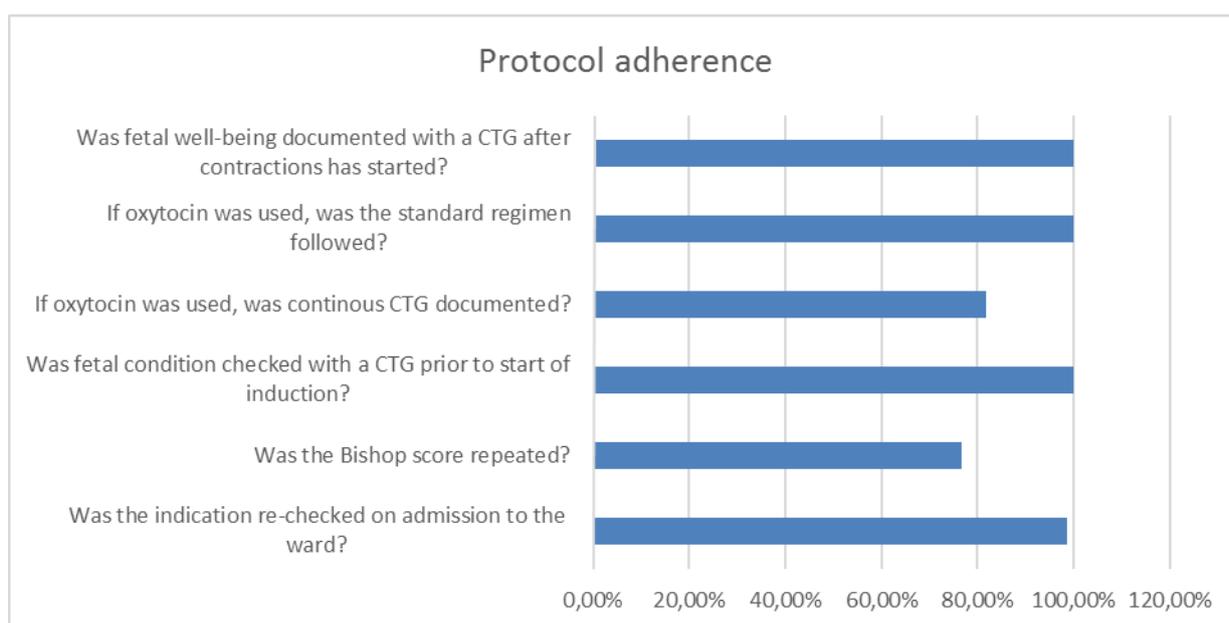
The 6 items on the checklist (criterion 1 of the audit tool) that carries the most weight in terms of prevention of harm is demonstrated in Figure 10.3.8. For the completed checklists, compliance to these aspects was 90% (n=86/95).

Figure 10.3.8 Adherence to the 6 critical safety aspects of the checklist.



There are also 6 critical items on the protocol adherence audit sheet and 4 of these relate to fetal well-being. Documentation of continuous fetal monitoring during the use of oxytocin was only present in 81% (n=25/31) of files. This is shown in Figure 10.3.9.

Figure 10.3.9. Adherence to the 6 critical safety aspects of the protocol.



Waiting times was measured as the number of hours that a patient waited before the induction is started. It was measure from admission time to the time of the first administration of any drug, insertion of a bulb catheter or AROM. Patients are admitted to the antenatal ward first, but vaginal gel and AROM are only done in the labour ward. This resulted in longer waiting times as they have to wait for a bed to become available. Misoprostol can be given in the antenatal ward, and this is reflected in the shorter waiting time. This is shown in Table 10.3.4.

Table 10.3.4: Average waiting time (in hours) before start of induction.

	Average	Range
<b>Misoprostol</b>	7 hours	2-15
<b>Artificial rupture of membranes</b>	18 hours	4-26
<b>Prepidil gel</b>	9 hours	4-22

The average length of stay was calculated based on the actual number of days that a patient stayed in the hospital, from first admission to discharge. The postpartum stay will evidently be longer for caesarean deliveries and their stay was calculated separately. Patients with maternal disease also had a longer hospital stay, as can be expected, but their numbers were small. This is shown in Table 10.3.5.

Table 10.3.5. Length of hospital stay.

<b>Median number of days spent in hospital</b>		
	<b>Vaginal deliveries n=97</b>	<b>Caesarean deliveries n=53</b>
<b>Misoprostol induction (single course)</b>	3 days (1-11 days)	4 days (3-7 days)
<b>Misoprostol induction (more than one course)</b>	3 days (2-6 days)	6 days (5-11 days)
<b>AROM</b>	2 days (1-3 days)	5 days (3-10 days)
<b>Spontaneous onset of labour</b>	2 days (1-3 days)	4 days (3-6 days)
<b>Prepidil gel</b>	2 days (1-4 days)	3 days (2-4 days)
<b>Bulb induction</b>	1 day (1-3 days)	4 days (3-6 days)

## 10.4 Discussion.

A *failed induction* was not described in the protocol, and clinicians used the term for a variety of clinical scenarios. It has since been defined as the failure to establish sufficient cervical changes after pharmacological and mechanical ripening to enable artificial rupture of membranes or to achieve regular contractions, or if regular contractions and cervical changes do not occur after 12-18 hours of oxytocin administration. The indications for CS for failed inductions will be included in the next round of audits to monitor this aspect. There was no other aspect of the protocol that needed revision.

The clinical part of the audit produced some valuable information. Seventy percent (n=105/150) of women booked for elective induction at Tygerberg hospital labour ward were massively or super obese. Obesity is common in the SA population (56.6% of SA women are obese) (5). A body mass index of 40kg/m<sup>2</sup> is an indication for specialist referral, leading to a selection of patients with obesity. Apart from the obvious medical, anaesthetic and intra-partum risks involved with obesity, the labour ward should also be equipped with the necessary equipment (e.g. beds that can lift a >140kg patient). Most patients booked for elective induction during 2012 was for gestational diabetes or a previous intra-uterine death (IUD). Induction of labour increases the bed occupancy rates in the antenatal and labour ward (the upper end of the range was 11 days for vaginal delivery with misoprostol induction). The previous IUD group has since been stratified into risk categories and from 2014 the women at lower risk for repeat IUD are induced at 40 weeks if still undelivered, to reduce bed occupancy without compromising safety (6).

When the Bishop score was favourable for rupture of membranes, the average waiting time from admission in the antenatal ward to rupture of membranes in the labour ward was 18

hours. This is unnecessary wastage and these patients should rather be admitted directly to the labour ward to improve patient flow.

Few women with a previous CS had a successful vaginal delivery with induction of labour when the Bishop score was less than 8. This was mostly women with gestational diabetes and high BMI. Other clinical conditions should also be included in the audit. This aspect should be included in the counselling information sheet for woman contemplating vaginal birth after a previous CS.

The safety aspects audited showed mostly good adherence to protocol. The documentation of continuous fetal monitoring after the initiating of oxytocin needs improvement. The audit demonstrated that adherence to a clinical protocol can be measured on an ongoing basis by case note review. This type of quality assurance audit does not need randomisation or even large numbers of folders. A snapshot audit of one week every three months could give enough information for this to be routinely included in a maternity dashboard. The protocol and paper version of the audit tool used is attached as addendums 1 and 2.

## 10.5 References.

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4. Patient Safety Checklist No. 5: Scheduling Induction of Labor. *Obstet Gynecol.* 2011 Dec;118(6):1473.
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6. Gebhardt S, Oberholzer L. Elective Delivery at Term after a Previous Unexplained Intra-Uterine Fetal Death: Audit of Delivery Outcome at Tygerberg Hospital, South Africa. *PLoS ONE.* 2015 Jun 15;10(6):e0130254.

## 10.6 Addendums

### Addendum 1

#### Induction of labour protocol

**TYGERBERG HOSPITAL**  
Department of Obstetrics and Gynaecology: General Specialist Services

**PROTOCOL FOR INDUCTION OF LABOUR**  
(Based on the accredited provincial guideline, circular H71 of 2007)

ENSURE THAT THERE IS A VALID INDICATION FOR ALL INDUCTIONS OF LABOUR (IOL)

THE INDICATION SHOULD BE COMPELLING ENOUGH FOR CAESAREAN SECTION (C/S) IF IOL FAILS

EXCLUDE ANY CONTRA-INDICATIONS FOR IOL

ALL IOL MUST FIRST BE DISCUSSED WITH A CONSULTANT

COMPLETE THE IOL CHECK LIST BEFORE STARTING THE INDUCTION

**Common Indications for labour Induction**

Eclampsia	Prelabour Rupture of Membranes (at $\geq 34w0d$ )
Pre-eclampsia*	Preterm Rupture Of Membranes (at $34w0d$ )
Gestational / Unclassified Hypertension (at $40w0d$ )**	Suspected Chorioamnionitis
Chronic Hypertension (at $40w0d$ )**	Post term / Prolonged Pregnancy (at $42w0d$ )
Diabetes in Pregnancy (at $38w0d$ )**	Intra-uterine fetal death (IUFD) (at any gestation)
Previous Abruption of unknown cause (at $38w0d$ )	IUGR / Fetal growth restriction
Previous IUFD $>28w$ of unknown / repeatable cause	Fetal Anomalies

\* Gestation of induction dependent on severity of disease  
\*\*All maternal indicated inductions are dependent on no organ dysfunction with normal fetal Dopplers and normal growth.

**Absolute contra-indications for labour Induction**

Malpresentation (e.g. transverse lie, foisting breech)	Cord presentation
Contracted or Abnormal Pelvis	Active genital herpes
Major placenta praevia	Maternal convenience only
Previous major uterine surgery incl. classical caesarean section	
Macroscopic fetus ( $>4.5kg$ in non diabetic mothers, $>4.0kg$ in diabetic mothers)	
Any gynaecological, obstetrical or medical condition that precludes safe vaginal delivery	

**Indications for induction in the antenatal ward (F2)**

*If BMI  $<50$  and no severe maternal disease*

Chronic hypertension, good control (at $40w0d$ )	Gestational or unclassified hypertension (at $40w0d$ )
Mild-moderate pre-eclampsia (at $38w0d$ )	Post-term pregnancy (at $41w6d$ )
Prolonged rupture of membranes (at $\geq 34w0d$ )	Suspected chorioamnionitis
Diabetes mellitus, with adequate control at $38w0d$ if normal Dopplers	
Idiopathic / moderate IUGR (no AEDV)	
Intra-uterine death in stable mother (not due to abruption/placenta)	
Fetal anomalies (as decided by level 3)	
Previous idiopathic abruption/placenta (at $38w0d$ )	
Previous IUFD $>28$ weeks gestation, of unknown/repeatable cause in uncomplicated pregnancy at $38w0d$	
Logistic factors (e.g. history of precipitous labour in a rural patient, long distance from the hospital)	

**Indications for induction in the induction suite (C2A):**

*All patients with severe maternal disease\**

All patients who need tertiary care due to maternal reasons (e.g. cardiac lesions, BMI $>50$ etc)
Early-onset severe pre-eclampsia (viable and non-viable pregnancies)
Severe fetal compromise (severe IUGR with AEDV)
Grand Multiparas
Previous precipitous labour

\*For these patients formal consent (± C/S) including family planning consent is needed prior to IOL.

**Summary: Procedure for IOL ( $>26W$ )**

**A. PROCEDURE FOR IOL FOR GESTATION OF 26 WEEKS AND MORE: (HIV NEGATIVE: or HIV POSITIVE WITH NEGATIVE VIRAL LOAD)**

- Do a full maternal and fetal assessment with emphasis on:
  - Abdominal examination (Lie, presentation, EPW, head above brim)
  - Cervical assessment (Bishop score)
  - 10 minute CTG to exclude fetal suspicious or pathological CTG
  - For all inductions an Induction Checklist form must be filled in

**Modified Bishop Score**

Cervical Feature	Score			
	0	1	2	3
Dilatation	$< 1cm$	1-2cm	3-4cm	$\geq 4cm$
Length	$>4cm$	3-4cm	1-2cm	$<1cm$
Station	-3	-2	-1 / 0	-1 / +2
Consistency	Firm	Medium	Soft	
Position	Posterior	Mid	Anterior	

**IF THE CERVIX IS FAVOURABLE (BISHOP SCORE 8 OR MORE):**

**1.1. Consider artificial rupture of membranes / amniotomy (ARoM)**

- Should only be done if there are no contra-indications and a normal CTG
- This is a sterile procedure only to be done in emergency centre
- Rupture of membranes should be followed by oxytocin administration one-hour later, if not adequate contractions by then. (3 contractions of 40s per 10 min)

**Contra-indications for ARoM**

- HIV positive (unless viral load known to be negative; or  $>4$  weeks compliant on ART)
- Breech
- IUFD (except if acute abruption suspected)
- Unengaged presenting part (except in controlled ARoM with severe polyhydramnios)
- Mid-trimester inevitable miscarriage

[\* In the preterm fetus keep the membranes intact as long as possible]

**1.2. Oxytocin for IOL**

- Only administer in emergency centre with continuous CTG
- Not to be used within 6 hours of any prostaglandin administration
- Suitable for IOL after SROM, irrespective of Bishop score
- Suitable for VBAC induction

**NB! Important points on Oxytocin**

- Avoid oxytocin if membranes intact when Bishop score is unfavourable (i.e.  $< 8$ ).

**Exceptions!** (i.e. oxytocin can be given in spite of intact membranes):

- HIV positive with failed or contra-indicated misoprostol
- ARoM and misoprostol both contra-indicated

**Consideration!** In a multigravida,

- WEAN infusion after 2 hours of sustained 3 or 4 strong contractions/10 min
- If contractions fade away after lowering the dose, increase it again to the previous level and attempt weaning again after 30 minutes.

**1.2.1. Preparing the infusion:**

- Put 10 Units Oxytocin in 1 l Normal Saline as a side infusion
- Rinse administration set before connecting with IV line
- Note drug content on vial/label

**Use standard protocol sheet for Oxytocin Infusion:**

- Start at low dose (1-2mU/min) (at 12 qpm if using 60 dropper set or 12ml/h if IVAC)
- After every 30 min: assess CTG & contractions. Only increase dose when CTG is normal and when less than 3 strong ( $>40s$ ) contractions in 10 minutes palpated
- Increase with 12mU/h increments at 30 minute intervals until 3 to 4 strong contractions / 10min. Up to a maximum of 72mU/h (12mU/min)
- Stop oxytocin when not in labour after 6 hours on maximum dose!

Discuss further management with the consultant.

**NB! Also stop infusion when:**

- 5 or more contractions / 10minutes
- Uterus not relaxing between contractions
- CTG is suspicious or pathological

Can restart at lower dose once incident has settled

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**2. IF THE CERVIX IS UNFAVOURABLE (BISHOP SCORE <9)**

- Always ensure that a full maternal and fetal evaluation was done first!

**2.1. Misoprostol IOL** (oral dose of 50µg 4-hourly):

- Exclude contra-indications for misoprostol:

**Contra-indications for misoprostol (Use PREPIDIL GEL instead)**

- Previous uterine surgery  
[Open uterine surgery / When the uterine cavity was entered]
- Grande multiparity (Parity 5 or more)
- IUGR with AEDV
- Placental insufficiency (strongly suspected or proven)
- Severe pre-eclampsia (consultant decision needed)
- Previous CS

- Do CTG for 10 minutes- if reassuring pattern, give misoprostol (Cytotec®) 50-µg (¼ tablet) orally  
Not sub-lingually or buccally!
- Continue CTG monitoring for 45 minutes after administration
- Repeat the same procedure at 4-hourly intervals for a total of 6 doses of Misoprostol.
- Stop as soon as the patient has 2 or more regular contractions per 10 minutes, and re-evaluate the cervix.

**2.2. If Bishop score is still < 8 after 6 doses of Misoprostol**

- Discuss with the consultant again

**2.2.1. Consider 2<sup>nd</sup> Course of Misoprostol**

- Let the patient rest for 24 hours (if maternal and fetal conditions are stable)
- Repeat a course of 6 doses after the rest.

**2.2.2. Consider Intra-cervical balloon or Extra-Amniotic Saline Infusion (EASI)**

- If still unfavourable cervix after two courses of misoprostol
- Start with **mechanical distension of the cervix**- either with **Intra-cervical balloon** or **EASI**

**3. INTRA-CERVICAL BALLOON OR EASI FOR IOL**

**3.1.** These mechanical induction methods are **NOT** the recommended method for:

- Patient with overt lower genital tract infection
- Immuno-compromised patients / AIDS
- Patients with ruptured membranes

**NOTE 1** If these methods are used in these circumstances (e.g. if other methods have failed and none of the alternative methods are suitable), then antibiotic cover is indicated. (PGWC guideline, oral antibiotics for 5 days)

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**3.2. Technique for Intra-cervical balloon:**

- Aseptic technique throughout, pass sterile speculum (use a gynaecology examination couch)
- Disinfect the cervix
- Choose catheter with at least 30ml but preferably 50ml balloon
- Pass Foley's catheter tip through the internal os of the cervix
- Inflate balloon and retract until resistance
- Tape catheter to the inner thigh with light traction\* – patient can be allowed to mobilize with this
- Start with oxytocin if necessary after expulsion of the balloon.

\*Can use 500 ml bag tied with string to catheter and suspended over the edge of bed to increase traction

**3.3. EASI Technique:**

- Could be considered if the induction is urgent or catheter expulsion has not occurred after 4-6 hours.**
- Infuse initial 200ml saline bolus at room temperature
- Infuse saline now at room temperature at 40-50ml/h through the intra-cervical catheter
- Do not exceed 2 litres in total

**3.4. ARoM** after catheter expulsion is preferably delayed until the patient is in active labour, contracting regularly

**3.5. Oxytocin** is needed in the majority of patients with intra-cervical catheter to initiate contractions. The timing of oxytocin administration is either

- As soon as catheter is expelled OR
- As soon as catheter is placed.

If completely impossible to do EASI or to rupture membranes, consider Caesarean section for failed induction of labour (discuss with the consultant on duty)

**4. PREPIDIL GEL FOR IOL**

**4.1.** Prepidil is very expensive and NOT much more effective than misoprostol or the intracervical balloon catheter. It should therefore only be considered if these much cheaper alternatives are contraindicated or technically not possible.

**4.2.** Use only if unfavourable cervix

**4.3. Technique for Prepidil insertion:**

- Pass a sterile speculum under an aseptic technique with good lighting
- Insert in the endocervical canal but never past the internal os.
- CTG for 60 minutes after each dose
- Maximum 6-hourly, maximum 3 doses in 24 hours

**NBI** Suitable for VBAC but in such cases: • Attempt ARoM after 1 dose  
• Give maximum 2 doses  
• Be aware of risk of uterine rupture

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**B. PROCEDURE for IOL FOR GESTATION OF 26 WEEKS AND MORE (HIV POSITIVE WITH UNKNOWN VIRAL LOAD):**

**1.** If patient has been compliant on highly active anti-retroviral treatment for at least 4 weeks, the viral load can be regarded as low or negative and IOL done as above. Try and obtain the latest viral load result first.

**2.** If the viral load is high or suspected to be high, do IOL as follows:

- Do not rupture membranes unless delivery is inevitable
- Follow the same guidelines as for misoprostol or prepidil gel and balloon catheter
- If labour does not start after EASI and Oxytocin, do a Caesarean section for failed induction of labour (if maternal condition allows for anaesthetic).
- If maternal condition not favourable for anaesthetic (advanced HIV disease), do a sterile rupture of membranes and try and deliver baby as soon as possible to minimise risk of HIV transfer. (Discuss with consultant)

**C. PROCEDURE FOR HYPERSTIMULATION DURING AN IOL:**

**Be prepared for hypercontractility when using Oxytocin (4-12% of cases) or any Prostaglandins (up to 2% of cases):**

**Hypercontractility:**

- Tachysystole (6 or more contractions/10 min for 20 minutes) or
- Hypertonus (contraction lasting longer than 90s)
- Hyperstimulation syndrome: above together with abnormal CTG pattern

**If hyperstimulation syndrome develops\*:**

- Stop any uteronic agents (oxytocin administration etc.)
- Do intra-uterine resuscitation (turn mother on left side, give 40% O<sub>2</sub> with face mask / nasal prongs for no more than 30 minutes, give a 200 ml IV crystalloid fluid bolus)
- Suppress contractions with:
  - Salbutamol 250 µg SC or in 10 ml water, slowly IV or
  - Nifedipine 30 mg PO stat
 [Provided there are no contraindications to the specific drug] [Refer to PTL Protocol]
- If CTG persistently pathological or suspicious prepare for immediate delivery.

\*If hyperstimulation responds to tocolysis, wait 6 hours and start misoprostol again / wait 1 hour and start oxytocin again at lower dose

7

**D. PROCEDURE for IOL FOR GESTATION OF 26 WEEKS AND MORE WITH AN INTRA-UTERINE DEATH or SEVERE FETAL ANOMALY (NO FETAL MONITORING DONE)**

- Use the same protocol as for viable pregnancies, without the need for CTG monitoring

**NBI Note on vaginal vs. oral misoprostol:**  
Vaginal misoprostol is as effective as oral misoprostol for effecting delivering within 48 hours, with the disadvantage of repeated vaginal examinations needed.  
There were four fatal cases of clostridium sepsis reported in the literature; associated with vaginal misoprostol usage and it is probably safer to use oral misoprostol.

**E. PROCEDURE for IOL FOR GESTATION < 26 WEEKS WITH AN INTRA-UTERINE DEATH or SEVERE FETAL ANOMALY (NO FETAL MONITORING DONE) (no uterine scar)**

**1. Sure gestation of < 24 weeks**

- Oral misoprostol 200µg 2-hourly for 2 doses
- If no response then oral misoprostol 400µg 2-hourly for 2 doses (Maximum 1600 µg daily dose)

**2. Sure gestation of 24w0d - 25w6d**

- Oral misoprostol 100µg 2-hourly for 2 doses
- If no response then oral misoprostol 200µg 2-hourly for 2 doses (Maximum 800 µg daily dose)

**NBI** If no response to above induction regimes then ensure again that pregnancy is intrauterine.  
**NBI** Doses can be repeated after 24 hours. EASI can be done if no response on misoprostol.

**F. PROCEDURE for IOL FOR GESTATION < 26 WEEKS WITH AN INTRA-UTERINE DEATH or SEVERE FETAL ANOMALY (NO FETAL MONITORING DONE) (with a previous uterine scar)**

**3. Sure gestation of < 24 weeks**

- Oral misoprostol 100µg 2-hourly for 2 doses
- If no response then oral misoprostol 200µg 2-hourly for 2 doses (Maximum 800 µg daily dose)

**4. Sure gestation of 24w0d - 25w6d**

- Oral misoprostol 50µg 2-hourly for 2 doses
- If no response then oral misoprostol 100µg 2-hourly for 2 doses (Maximum 400 µg daily dose)

**NBI** If no response to above induction regimes then ensure again that pregnancy is intrauterine.  
**NBI** Doses can be repeated after 24 hours. EASI can be done if no response on misoprostol.

8

## Addendum 2

Audit tool for case note review- paper version.

<b>Folder Audit:</b>															
<b>Facility:</b> _____				<b>Month:</b> _____											
The audit is an assessment of the ADMISSION NOTES for the FIRST admission to the triage area of the hospital; regardless of whether the patient was admitted or not. This part of the audit is on the physical presence and content of the actual written notes, NOT on the quality of the notes. A standardised format of notes was used when notes contain in (some) order the history, physical findings, investigations, diagnosis, treatment and outcome. If any entry is only partial (e.g. syphilis status recorded but not Rhesus) or incomplete it is scored as "No (=0)".															
No.	INPATIENTS	X	OUTPATIENTS	Folder	Yes = 1 No = 0 N/A = not applicable								Comments		
Question / Aspect															
1	Admission notes signed and initials & surname written/printed in block letters (student/intern)														
2	Admission notes countersigned and initials & surname written/printed in block letters by a registered doctor														
3	The time and date when the notes were made are present														
4	A standardised format was used to record notes (see instructions)														
5	The bio-psychosocial history of the patient, including allergies and idiosyncrasies are clearly documented														
6	A brief obstetric history is documented.														
7	The patient's HIV status including CD 4 count, Viral Load and current medication is clearly stated														
8	Syphilis and Rhesus status is documented														
9	The current medication is correctly documented. (Not taking any medication = 1; On medication and documented = 1; Notes on meds omitted but patient on medication = 0)														
10	The observations (Blood pressure, pulse rate, respiratory rate and temperature) is documented.														
11	The clinical examination is documented.														
12	The abdominal examination is documented fully.														
13	An assessment of the patient's condition was made.														
14	The condition of the fetus was documented, including CTG where appropriate.														
15	A clinical risk assessment was done that included thrombo-embolic risk assessment.														
16	A proposed clinical management plan was formulated.														
17	Medicine administration chart in file														
18	Medications administered signed, dated & time recorded														
19	Dosage reflected														
20	Only authorized abbreviations used														
21	All records are legible														
Actual Score															
Maximum possible score ( Sum of all questions minus the not applicable responses)															
<b>Sum of actual score/Sum of possible score X 100</b>															
<b>Audit performed by:</b> _____ <b>Signature</b> _____ <b>Date:</b> <table border="1" style="display: inline-table; vertical-align: middle;"><tr><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td></tr></table>															

## Chapter 11

Medical liability in the Western Cape, South Africa: an analysis of public sector obstetrics and gynaecology professional liability claims from 1995-2014.

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## **Chapter 11. Medical liability in the Western Cape, South Africa: an analysis of public sector obstetrics and gynaecology professional liability claims from 1995-2014.**

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## 11.1 Introduction

There has been an exponential increase in medical negligence claims in South Africa in recent years, mirroring the same rise in developed countries in the past decades. Claims in South Africa increased by more than 130% since 2010 (1). Malherbe (2) speculates about the possible causes; these include a deterioration in professionalism, an increase in public awareness of access to justice, legal firms advertising in the lay media and technological advances in medicine; especially in neonatal care. The continuous advances in medical care have made the practice of obstetrics and neonatology much safer for the individual patient, but not for the obstetrician and his practice (3). Since 2014 there was a sharp increase in medical insurance costs for private practising obstetricians in South Africa, pressuring many to abandon term obstetrics in private practice (4)(5). The South African public sector hospitals offer state indemnity to employees, but there has been a parallel rise in malpractice claims against Provincial hospitals as well. Seggie (6) argues that the two main reasons for the sudden escalation in malpractice claims are changes in legislation and the current overcrowded-and-underfunded situation in state hospitals. The changes in the Road Accident Fund legislation made it a less lucrative source of income for lawyers; and the Contingency Fees Act allow attorneys to offer free legal assistance for cases that have a good chance of succeeding in court, only taking a percentage payment once pay-outs have been made.

Shwayder (7) highlights nine prime areas for obstetric litigation ranging from the antenatal period (errors or omission in antenatal screening and diagnosis, ultrasound diagnosis) to birth (neurologically impaired fetus, brachial plexus and other birth trauma). Junior doctors are at higher risk for claims. This last aspect is particularly important for South Africa; as adequate senior supervision is not always available after hours for trainees. Also, junior doctors in small district hospitals are frequently expected to manage emergency caesarean sections (CS) in the second stage of labour, vaginal birth after previous CS and complicated

vaginal birth without adequate training or supervision (8). The South African Constitution states that *everyone has the right to have access to health care services, including reproductive health care*, and obliges the State to *take reasonable legislative and other measures within its available resources to achieve the progressive realisation of this right* (9). The challenge of providing quality care in a resource-limited environment raises the question of whether a health care worker can be held accountable for an adverse outcome when there were system failures beyond his or her control. McQuoid-Mason (10) argues the potential liability in an actual case of uterine rupture where there was delays at all levels- ambulance transport, nurse shortage, delay on route to theatre and broken equipment, a very common South African scenario. Health care personnel can only be held liable if they intentionally or negligently caused a delay in administering care, but where that delay was caused by administrative factors within the ability (and budget) of health care managers to rectify they (the managers) could be held liable for failure to do so. In South African law, culpable homicide is the only common-law crime for which a negligent practitioner can be held liable. The proof of negligence (as opposed to intention) is sufficient, and conviction has already been made in a case of a general practitioner not calling for specialist help in a complicated delivery (11).

In an analysis of obstetrics and gynaecology liability claims from Barcelona, Spain the most frequently claimed event was obstetrics (33% of cases) whilst the majority of gynaecology cases were due to complications arising from hysterectomy and the treatment of gynaecological cancers (12). The authors concluded that particular events need special emphasis as it occurs frequently and is usually difficult to defend; these are retained foreign objects, tubal ligation, ultrasound diagnosis and neurologically impaired new-borns. Clark et al (13), in an analysis of 189 closed perinatal claims found that more than half of a hospital's litigation costs might be avoided if a delivery was conducted in a facility with 24-hour specialist obstetrician attendance; with adherence to well-structured protocols for

medication, careful management of labour in a previously scarred uterus standardised note-keeping for unexpected complications such as shoulder dystocia.

Analysis of closed liability claims can thus help to identify priority areas where intervention may help to reduce errors (14). In South African law a plaintiff has to file papers within three years of the alleged incident, otherwise the claim is extinguished by prescription. However, prescription does not run against minors, so a claim for the child's losses only prescribes three years after the minor turns 18. In the public sector the first defendant is the provincial government (usually the MEC for health), who is vicariously liable for his/her employees. The defendant then obtains expert opinion on the merits, based upon which it will determine together with the State Attorney and Counsel whether the case is worthy of financial settlement or whether it should be defended.

Not all medical errors amount to negligence, and identification of error is also used as an opportunity for education and prevention (15). Leape et al (16) classify medical errors into diagnostic (e.g. delay in making a diagnosis), treatment (e.g. errors during surgery), preventative (e.g. inadequate monitoring) and other, including communication and equipment failure.

The main objective of this chapter was to identify the common events or themes leading to medical malpractice litigation in the Western Cape Provincial health system, the contributing and avoidable factors as well as the relevant trends over the period. The ultimate aim is to learn how similar cases can be prevented and to make recommendations to improve patient safety.

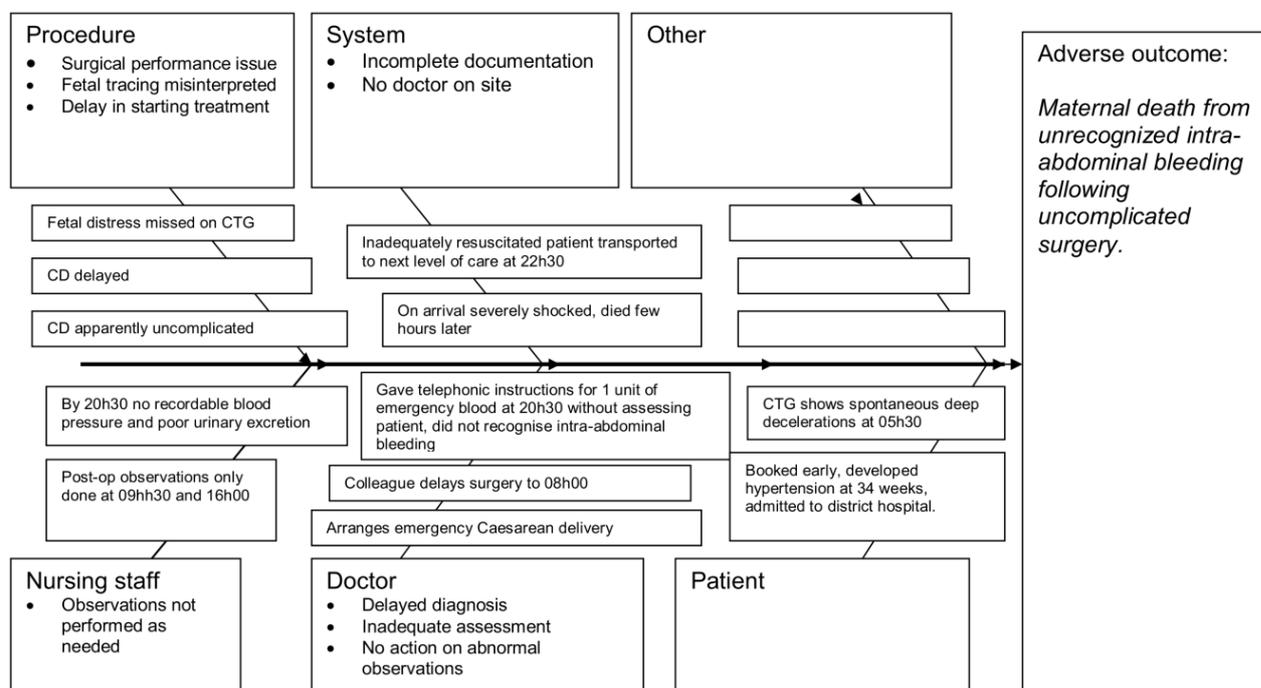
## 11.2 Methods

A retrospective analysis was conducted of 301 consecutive obstetrics and gynaecology-related files opened in the medico-legal unit of the Western Cape Department of Health from 1995 to 2014. Risk management files of cases without any legal consequence (cases that were reported proactively by hospital managers; but with no subsequent legal action on behalf of the patient) were included in the review.

Each file was scrutinised to identify the factors that may have been associated with the adverse outcome(s). A cause-and-effect analysis of each folder was done based on the methods as used previously by White (17)(18) and Pichert (19). Fishbone diagrams were constructed for each folder to portray the possible relationships between the adverse outcome and any contributing factors. A fishbone diagram, also known as a cause-and-effect diagram or Ishikawa diagram (after its inventor (20)) is a well-known visualization tool for categorising the potential causes of a problem in order to identify its root causes.

Adverse incident(s) were the main episode leading to the legal case. The adverse incidents were then clustered into main effects, the general category of the claim. As example, a case of neglected second stage of labour with no fetal monitoring (adverse incidents) leading to a claim for a neurologically damaged baby (the effect). The cluster of 'birth injuries' will include any of the following adverse incidents: failed vacuum, failed forceps, difficult instrumental delivery, Erb's palsy and accidental fetal injury during surgery. There may be overlap- e.g. 'shoulder impaction' can cause a birth injury or a neonatal death, and maternal sepsis can be classified under 'sepsis' or 'maternal death'. As deaths are investigated via a different process (maternal death usually go through a full inquest) these endpoints were clustered separately. An example of a fishbone analysis of the causes leading to an adverse effect (maternal death) as well as the contributing causes (see below) is shown in Figure 11.2.1.

Figure 11.2.1. An example of a fish-bone diagram for a hypothetical case of unrecognised intra-abdominal bleeding.



Folders reviewed individually may show discrete events where a health care worker made an unwitting medical error or where some random system error caused harm, but which are difficult to address outside the scope of standard morbidity and mortality review. To isolate the individual practice and system breakdowns at the root of the medical error, the data was aggregated into common contributing factors, as it may reveal opportunities for improvement at a higher or system level. These factors were roughly based on the Harvard Risk Management Foundation Malpractice Claims codes, a set of codes developed into proprietary codes by the Controlled Risk Insurance Company (CRICO), a recognized leader in evidenced-based risk management, a group of companies owned by and serving the Harvard medical community (21).

Diagnostic errors can be of three types: delayed diagnosis (enough information is available to make a diagnosis but it is inadvertently delayed), a wrong initial diagnosis or a missed

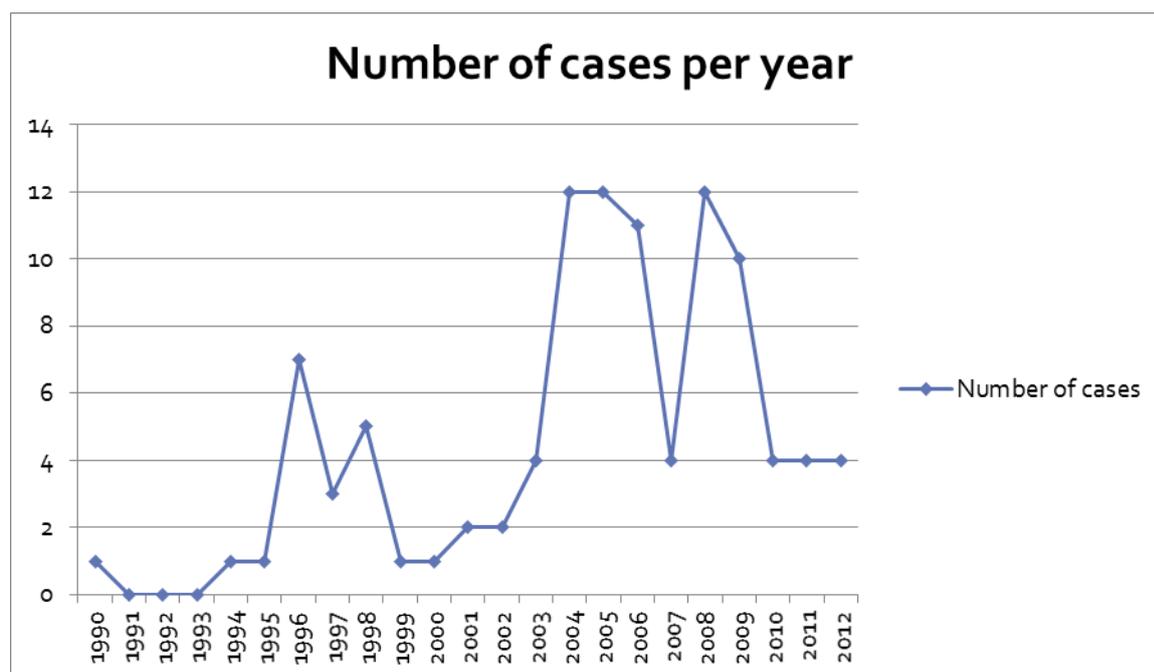
diagnosis (22). All cases where human errors in diagnosis contributed to the claim or event were coded accordingly. Any file where a failure or breakdown in continuation of care or handover contributed to the adverse outcome was coded as issues with 'continuity of care'.

Avoidable factors in medico-legal claims can have two implications. In morbidity or mortality reviews, avoidable factors are those that could have prevented the incident from arising in the first place; it is often divided in "probable" (most likely) or possible (less likely) factors. In medico-legal claims there are also the factors that may have disadvantaged successful defence of the case, e.g. poor quality clinical notes or missing fetal heart rate tracings, missing folders or incomplete documentation of vital signs. All possible avoidable factors were analysed and classified as above. Any patient identifiers were removed to preserve identity and the coded data was entered in a spreadsheet (Microsoft™ Excel 2013) and analysed with descriptive statistics (frequency counts and proportions).

## 11.3 Results

Obstetrics and gynaecology (O&G) amounted to 17% of the total claims managed by the medico-legal department within this timeframe. There were 301 O&G cases in the time period investigated, of which 221 (73.4%) were maternity related incidents and 80 (26.6%) gynaecology. Of the 221 maternal events, 36 (16.3%) took place during the antepartum period, 134 (60.6%) intrapartum and 51 (23.1%) directly after delivery. Not surprisingly, neonatal encephalopathy was the most important basis for litigation (16.2% of all cases, or 36.6% of all intrapartum events). Seventy-five claims were made for a total of R124 061 747. Of this, R71 174 939 was for claims related to neonatal encephalopathy. The increase in claims brought for intrapartum events is shown in Figure 11.3.1. The year in question refers to the year in which the baby was born, not the year in which the claim was made, therefore the time period includes babies born before 1995, and stops at 2012 as cases that were lodged after that are still open and not available for audit.

Figure 11.3.1. Number of claims for intrapartum events.



The causes as derived from the Fishbone analysis are listed in Table 11.3.1, as well as the main effects, which could be aggregated into 13 main categories. Not every individual adverse event is listed, but they were all taken into account for the analysis. The percentage of claims by effect (cause of action as set out in the Court papers) is depicted in Figure 11.3.2. There are two groups that dominate- surgical events (organ injury, failed procedures, retained foreign objects together) and death of the baby (each accounting for 21% of the allegations).

Figure 11.3.2. Percentage of claims by allegation type.

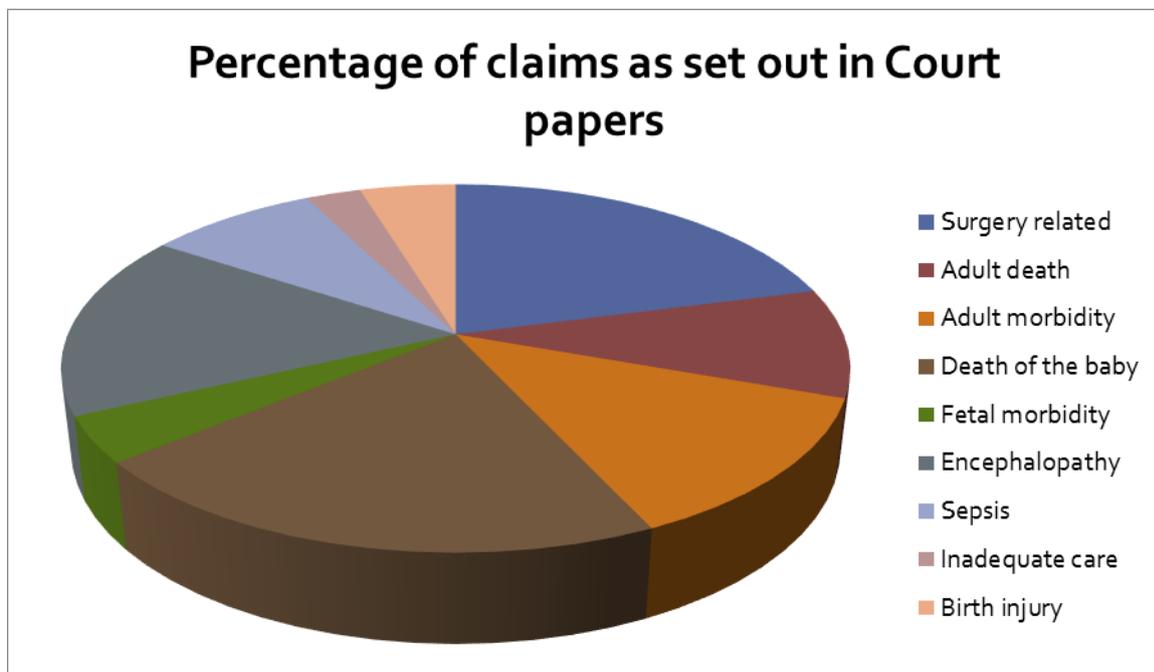


Table 11.3.1. Cause and main effect clusters

Main adverse incidents as reported in the clinical notes, court papers and expert witness reports.	Main effect cluster (general category of the claim or allegation)	Number of files (n=301)	Percentage of total files
Prolonged second stage, poor outcome following instrumental delivery, accidental intravenous infusion of milk, breech delivery with entrapment of head, post-maturity, fetal distress.	Neonatal encephalopathy	49	16.3%
Vesico-vaginal fistula following vacuum delivery, burn wounds due to fibre-optic cable or electro-cautery device, third degree tear, excessive blood loss during surgery, emotional distress, anaphylactic reaction to drugs, delay in transfer leading to complicated delivery,	Adult female morbidity or disease	38	12.6%
Rectum, colon, small bowel, bladder, ureter injury during surgery. Perforation of uterus.	Organ injury during surgery	32	10.6%
Undiagnosed second twin, prolonged labour, delay to theatre, undiagnosed maternal disease, inevitable miscarriage but baby of viable size at delivery, abruptio, fetal distress not acted on.	Intra uterine death	32	10.6%
Women turned away from hospital, no fetal monitor available, hypoglycaemia after delivery not adequately treated, shoulder impaction, defective incubator, administration of undiluted intravenous potassium, delay in finding doctor to do CD, unauthorised administration of oxytocin, death during inter-hospital transfer.	Neonatal death	31	10.3%
Severe pre-eclampsia, complications of spinal anaesthesia, collapse after drug administration, oesophageal intubation during anaesthesia, bowel injury during hysterectomy, retained swabs leading to sepsis, mother turned away from institution, too early extubation, delay in starting antibiotics for pelvic infection, air embolism during hysteroscopy,	Adult female death	29	9.6%
Failed sterilisation leading to unintended pregnancy	Failed sterilisation	19	6.3%
Sepsis following vaginal delivery, Caesarean delivery, evacuation of the uterus, perforation, retained products of conception.	Sepsis	25	8.3%
Failed vacuum, failed forceps, difficult instrumental delivery, shoulder impaction, Erb's palsy, fetal trauma during CD, failed vacuum, birth injuries, shoulder dystocia	Birth injury (live baby)	14	4.7%
Retained swabs in abdomen or vagina, retained instruments, retained drains.	Retained foreign object during surgery	12	4.0%
Meconium aspiration, burns from heating blanket, mother received experimental drugs as part of study and claimed not to be informed, depressed skull fracture following fundal pressure. Neonatal suppression due to maternal administration of opioids.	Neonatal morbidity	08	2.7%
Counselling inadequate, unprofessional conduct of doctor, issues with consent, failure to inform parents of a diagnosis of Down syndrome, women discharged only to deliver shortly thereafter at home, Alleged mismanagement.	Care inadequate	08	2.7%
Missed diagnosis of hydrocephalus, undiagnosed congenital abnormalities	Fetal disease	04	1.3%

A total of 80 contributing factors emerged from the folder review and are depicted in Tables 11.3.2 to 11.3.4. The contributing factors linking to any surgical or other intervention or

procedure were classified under 'procedure or intervention errors' and this encompassed all surgical interventions, partogram completion and interpretation and fetal monitoring (Table 11.3.2). The contributing human factor codes (classified as 'human errors') included doctors, nurses, the patient and aspects related to communication and diagnosis (Table 11.3.3). 'System' errors were grouped to include administrative issues, medication, equipment, transport, blood products and note keeping (Table 11.3.4).

Table 11.3.2. Contributing factors related to procedure or intervention error.

General category of contributing factors (as a percentage of the 301 folders)	Contributing factors, as coded	Number of occurrences*
Surgery (37%)	Organ injury	36
	Failure to achieve intended result	23
	Wrong procedure done	1
	Difficult procedure	29
	Excessive blood loss	3
	Prolonged surgery time	2
	Retained foreign object	12
	Surgical performance issue	6
Fetal Monitoring (15.9%)	No fetal monitoring documented	21
	Infrequent fetal monitoring	17
	Fetal tracing misinterpreted	4
	Fetal distress not recognised, fetus monitored	5
	Fetal distress not recognised, fetus not monitored	1
Second stage of labour (33.9%)	Failed instrumental delivery	5
	Instrumental delivery difficult	5
	Partogram not completed	20
	Incorrectly completed (misinterpretation)	22
	Abnormality on partogram not acted on	10
	Second stage prolonged	40
Care and treatment (36.5%)	Continuity of care	93
	Failure to monitor patient	11
	Premature discharge	4
	Inappropriate discharge	2
Medication error (4.3%)	Reaction to medicine	9
	Medication not given as prescribed	1
	Medication not available	1
	Wrong drug given	2

\*Most patients had more than one contributing cause, the total will be more than the number of case files.

Table 11.3.3. Contributing factors related to human error or omission.

General category of contributing factors	Contributing factors, as coded	Number of occurrences*
<b>Communication</b> (23.5%)	Between patient and caregiver	10
	Amongst caregivers	25
	Patient dissatisfaction only	27
	Abusive staff	4
	Consent not obtained (surgery performed without informed consent)	2
	Consent inadequate (surgical procedure deviated from that stated on the consent form)	3
<b>Diagnosis</b> (33.9%)	Missed diagnosis (High Risk patient not identified)	12
	Missed diagnosis (History overlooked)	
	Wrong initial diagnosis	1
	Delayed diagnosis	11
	Delayed diagnosis- failure to order test	76
	Delayed diagnosis- test results not checked	1
<b>Doctor</b> (24.9%)	Wrong therapy given	2
	Delay in starting treatment	9
	Choice of therapy inappropriate	2
	Inadequate assessment	53
	Inappropriate actions (e.g. fundal pushing)	4
	No action on abnormal observations	5
<b>Nursing</b> (5.3%)	Inadequate assessment	1
	Delay in starting treatment	1
	Choice of therapy inappropriate	1
	Inappropriate actions (e.g. fundal pushing)	4
	No action on abnormal observations	8
	Observations not performed as needed	1
<b>Patient</b> (4.3%)	Patient refused examination	1
	Patient refused fetal monitoring	1
	Restless during labour	1
	Did not initiate antenatal care	2
	Infrequent antenatal visits	1
	Did not follow instructions	1
	Did not return on prescribed date	3
	Refused hospital treatment	3
<b>Senior supervision</b> (2%)	Consultant refused to see patient.	1
	No senior doctor available	2
	Delay in obtaining consultant opinion	3

\*Most patients had more than one contributing cause, the total will be more than the number of case files.

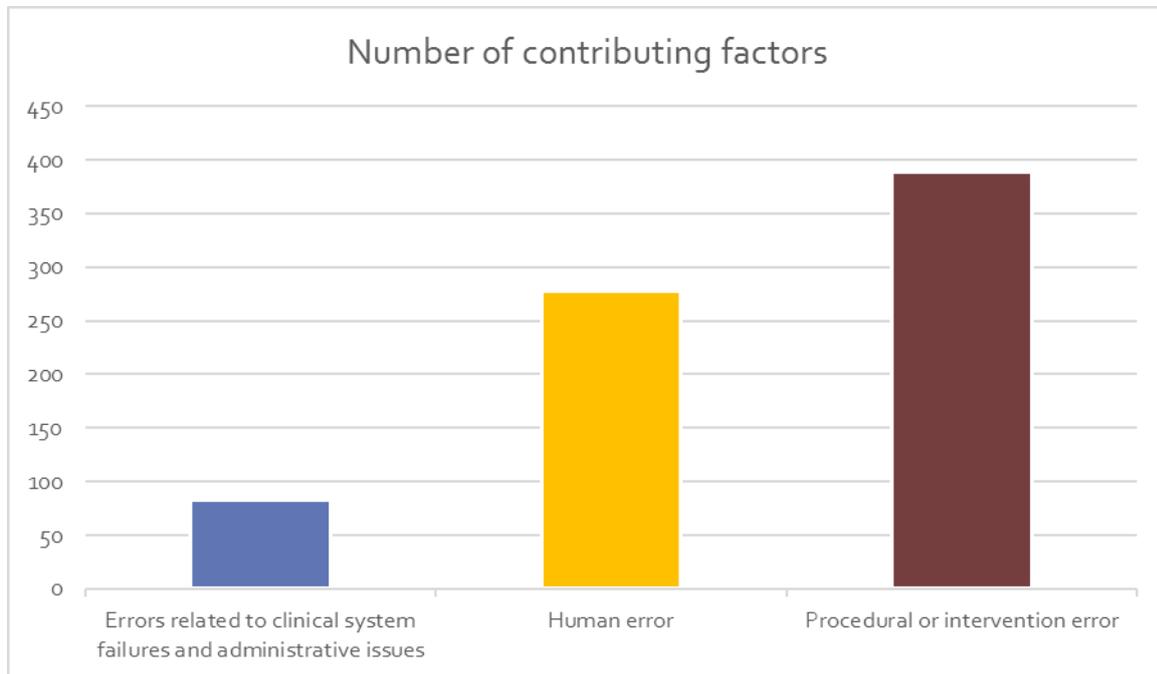
Table 11.3.4. Contributing factors related to clinical system failures and errors in administrative Issues

General category of contributing factors	Contributing factors, as coded	Number of occurrences*
<b>Documentation (12.3%)</b>	Insufficient documentation: failure to document adequate details	30
	Content related: Inconsistent documentation	6
	Content related: Discharge instructions inadequate	1
<b>Administration (8.9%)</b>	Management at incorrect level of care	7
	Patient refused entry into facility	2
	Failure to follow policy	3
	Lack of policy or protocol	1
	Inadequate staffing	1
	No bed available in institution	1
	No doctor on site	1
	Test results not available	1
	Cardiotocograph tracings not in folder	4
Insufficient documentation: Folder missing	6	
<b>Other (6.3%)</b>	Equipment failure	4
	Blood products not available	2
	Lack of transport between institutions	8
	Theatre not available (occupied)	5

\*Most patients had more than one contributing cause, the total will be more than the number of case files.

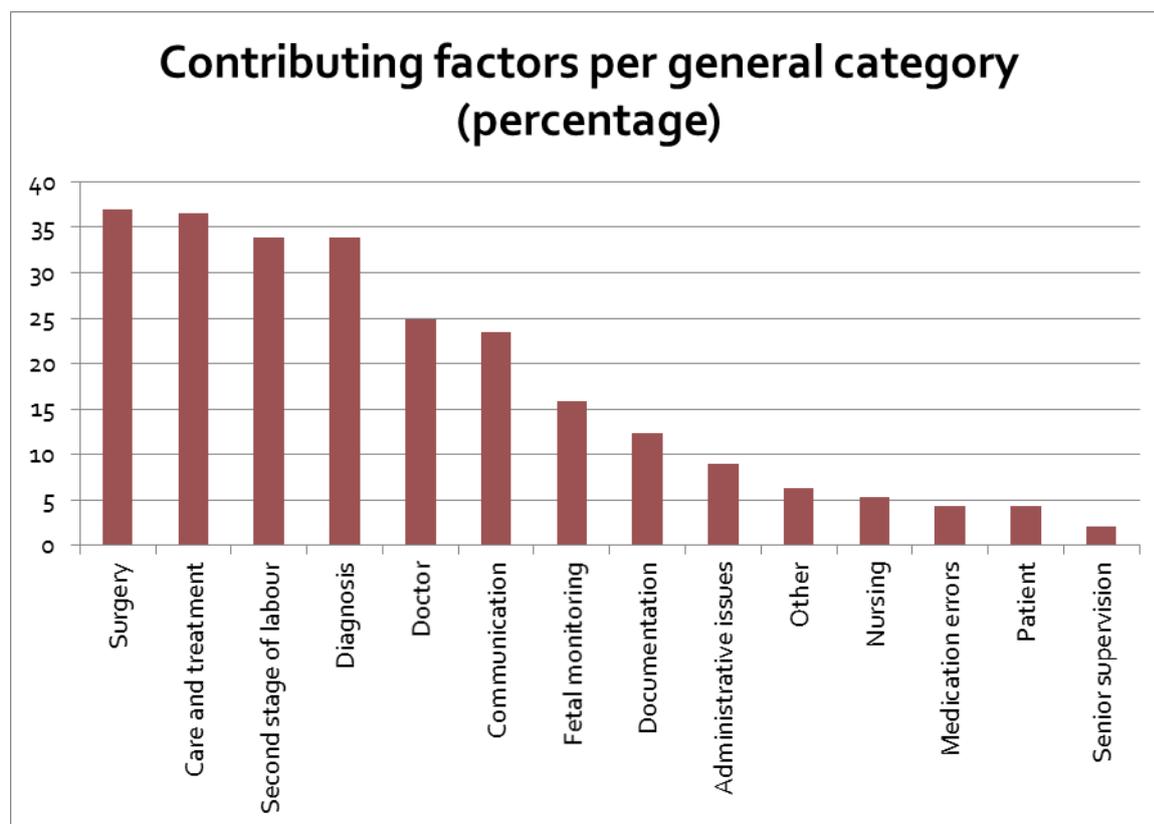
A schematic representation of the actual number of contributing factors in each general category of error is given in Figure 11.3.3.

Figure 11.3.3. General categories of errors and actual number of contributing factors in each category.



The contributing factors in each general category are shown in Figure 11.3.4, in decreasing order of occurrence.

Figure 11.3.4. Contributing factors per general category of error.



There may be more than one contributing factor per patient file, resulting in the total percentage being more than 100%. In almost a quarter of files assessed (23.5%) there was concerns detected with care and treatment, of which the most important was issues with continuity of care. Difficulties with diagnostic skills could be attributed to 33.9% of cases.

The 20 most important individual contributing factors are shown in Figure 11.3.5. The most important factor was a breakdown in the continuity of care. The three types of diagnostic errors are all amongst the uppermost 20 factors.

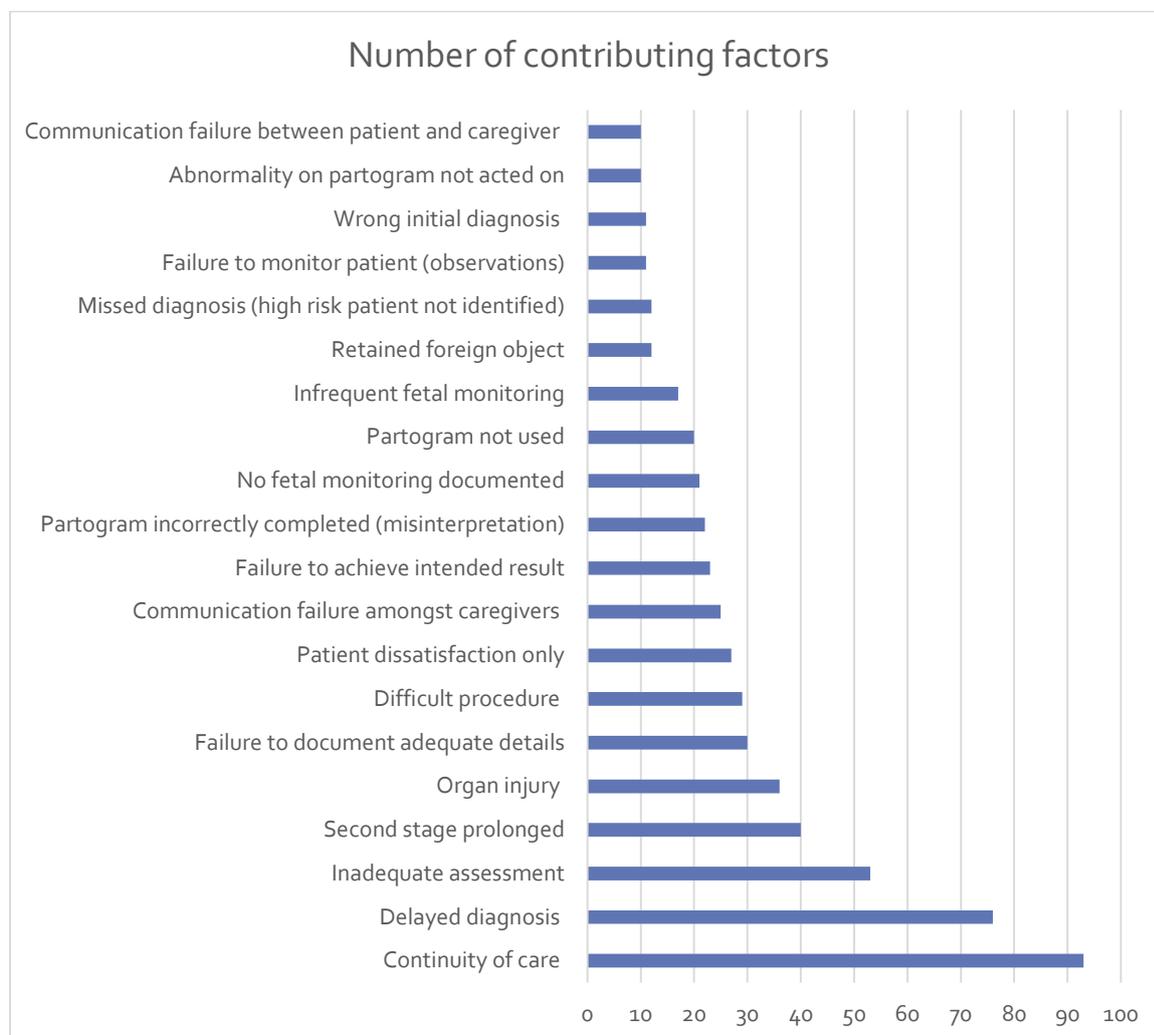
Surgical events leading to significant morbidity (excluding sepsis) accounted for 20.9% of files, and there were an additional eight surgical complications that lead to death; three of these during endoscopic procedures. A total of 27.6% of deaths were due to direct surgical

complications including anaesthetic complications and organ injury, but excluding sepsis that followed on surgery. Sepsis as the main event leading to a claim (8.3% of files) was classified separately, but more than 90% of the files opened with sepsis as the main allegation followed on surgery. There were two claims for sepsis after gynaecological surgery and one following vaginal delivery. All the rest (72% of sepsis claims) followed after routine CD.

Organ injury during gynaecological surgery (7.6% of all files) constituted bladder injury (30% of these cases, all during open procedures), bowel injury (30% of cases during open surgery, 15% during endoscopic procedures) and ureter (25%, all during open surgery). A further nine cases of organ injury occurred during CD (4 bowel, 4 bladder and 1 ureter injury). Retained foreign objects (3.9% of all files) was typically swabs left behind in the abdomen following open surgery (half of these cases), followed by vaginal swabs left behind after suturing tears or episiotomies.

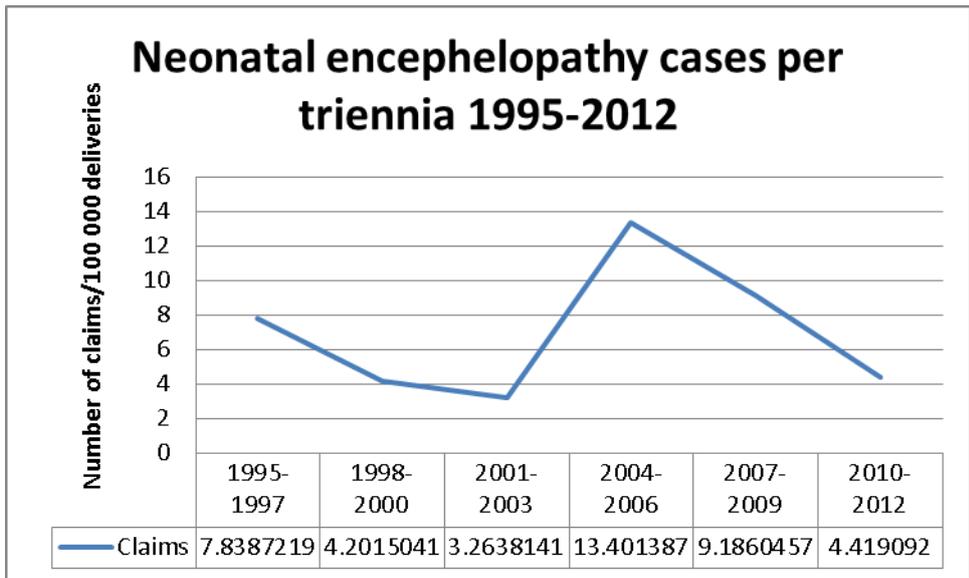
One failed sterilisation merits discussion- Mrs JE was sterilised by laparoscopic Fallope ring application in January 1999, completing the customary counselling and consent form stating the risk of failure of the procedure. She was pregnant in April 1999 and refused an offer for termination of pregnancy on religious grounds. At 37 weeks she was admitted with hypertension in pregnancy and induction of labour was started. A caesarean section for fetal distress followed, and the surgeon noted that the Fallope rings were applied on both round ligaments and that the tubes were still patent. She then sustained severe hypoxic brain injury following massive blood loss requiring repeated surgery for intra-abdominal bleeding due to diffuse intravascular clotting, caused most likely by amniotic fluid embolism (AFE).

Figure 11.3.5. Top 20 individual contributing factors.



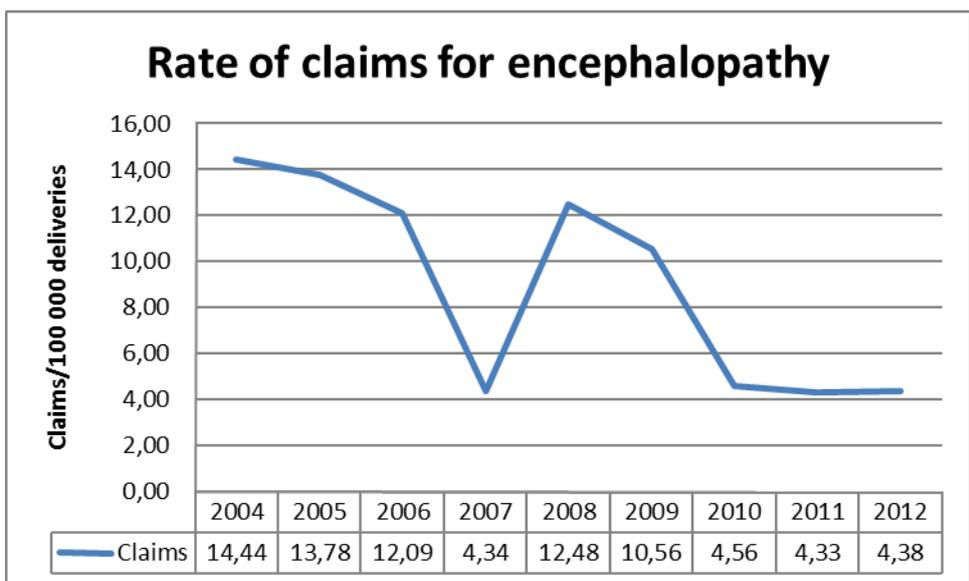
There were 1 520 506 deliveries in the Western Cape during 1995-2014. The rate of obstetric claims amounts to 2.36 claims per 100 000 deliveries for antepartum events, 8.81/100 000 for intra-partum events and 3.35/100 000 for postpartum events. For neonatal encephalopathy, as the numbers are smaller the number of claims were grouped in triennia from 1995-2012. The rate of claims per 100 000 deliveries for encephalopathy per triennia is shown in Figure 11.3.6.

Figure 11.3.6. Neonatal encephalopathy claims per triennia, 1995-2012.



The claims peaked in the 2004-2006 triennium. The annual claims for encephalopathy from 2004 to 2012 is shown in Figure 11.3.7. The rate has remained the same from 2010-2012.

Figure 11.3.7. The rate of claims for neonatal encephalopathy per 100 000 deliveries since 2004.



The Perinatal Problem Identification Program (PPIP) (23) is a classification tool for perinatal deaths; and all deaths are entered after a mortality review meeting. In the Western Cape alone, from 2000-2014, there were 418 stillbirths in the weight group >2500g and category 'stillbirth, alive on admission' where the cause of death was attributed to labour-related intrapartum asphyxia or birth trauma (Western Cape Provincial database; data extracted on 1 August 2015). For 59 of them, the most likely avoidable factor was attributed to problems with intrapartum fetal monitoring.

## 11.4 Discussion

This study has identified all the clinical and administrative system failures involved in liability claims in O&G in the Western Cape and defined shared features of factors contributing to the outcome. By far the largest number of claims as well as the vast majority of contributing factors relate to clinical management (surgery and management of the second stage dominates) and very few to administrative or supervisory aspects. The practice of O&G assumes that gynaecological pathology makes up half of all women seen, while in reality more than 75% of O&G visits in hospitals in the Western Cape are for obstetric-related conditions. The fact is that South Africa is now following the pattern of litigation in developed countries during the past decade.

Far too many cases involve birth-related injury. The definition for neonatal encephalopathy has changed over the years and differs between studies. Ideally only term babies (or birthweight >2500g) should be included in the denominator when calculating rates of encephalopathy, but this is not always feasible and the denominators used by various reported studies vary. In this review all claims made for a neurological injury that may have been related to intra-partum hypoxia was classified as neonatal encephalopathy. The incidence worldwide may be as high as 3/1000 live births but most of these babies die. It is estimated that about 30% of encephalopathy cases in developed countries will be related to intra-partum hypoxia and about 60% in developing countries (24). Modelling estimates of the incidence compared to observed values from studies place the incidence of encephalopathy in South Africa at 2.3/1000 live births, the same as for China and just lower than India (estimated at almost 2.9/1000) (25). In the Western Cape at least 4/100 000 births will lead to a claim for neonatal brain injury, which still is only a fraction of the number of babies born with this condition. It is suggested that the claim rate of 4-12/100 000 total births can be used as a benchmark for middle-income countries.

Emphasis should be on teaching the fundamentals of intrapartum obstetrics in training undergraduate and postgraduate nursing and medical programs. This critically important aspect of the discipline at postgraduate level is competing with minimal invasive surgery, newer technology, ultrasound, maternal medicine and prenatal diagnosis. A similar irony as was observed by Cohen and Schifrin in developed countries (26). Although encephalopathy cases and pay-outs dominate the media, there are a surprising number of other intrapartum related birth injuries, substandard management of instrumental deliveries recorded. Alleged negligence in the treatment of neonates also needs attention in training programmes. In 17% of South African community health clinics recently surveyed by Pattinson et al there was no ability to do basic bag-mask ventilation of a new-born infant (27).

Failed sterilisation is usually difficult to defend. There are more than 6500 sterilisations performed in the Western Cape every year. There is an accepted failure rate of 8 per 1000(28) worldwide and a first year failure rate of <5 per 1000 (29). No failure rates are available for the Western Cape. There were only 19 claims made over the 20 years of the study period. If one expects about 32 women with failed procedures every year, only 2.9% of them will instate legal action. The number of sterilisation failures (23.7% of all the gynaecology cases) is slightly higher than reported in the literature (19% of gynaecology cases in the UK) (30). No claim for wrongful birth has been made after a failed sterilisation. In most cases some compensation was made.

There are four possible mechanisms leading to a failed procedure: the procedure is done on the wrong structure, incomplete occlusion of the tubes, fistula formation in the tubes and spontaneous recanalisation. Only the last two are not due to the fault of the operator (31). Common sense dictates that failures within a few weeks or months after the procedure would be due to operator fault and that later pregnancies follow fistula formation or recanalisation. Varma and Gupta (32) supports the reasoning that negligent failures occur

significantly earlier than non-negligent failures. The mean intervals for negligent and non-negligent failure were 7.5 and 14.2 months, respectively.

The failed sterilisation procedure referred to earlier could not be defended, as the procedure was done on the wrong structure, thus the consent form and the clause relating to failure of the operation was not valid. However, the expert witness's statement that the rare occurrence of an AFE could not have been foreseen as a complication of failed sterilisation was not accepted. The Supreme Court of Appeal ruled that, as AFE is only associated with pregnancy, the damages caused was a direct result of the negligent sterilisation procedure and the case was settled for R4 700 000 in 2011. The implication of this judgement is that all inherent possible consequences (even as rare as AFE) of pregnancy should form part of the counselling of a woman during the pre-sterilisation consultation (and by implication any women counselled for pregnancy or termination of pregnancy).

The outcome of medico-legal cases can either be a negotiated settlement or the case can be defended. Some remain unresolved or inactive and some get withdrawn. The sterilisation case was the only case that went to court that was unsuccessfully defended.

Pearlman deliberates that patient safety must be a vital standard of O&G practice and that it is within the ability of obstetricians to control this and to position themselves as leaders in the patient safety movement (33). The best defence remains good contemporaneous note keeping (7), and to set the minimum standard for clinical notes in maternity care, a Western Cape policy document (developed by the author) was released in August 2015; adapted from and based on the NHS Clinical Record Keeping Policy, the Standards for the Clinical Structure and Content of Patient Records from the academy of Medical Royal Colleges (34) and the Generic Medical Record Keeping Standards of the Royal College of Physicians (35).

Like most interventions to promote patient safety, to demonstrate a positive change, it should be possible to measure the effect of the implementation (36). To this effect, a simple audit tool was developed to be used in conjunction with the policy; to get users to audit their own notes, or that of their peers, in an effort to improve the quality of note keeping. It also forms part of the proposed dashboard for Tygerberg hospital (see chapter 12).

In the tiered system of maternity care in the Western Cape, a pregnant woman moves between clinics and hospitals depending on the severity of her clinical condition, and it is unlikely that she will see the same health care provider with every visit. Once she needs admission in a large hospital, multiple health professionals or teams working in shifts contribute to the care of a single patient. A shift system of working hours in high-volume emergency centres improves patient flow whilst still allowing for reasonable working conditions, but has challenges with the continuity of information. In many of the smaller district hospitals there is not a dedicated doctor on the premises, but on call from home or the emergency centre. To ensure continuity of care, there must be a safe transfer of information and accountability between health care professionals, during which sufficient and relevant information should be exchanged to ensure patient safety; and for which very specific criteria and responsibilities have to be set.

Clinical guidelines are essential and should set the standard for high-quality evidence-based health care, and there are many published interventions to support putting it into practice. However, systematic reviews have not been able to show dramatic changes after implementation, but it may be feasible in many settings (37). Training opportunities should emphasise how to apply guidelines and protocols to clinical practice (38) and audits of adherence and compliance to protocols should be conducted at regular intervals (see Chapter 10). The ongoing ESMOE (Essential Steps in the Management of Obstetric Emergencies) skills training in South Africa may help improve care. The number of adverse

events that eventually lead to a claim is currently just the tip of the iceberg. We should move from learning from our mistakes to avoiding them.

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## Chapter 12.

Discussion: clinical indicators for a local maternity dashboard.

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## **Chapter 12. Discussion: clinical indicators for a local maternity dashboard**

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This thesis described shifts in maternity services in a specific geographical area in the greater Cape Town metropolitan city and the impact it had on the central hospital as well as with its relation to the district it serves. The maternity service at Tygerberg hospital is large and overburdened, like most of the obstetric services in SA and it is important to try and maintain a service with high quality and safety standards. Clinical performance and governance can be represented visually with a score card, the so-called *Maternity Dashboard* (1). This gives a visual overview of the implementation of clinical governance as it happens; it is easy to understand and has been shown to be beneficial in monitoring the performance of maternity units (2). The dashboard can help a hospital to find areas of good clinical practice and to identify those areas that need improvement (3).

The most common indicators used in maternity care are listed in Table 12.1.1. It includes process indicators (to measure how the system works) and outcome indicators that measures the final result.

Table 12.1.1. The most common indicators used in maternity care that can be included in a maternity dashboard.

<b>Process and outcome indicators for maternity care</b>
<b>Number of neonates born after 20 weeks' gestation</b>
<b>Number of women who gave birth</b>
<b>Percentage of women who gave birth preterm (i.e. before 37 weeks' gestation)</b>
<b>Percentage of women who died</b>
<b>Caesarean section rate</b>
<b>Assisted delivery rate</b>
<b>Percentage of women with a third- or fourth-degree perineal tear</b>
<b>Percentage of women who had a postpartum haemorrhage &gt;500 mL</b>
<b>Percentage of women with eclampsia</b>
<b>Percentage of neonates with an Apgar score &lt;7</b>
<b>Percentage of neonates admitted to the special care baby unit</b>
<b>Total stillbirth rate</b>

<b>Fresh stillbirth rate</b>
<b>Macerated stillbirth rate</b>
<b>Perinatal mortality rate</b>

Introducing maternity dashboards into a low-resource setting in a neighbouring country (Zimbabwe) has proven to be feasible and resulted in local actions that improved the quality of health care (4). Although the dashboard can be adapted to the local setting, the challenge remains to refine the instrument to the minimum set of indicators that generate the maximum amount of information, whilst still being easy to collect from routinely available data.

Boulkedid et al used a Delphi survey technique to narrow down selected indicators that reflect on quality of obstetric care to a list of 18 (5). Of those, 3 are not applicable to the public sector of South Africa (routine nuchal translucency screening, three-marker biochemical screening in the first trimester and vaginal screening for group B haemolytic streptococcus). Two more are only applicable to low-risk women and will therefore not be relevant to Tygerberg hospital (it measures the term singleton vertex CS rate in low risk women). Of the remaining 13, indicators relating to perineal trauma (third or fourth degree tears and number of women with intact perineum) will be difficult to measure in Tygerberg as there is not currently a reporting system for perineal tears. A third degree tear is also a criterion for referral to a specialist, so all serious perineal damage from the referral hospitals will be included in the hospital theatre statistics and therefore that will not be reliable to use as an indicator specific to Tygerberg hospital injuries.

A similar Delphi process of elimination was used by Sibanda and colleagues who started with a list of 290 indicators and rationalised it to 12 core quality indicators (6). Their final set of indicators is shown in Table 12.1.2 and is not much different to those shown in Table 12.1.1.

Table 12.1.2. Intrapartum care quality indicators from a systematic consensus approach (6).

Quality indicator	Definition
<b>Births</b>	Numbers of babies born and women delivered
<b>Induction of labour</b>	Women with induced labour
<b>Multiple births</b>	Women with multiple births
<b>Preterm births</b>	Women delivered $\leq 37$ and $\geq 34$ weeks
<b>Caesarean sections</b>	CS rate according to Robson.
<b>Instrumental vaginal deliveries</b>	Instrumental vaginal delivery rate
<b>ICU admissions from obstetrics</b>	Women admitted to ICU from obstetrics
<b>3rd &amp; 4th degree tears</b>	3rd or 4th degree tears following vaginal delivery
<b>APGAR scores</b>	Term babies with 5 min APGAR scores $< 7$
<b>Postpartum haemorrhage <math>\geq 1000</math> ml</b>	Mothers with primary PPH $> 1000$ ml
<b>NICU admissions at term</b>	NICU admissions at term $\geq 37$ weeks
<b>Stillbirths</b>	Total stillbirths

This information was used to adapt the prototype RCOG maternity dashboard so that it can be applicable to the clinical circumstances at Tygerberg hospital (1). Indicators were chosen to reflect aspects of activity, staffing, clinical outcome, safety and risk management. Indicators that is routinely collected or easy to obtain was given preference to ensure effective completion.

The proposed dashboard is shown in Table 12.1.3. It is in Excel format and the dashboard itself is colour coded with conditional formatting to automatically generate *green* when the goal is attained, *yellow* when it is slightly off target and *red* when it should be flagged for action.

The following indicators were chosen for inclusion:

- Measures of activity (data obtained from the perinatal and functional business unit database):
  - Number of births
  - Number of CS
  - CS rate
  - Number of vacuum deliveries
  - Number of forceps deliveries
  - Head count of all high risk clinic visits
- Staffing (data obtained from duty rosters and off-duty sheets)
  - Number of midwives per shift as a ratio to the number of births per month
  - Number of doctors per shift as a ratio to the number of births per month
- Clinical indicators:
  - Maternal morbidity (data obtained from ongoing severe acute maternal morbidity (SAMM) audits using the WHO SAMM criteria (7)):
    - Admissions to critical care
    - Massive blood transfusion ( $\geq 5$  units of red cells)
    - Post-partum hysterectomies
    - Uncontrolled eclampsia
    - Platelets  $< 50\ 000$
- Neonatal morbidity (data obtained from the routinely collected perinatal (PPIP) data)
  - Number of deliveries referred for head cooling (hospital data)
  - Antepartum stillbirths
  - Intrapartum stillbirths
  - Early neonatal deaths
  - Number of births with 5 minute Apgar  $< 7$  (8)
  - Perinatal mortality rate
- Risk management
  - Number of Surgical Site Infections (SSI data are collected routinely by the unit for infection control)
  - Audit of doctor's notes (see chapter 7)
  - Adherence to protocol audit (see chapter 10)
  - Bed occupancy in the maternity centre (routine hospital data)
- Patient and provider satisfaction
  - Number of formal complaints managed (obtained from the hospital quality assurance office)
  - Patient satisfaction survey
  - Staff satisfaction survey
  - Number of epidurals performed (a dedicated anaesthetist provides pain management during office hours in the labour ward)

The goals were set using the available data from 2014 and 2015 to obtain average numbers wherever possible. There are no formal staffing norms available for midwives (professional nurses) working in regional or tertiary hospitals in SA. Pattinson argues that nursing care of any woman in labour should be the same as in a high care setting, as woman can only be called truly low risk about 72 hours after delivery (9). This implies one-on-one nursing or at least one midwife per 2 women in a labour ward. One-to-one care during labour is recommended by the National Institute of Health and Clinical Excellence (NICE) (10).

The average length of stay for any women in the 19-bed Tygerberg hospital labour ward is currently 24 hours (obtained from routine hospital data). The labour ward is a high care setting (specialist referral centre) and not all women who are managed here will deliver during their first stay. With 19 beds and an average stay of 24 hours, 570 women (19 x 30) could be managed in a month with 100% bed occupancy (or 6840 per year). This is just lower than the current number of deliveries per year, as bed occupancy is >100% for many days per month. With one-on-one nursing, which is not affordable in SA, 19 professional nurses are needed per shift.

To provide one midwife on the floor for 24 hours per day, 5 posts need to be filled in order to cover the day and night shifts as well as leave requirements. This means 95 professional nurse posts must be allocated to the Tygerberg hospital labour ward (5x19). The current reality is 38 funded posts. With additional overtime and agency staff added, it is currently possible to provide 10 professional nurses per day shift and 10 per night shift (one professional nurse for every 2 women admitted). This was taken as the minimum acceptable standard to calculate a midwife/birth ratio for the dashboard. With this allocation, each midwife conducts 350 deliveries per year, which is double the minimum number recommended by the WHO to ensure cost-effectiveness (11). The current ratio is therefore about 29 births per midwife per month.

The midwife:birth ratio (MBR) could then be calculated as follows:

MBR= [number of midwives working per 24 hour day for one calendar month/number of days per month]: number of births per month.

The suggested norm is 20:600 (or 1:30). A number of <1:30 would be regarded as a red flag.

This is not as sophisticated as the calculations contained in the Birthrate Plus™ midwife staffing system in use in the UK (12), which recommends 38 births per whole time equivalent midwife for a tertiary level service.

Table 12.1.3. A maternity dashboard adapted for Tygerberg hospital.

0		Goal	Red Flag	Measurement	Data source	
Activity	Delivery	Births	<650 per month	>700	Births	PIPI
		Caesarean sections	<350 per month	>400	CS	PIPI
		CS Rate	<47%	>50%	CS	PIPI
		Vaccuum deliveries	80	<60	Vaccuum deliveries	PIPI
		Forceps deliveries	20	<10	Forceps deliveries	PIPI
	High risk clinic visits	4000 per month	>4300	Head count	FBU	
Workforce	Staffing	Midwife/birth ratio	1:30	<1:30	Midwives per shift:births per shift	Off duty sheets
		Doctor/birth ratio	1:150	<1:150	FTE doctors per shift:births per shift	Duty rosters
Clinical indicators	Maternal morbidity	Admissions to critical care	<270 per month	>300/month	admissions	OCCU
		Massive blood transfusion	<10	>12	Nr of patients	Blood bank
		Post Partum hysterectomies	<8	>12	Nr of patients	Theater register
		Uncontrolled eclampsia	<5	>8	Nr of patients	SAMM
		HELLP syndrome	<10	>12	Nr of patients	SAMM
	Neonatal morbidity	Number of deliveries referred for head cooling	<8	>10	Nr of patients	HIE meeting
		Antepartum stillbirths	<60	>70	Stillbirths, dead on arrival	PIPI
		Intrapartum stillbirths	<10	>15	Stillbirths, alive on arrival	PIPI
		Early neonatal deaths	<8	>10	Death register	PIPI
		Number of births with 5 minute Apgar <5	<15	>20	Apgar scores	PIPI
		Perinatal mortality rate	<22/1000 (>1000g)	>30/1000		PIPI
	Risk management	Number of Surgical Site Infections	<5 per month		Nr of patients	SSI data
		Audit of doctor's notes	>80% compliance to standard	<70% compliance		Audit
		Adherence to protocol audit	100% adherence to protocol audited	<80%		Audit
		Bed occupancy maternity	<90%	>100%		Hospital data
	Patient and provider satisfaction	Number of formal complaints managed	<5	>8	Number	QA office
		Patient satisfaction survey	>85%	<80%		Code of conduct questionnaire
		Staff satisfaction survey	>85%	<80%		Code of conduct questionnaire
		Number of epidurals performed	25 per week	<22	Nr of patients	Epidural register

- CS Caesarean section
- PIPI Perinatal Problem Identification programme
- FBU Functional business unit
- OCCU Obstetrical critical care unit
- SAMM Sever Acute Maternal Morbidity
- HIE Hypoxic ischaemic encephalopathy
- SSI Surgical site infections
- QA Quality assurance
- HELLP Haemolysis, low platelets, elevated liver enzymes

The dashboard will be implemented from January 2016 for a trial period of one year. There are two existing monthly meetings where the red flags will be discussed, namely a quality assurance meeting with all nursing unit managers and a monthly functional business unit meeting with the medical managers. The use and value of the dashboard as an instrument to monitor and potentially improve the quality of care in this setting will be the subject of a new prospective study.

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