

Obstetric outcomes of grand multiparous women in Soweto

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Witwatersrand, in partial fulfilment of the requirements for the degree of Master of Medicine
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DECLARATION

I, Shastra Bhoora, declare that this research report is my own work.

It is being submitted to the Faculty of Health Sciences for the degree of Master of Medicine in Obstetrics and Gynaecology, at the University of the Witwatersrand, Johannesburg.

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

28 October, 2014

DEDICATION

I dedicate this research report to grand multiparous women around the world. May their choices always be respected and may the health system never fail them.

PRESENTATION ARISING FROM THIS STUDY

09-Mar-2012	31 st Perinatal Priorities Conference in South Africa Session 8: Better care for labour and delivery	Protea Hotel Kruger Gate, Mpumalanga
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ABSTRACT

Background

Grand multiparous women, defined as women who have had five or more deliveries, have historically been considered to be at risk for maternal and fetal complications. Over the years, these complications have been attributed to physiological changes as a result of high parity, maternal age, age-related medical conditions and socioeconomic status. Recent research has indicated a strong relationship between access to health care, especially in the antenatal phase, and outcomes.

This work aimed to describe maternal, obstetric and fetal complications occurring in GM women, to determine their attendance at antenatal clinic, to review their modes of delivery and to identify any demographic characteristics related to GMP.

Methods

This was a prospective, descriptive study undertaken at Chris Hani Baragwanath Academic Hospital, a tertiary and regional hospital situated in Soweto that serves approximately two million people within its jurisdiction. In excess of 23 000 deliveries take place there each year. The labour ward attends mostly to high-risk women and approximately 20% low-risk walk-ins. Another 10 000 births are conducted at midwife obstetric units in Soweto. This study surveyed a sample of pregnant women presenting at Chris Hani Baragwanath and the referring midwife obstetric units who had had five or more viable deliveries, including the current birth, and was conducted over four months in 2011.

Results

A total of 122 women were included with 124 deliveries as there were two twin pregnancies. Detailed data were available for 98 of these women. The study group were largely of advanced maternal age and were generally healthy. The attendance rate at antenatal care was high (91.35%). Antepartum and postpartum complications were infrequent and there were no intensive care unit admissions or maternal deaths. The CS rate was high (32.79%), with more emergency CSs performed than elective CSs. The majority of the emergency CSs performed was as a result of fetal distress. There were four stillbirths (3.23%), and 25 (20.16%) of infants weighed <2500g at birth.

Conclusion

This study showed good maternal and fetal outcomes in a group of GM women who have access to and who largely attended antenatal care facilities. The results, albeit from a small sample, do not support traditional views that GM women are at risk of poor outcomes due to advanced maternal age, physiological changes as a result of high parity or low socioeconomic status. GM women who are generally healthy and are afforded access to adequate health care facilities should have good pregnancy outcomes.

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List of Abbreviations

Abbreviations	
ANC	Antenatal clinic
APH	Antepartum haemorrhage
BBA	Born before arrival
CHBAH	Chris Hani Baragwanath Academic Hospital
CS	Caesarean section
DM	Diabetes mellitus
GM	Grand multiparous
GMP	Grand multiparity
HIV	Human immunodeficiency virus
HPT	Hypertension
IOL	Induction of labour
IUFD	Intra-uterine fetal death
LBWR	Low birth weight rate
MOU	Midwife obstetric unit
MSL	Meconium stained liquor
NVD	Normal vaginal delivery
PE	Pre-eclampsia
PG	Prostaglandins
PPH	Postpartum haemorrhage
RPOC	Retained products of conception
UAE	United Arab Emirates
VBAC	Vaginal birth after caesarean section

Definitions of Medical Terms

Anaemia	Haemoglobin <11.0g/dL
Bronchopulmonary dysplasia	Chronic lung disorder most common among children born prematurely
Gestational diabetes mellitus	DM first recognised in pregnancy
Grand multiparity	Five or more completed pregnancies reaching gestational viability (≥ 26 weeks)
Great grand multiparity	Ten or more completed pregnancies reaching gestational viability (≥ 26 weeks)
Gestational hypertension	Development of hypertension after 20 weeks gestation without the presence of proteinuria
Intraventricular haemorrhage	Bleeding into the brain's ventricular system, commonly occurring in preterm infants
Low birth weight	Birth weight <2500 g
Macrosomia	Birth weight ≥ 4000 g
Maternal mortality ratio	Number of maternal deaths divided by all live births over a given period. This is expressed as a ratio of deaths per 100 000 live births
Multiparity	Two to four pregnancies
Perinatal mortality rate	Number of stillbirths and number of early neonatal deaths divided by all births over a given period. This is expressed as a proportion per 1000
Post dates	Pregnancy with gestational age ≥ 41 weeks
PPH	Blood loss ≥ 500 mL at NVD or ≥ 1000 mL at CS
Pre-eclampsia	Development of hypertension and significant proteinuria after 20 weeks gestation
Preterm labour	Labour before 37 completed weeks
Primiparity	One completed pregnancy reaching gestational viability
Unbooked	No attendance at antenatal clinic
Uterine hypertonus	Single contraction lasting longer than two minutes
Uterine rupture	Disruption of the pregnant uterine serosa, the bladder or the broad ligament
Uterine tachysystole	Six contractions in a 10-minute period
Very low birth weight	Birth weight <1500 g

1 INTRODUCTION

“While it is difficult to define the grand multipara precisely, she may be described as an obese, overtired, hypertensive woman with poor muscle tone and a tendency towards anaemia – a woman that is borne more than her share of children” Oxorn (1). This was the view in 1955 and since then this opinion has changed little.

Prior to 1960 GMP was considered to be eight or more deliveries (2). In 1993 the International Federation of Gynaecology and Obstetrics (FIGO) defined GMP as five or more deliveries. The South African textbook of Clinical Obstetrics supports the description that GMP is defined as five or more pregnancies that have reached viability (3). Great grand multiparity is currently defined as 10 or more deliveries (4). The more recent definition of GMP to start from parity five is because the risk for obstetrical complications, neonatal morbidity and perinatal death increases markedly at a parity ≥ 5 (5, 6, 7).

2 LITERATURE REVIEW

Bethel Solomons (5) described a woman who had more than one delivery as the ‘Dangerous Multipara’, a view in which every multiparous woman faced different risks compared with the very first pregnancy. In his 1934 article, he regarded multiparous women with great respect and caution, and emphasised that ‘it was a mistake to suppose that in child bearing, practice makes perfect’. He believed that the grand multipara was a ‘more skilled housekeeper and that she knew the weaknesses of her husband and was the mother to more than one child and could not be replaced.’ This study and his findings have been referenced in the large body of research concerning GMP.

Solomons (5) found an alarming 34 maternal deaths and 10 cases of uterine rupture among multiparous women that occurred at the Rotunda Hospital in Dublin over a four-year period. He showed that more multiparous women died than primiparous women and that the rate of mortality ‘increased steadily and speedily’ from the fifth pregnancy. These deaths were assigned to complications that arose mainly during delivery. He concluded that multiparous women were at higher risk as a result of the thinning uterus and increasing size of the baby with consecutive pregnancies, which predisposed them to haemorrhage resulting from uterine rupture (5). The findings of this work engraved a clear message that multiparity was to be feared and treated with great attention and appreciation.

A systematic review on GMP was carried out in Belgium by Yves et al (2) and is referenced widely by authors who have conducted studies about GMP since the review’s publication. The review, which is the only one of its kind, considered 19 studies on GMP and four on great grand multiparity over a 44-year period from 1960 – 2004. Yves et al noticed a decline

in the incidence of GMP and a general improvement in clinical outcomes over the 44-year period.

2.1 Socio-demographics and geography

There has been much debate and discussion as to whether GM women and their babies experience more or less complications during pregnancy and labour (2). Many articles have been published about GMP and often the results contradict each other, especially when they are set in developed versus developing countries.

In developed countries there has been a decline in GMP, but in many developing countries GMP is still prevalent (6). Developed countries have a lower prevalence of GMP (3-4% of all births) compared to developing countries as a result of better access to contraception, antenatal care, skilful medical practitioners and adequate facilities that allow safe delivery (7). There are certain developed countries, however, that still experience a high incidence of GMP, owing to religious and cultural beliefs that consider contraception as taboo. Orthodox Jews are such an example, where in order to fulfil an Old Testament prescript (to 'be fruitful, multiply and fill the land'), contraception is not utilised and high parity is prevalent (8). Another example is the UAE where the government has a pronatalist policy, and offers economic benefits to large families and thereby encourages GMP (9). Women marry at an early age because of traditional, religious and cultural reasons. Many Emirati women under 35 years are reproductively active from as early as their mid-teens and throughout their reproductive years (9).

In developing countries GMP is still common owing to sociocultural factors, illiteracy, scarcity of family planning services, inadequate health facilities and high perinatal and infant mortality, the latter leading to a wish to replace lost children (2, 10, 11).

Studies in developed countries have typically shown good outcomes for both the mother and child while studies in developing countries have shown less positive outcomes. Of the studies reviewed for this research, 22 commented on the outcomes of GMP as summarised in table 2.1. Fourteen were set in developed countries and eight in developing countries. Of the 14 set in developed countries, eight reported positive outcomes. This is reversed in the studies set in developing countries, with only three reporting positive outcomes and five reporting negative outcomes of GMP.

Table 2.1 Summary of the 22 studies reviewed

Author (Reference)	Publication Year	Developed or developing country	Author's Conclusion
Baskett (12)	1977	Developed	GMP associated with an increase in APH, HPT and malpresentation
Al-Sibai (13)	1987	Developing	More than parity, age and overall-condition determine the prognosis
Fayed (14)	1993	Developing	Extreme GMP does not carry any added risks in a high socioeconomic state that offers a high standard of antenatal care
Hughes (9)	1994	Developed	GMP per se is not necessarily a major risk factor for either mother or fetus
Toohey (15)	1994	Developed	GM women do not have an increased risk of intrapartum complications
Goldman (6)	1995	Developed	GMP may pose an obstetric risk factor which necessitates excellent antenatal care
Kaplan(8)	1995	Developed	Women capable of entering their 10 th delivery are basically healthy. If offered adequate care, not high risk.
Babinzki (16)	1999	Developed	High parity should not be considered dangerous under satisfactory socioeconomic and healthcare conditions
Bai (17)	2002	Developed	Obstetric risks, neonatal morbidity and perinatal death increase with markedly from para 4
Bugg (18)	2002	Developed	In a developed country with satisfactory health care, GMP should not be considered dangerous.
Roman (19)	2004	Developed	Grand multipara appear to have fewer intrapartum complications; However, they present several prenatal risk factors
Simonsen (20)	2005	Developed	Young grand and great GM women are not at increased risk
Benecke (21)	2005	Developing	Provided adequate health care exists, there should be no difference between GM and multiparous patients
Nordin (22)	2006	Developed	The maternal fetal outcome of GM women is good and comparable to multiparous women
Severenski (4)	2009	Developed	GMP was associated with low socioeconomic status and poor prenatal care
Akwuruoha (23)	2009	Developing	GMP is associated with increased obstetric risks and adverse perinatal outcomes independent of maternal age.
Fadeev(24)	2010	Developed	Among older great GM women, maternal and neonatal outcomes are good when compared to women of lesser parity
Omole-Ohonsi (11)	2011	Developing	GMP still presents with risks in pregnancy. These risks can be minimized with adequate care.
Agrawal (10)	2011	Developing	GMP continues to be a grave concern with an adverse impact on obstetric and perinatal outcomes.
Vaswani (25)	2013	Developed	Different parities were at risk for different complications.
Afolabi (26)	2013	Developing	GMP still presents with risks in pregnancy. These risks can be minimized with adequate care.
Mgaya (7)	2013	Developing	GMP still presents with risks in pregnancy. These risks can be minimized with adequate care.

In Nigerian work from Aba, Akwuruoha et al (23) in 2009 described three maternal deaths of GM women that were unbooked and failed to arrive at the hospital timeously because of extreme distance. Two women died from PPH secondary to ruptured uteri after delivering at their homes and the third woman died from a septic uterus following an IUFD for more than three days. The perinatal mortality rate was also high. Twenty seven (43.6%) of the perinatal mortalities occurred in unbooked women. The overall unbooked rate for GM women was 10.6% (23). The rural component is a major risk in the management of these women as transport delays result in high mortality rates for both the mother and baby.

In a more recent article, 2013, Afolabi et al published work set in Nigeria (26). They showed that GMP continued to be regarded as a high risk factor and a challenge in obstetric practice in developing countries. The prevalence of GMP was found to be 2.5% in Nigeria. This figure was lower than previous years and was attributed to on-going civilisation, increased uptake of family planning as well as the promotion of gender equality. Despite the downward trend in the prevalence of GMP, there were concerning results when GM women were compared to multiparous women. Overall the GM group were unbooked women and were associated with hypertensive disease, placenta praevia, postpartum haemorrhage, anaemia, puerperal sepsis and urinary tract infections. Fetal distress was more common among the GM women and their babies were more likely to have low Apgar scores. Afolabi et al concluded that whilst the numbers of GMP are declining the adverse risks to both the mother and baby remain real. Further the work emphasised the importance of booking and delivery in a well-equipped facility to reduce complications in GMP.

Mgaya et al (7) highlighted in their study that $\leq 60\%$ of the health workers in rural Tanzania were aware of the definition of GMP. Ninety percent of the Tanzanian population live

≤ 10km from a health care facility and despite this good coverage health services remained inadequate because of lack of equipment and few medical resources. The study showed a higher risk of maternal and neonatal complications. There was a twofold greater likelihood of HPT and DM in the GM group compared with lower parity groups. Meconium stained liquor, placenta praevia and malpresentation were three times more likely to occur in the GM group than in the multiparous group. The aim of the study by Mgaya et al was to prove that GMP in 2013 still remains a risk in pregnancy and to alert their health care system to redirect resources to provide adequate management of labour, to have good referral systems as well as to enable the practice of basic and comprehensive obstetric emergency care.

A study from Croatia, despite its status as a developed country, revealed a greater number of perinatal deaths associated with GMP, resulting from limited resources in their health care system (4). The Croatian health care system was said to be socially oriented, particularly for women and children, and offered regular prenatal care and a minimum of four ultrasounds per pregnancy. In the last 20 years, however, the Croatian health care system has been burdened with immigrants from neighbouring countries, which has strained resources as the total number of deliveries amongst GM women increased (4). Roman et al (19) included poor education levels to be associated with GMP.

There are exceptions in developing countries where good obstetric care is accessible and the outcomes of GMP are good (14, 21, 22). It has been advocated that if all pregnancies are followed in antenatal clinics and deliveries carried out in well-equipped facilities, the risk of complications associated with GMP should decrease considerably (7, 11, 25, 26). Women in low socioeconomic groups should benefit from well-structured facilities (6, 7, 11, 25, 26).

2.2 Key complications experienced in GMP

There are various topics that are repeated and identified as pertinent across the literature when discussing GMP.

2.2.1 Changes in maternal physiology with increasing gestation

The physiological changes in the multipara were previously perceived as unpredictable, hence feared (5). Solomons (5) wrote that the lower segment of the uterus thinned with consecutive pregnancies, and this anatomical change increased the risk of uterine rupture and malpresentation, and also resulted in irregular contractions during labour as well as premature separation of the placenta that would compromise the fetus. The risk of uterine rupture was further increased by the greater size of the baby with every pregnancy. If disproportion was not identified, the labour may have been obstructed, resulting in uterine rupture (5).

In the review conducted by Yves et al (2), similar physiological changes were observed regarding GMP. It was noted that repeated stretching of the uterus is associated with progressive loss of muscle, which is replaced by connective tissue. The muscle loss resulted in uterine laxity and led to fetal malpresentation, non-descent of the presenting part, increased need for oxytocin stimulation, and a higher risk for uterine atony after delivery, with PPH (2).

The cervix of a grand multipara is often described as a multiparous os, meaning that the cervix before the onset of labour is less effaced and more dilated than in less parous women (27). Less activity is needed by the GM uterus to initiate a normal delivery as there is less utero-cervical resistance and increased uterine efficiency (27). Findings of ‘fragile, poorly elastic uterine wall with sparsely spaced myometrial fibres and increased hyalinisation and fibrosis’ were found in hysterectomy specimens from women who bore eight or more children. These changes were more likely to impede labour than to enhance it. The weakened

myometrium has an impaired ability to overcome the resistance of the lower uterine segment and cervix during the initial phase of labour (27).

Gurewitsch et al (27, 28) published two studies in 2002 and 2003 using the same study population group. These multinational studies were conducted in an American hospital in New York and in an Israeli hospital in Jerusalem from 1990 to 1995. The first considered the labour curve and asked the question, ‘does labor continue to improve with additional childbearing?’ (27). The labour curve was plotted to establish the nature of labour in GMP to test the common assumption that the progress of labour slows as parity exceeds four. The second study focussed on descent of the presenting fetal head in the second stage of labour (28). Participants in the study were required to be between 36 and 43 estimated weeks of gestation that went into spontaneous labour without complication. Multiple pregnancies and malpresentations were excluded.

In the first study (27), GM women were found to show a longer latent phase of labour similar to primiparous women. Once established in the active phase of labour, however, rapid cervical dilatation followed up to delivery. This accelerated rate from six centimetres dilatation was no different from the curves of other multiparous women. The hypothesis of their study that the progress of labour slows with advanced parity was challenged by the findings of the study. Afolabi et al (26) showed a higher prevalence of precipitate labour in GM women compared to the multiparous group, and this was statistically significant. GMP was also associated with a significantly shorter length of normal labour duration.

In the second study (28), GM women were found to have a higher station for longer until full dilatation was reached. The fetal head descended slowly in the latent and active phases of labour but then descended rapidly in the second stage of labour, supporting that in GMP the

fetal head remains high and unengaged in the first stage of labour and that GM women have a shortened second stage of labour.

2.2.2 Antepartum complications

GMP is strongly associated with advanced maternal age, and maternal morbidity and mortality in these women may more frequently be related to age-related risk factors (6). A study conducted in Lucknow, India (10) found that grand multiparas (mean age 32 years) were older than a control group of multiparous women (mean age 27 years).

Vaswani et al (25) controlled for age and only included women between the ages of 18 and 35 in their study, removing possible contributions of extremes of age on obstetrical and neonatal outcomes. Adverse outcomes were more common amongst the GM group compared to the parous group but less common amongst the great grand multiparous group when compared to the multiparous group. An inverted V graph illustrated that many antenatal and intrapartum complications showed a linear increase with increasing parity while some antenatal and intrapartum complications showed a declining trend with increasing parity (25).

Researchers have attempted to show that medical complications in GM women are the result of age and not of parity alone. The most common medical conditions that complicate GMP are HPT and DM (2, 6, 7, 9, 11, 13, 16, 26)

Goldman et al (6) found the age of GM women was significantly higher compared with the control groups in their study explaining the higher incidents among GMP of antenatal medical disorders, such HPT and DM. Women with HPT and DM are at a higher risk of obesity as it is difficult for these women to lose weight gained from repeated pregnancies (2).

Hughes et al (9) conducted a study in the UAE where young GMP is a well-accepted phenomenon. In their study, 47% of GM women included were below the age of 35 years.

Obesity, HPT and DM were highly prevalent in this study population and the authors concluded that ‘the mature grand multigravida in this population was not at significantly increased risk of the alleged associations of increased parity and advancing maternal age, with the exception of diabetes’ (22). A Malaysian study found that the difference in the prevalence of HPT and DM was not statistically significant in GM women as compared to multiparous women (22). The study further noted that GM women were, in general, older than 35 years.

Simonsen et al (20) observed that studies on GMP were habitually selected on the number of children born alone and in 1995 focused ‘on the unique risks associated with GMP in young women’. The women featured in their study conducted in Utah, United States of America, were between the ages of 18 and 34 years (the youngest was 18 years old) and were predominantly white. These women were compared to older women with similar profiles. Younger grand multiparas were found less likely to have completed high school, more likely to smoke, were unmarried, booked after the first trimester, and had a higher incidence of preterm labour and placental abruption. Overall, however, these younger women showed less intrapartum complications when compared to older grand multiparas, greater than 34 years old. The prevalence of HPT and DM were not remarked on in either group.

Booking for antenatal care has been highlighted as a key factor (7, 11, 20, 23, 26). GM women are notorious for not booking or booking late at the ANC, the reasons being that GM women who have had no problems in previous pregnancies often delay seeking medical care, and others find it difficult to attend ANC owing to time constraints imposed by their large, demanding families (23, 26).

Late or no booking in the advanced maternal age group results in a missed opportunity for trisomy screening (16), although there is no compelling evidence in the literature to support

the theory that GMP on its own carries a higher risk of chromosomal abnormalities than the rest of the pregnant population. The advanced maternal age, which is typically associated with GMP, is an independent factor associated with a high risk of chromosomal abnormalities, particularly Down's syndrome (29). Fardeev et al (24) researched the incidence of Down's Syndrome and found that there was no difference with increasing parity. In the review by Yves et al (2), congenital abnormalities were found less often with GMP and that seemed to be the general consensus across the literature. Severinski et al (4) in the Croatian study found a lower incidence of major congenital abnormalities in the GM group when compared to the multiparous women, despite most grand multiparas being beyond 35 years of age. Babinski et al (16) documented a small increase in the frequency of congenital abnormalities in the age group beyond 45 years, compared to women younger than 45 years. Fetal aneuploidy is the only congenital abnormality related to maternal age (30).

Anaemia is a universally recognised complication of pregnancy and has been reported in most studies reviewed on GMP (2, 4, 6, 7, 9, 10, 11, 23, 25, 26). Anaemia associated with GMP is compounded by the consequences of low social economic status (11, 23). In such women, repeated pregnancies do not allow sufficient time to replenish iron stores before embarking on a new pregnancy (18). Bugg et al (18) showed an increased incidence of antenatal anaemia amongst GM women. Twenty two percent of GM women compared to 16% of multiparous women presented antenatally with a haemoglobin level <10 g/dL. Prophylactic iron and folic acid supplements were offered to these women during antenatal care but if there had been a delay in booking they often already presented with anaemia (9, 13, 18, 22). GM women are nutritionally drained further because of prolonged lactation periods (31).

The most prevalent cause of maternal death in South Africa reported in the most recent Saving Mothers report 2008-2010 is non-pregnancy related infection with HIV infection being the most common contributory condition (32). There is no evidence linking GMP and HIV in the literature.

Henderson et al (31) hypothesised in their study conducted in Washington State that low bone mineral density and osteoporosis might be expected in GMP as a result of aging and repeated extended lactation events, typically as a result of numerous pregnancies with short recovery intervals. Dual energy x-ray absorptiometry scans of 30 GM women were compared with those of 30 nulliparous, premenopausal women. They found no association with GMP and lowered bone mineral density when compared to the control group (31).

2.2.3 Intrapartum Complications

GMP has been described as an independent risk factor for a variety of serious intrapartum complications (20). Intrapartum complications commonly associated with GMP include uterine rupture, abruptio placentae, placenta praevia, fetal malpresentation (abnormal lie due to placenta praevia, pendulous abdomen or lumbar hyperlordosis with an increased pelvic inclination) and dysfunctional labour (16). Solomons (5), as mentioned earlier, accounted for the danger of uterine rupture in multiparous women as being related to the anatomical thinning of the lower segment of the uterus with consecutive pregnancies and the increasing size of the baby with every pregnancy. In his view, subjecting the overused uterus of the multipara to 'pituitary extract' (containing oxytocin) could result in uterine rupture.

Baskett et al (12) highlighted the fact that malpresentations were common in GMP (9.0%) when compared to the overall hospital incidence (5.0%). This result agreed with findings from Al-Sibai et al (13), who found an increased prevalence of malpresentation in GMP

when compared to the total obstetric population. In addition, the prevalence of APH in GMP (5.8%) was higher than in the total obstetric population (2.3%). Hughes et al (9) however showed no statistically significant difference in prevalence of APH in GM women compared to multiparous women.

A Jordanian study that compared great GM women to multiparous women furthermore noted no significant difference in the incidence of intrapartum complications, with the exception of dysfunctional labour that was reported to be increased in the multiparous group (33).

In 2005, Benecke et al, from Cape Town in South Africa, compared antepartum and intrapartum complications as well as neonatal outcomes in GM women versus multiparous women (21). Benecke et al reviewed deliveries for 18 months in 2002 at the Tygerberg hospital in which they studied 101 GM women. The study found that abruptio placentae, placenta praevia and uterine rupture were not statistically significantly more frequent, although malpresentation occurred in 10% of the GM women (21). A larger study was prospectively done over five years in the same time period (2002-2006) in Nigeria (11).

Omole-Ohonsi et al (11) observed 1213 GM women and found an increased occurrence of gestational DM, HPT, heart disease, anaemia, APH, fetal malpresentations, cephalopelvic disproportion and fetal macrosomia among the GM group. This Nigerian study, like Benecke et al, concluded that the complications found were minimised by good antenatal care. The only study to report a high incidence of umbilical cord prolapse in GMP was in the study by Simonsen et al (20).

2.2.4 Postpartum complications

Postpartum haemorrhage is a leading cause of maternal deaths in countries of sub-Saharan Africa. (34). These include primary and secondary haemorrhaging, due to uterine atony,

RPOC and trauma to the genital tract and perineum. Obstetrical haemorrhage is the most common avoidable cause of maternal death and appears to be increasing according to South African statistics (32).

In Solomons' (5) discussion of the thinning uterus, uterine rupture and accidental haemorrhage were stated as 'essentially the disease of the multipara'. Solomons further noted that of the 148 cases of accidental haemorrhage, 130 were in the multiparous group. Yves et al (2) explained the expected prevalence of PPH in GM women to be related to a higher risk of uterine atony as a consequence of uterine muscle loss resulting in uterine laxity and the need for more postpartum oxytocin stimulation. Goldman et al (6) found that PPH was more common (4.8%) in grand multiparas compared to multiparas (2.3%) and primiparas (3.7%).

2.3 Modes of delivery

The mode of delivery of the grand multipara is an interesting point of discussion. It is often expected by the pregnant woman that delivery after the fifth baby should occur without complication (18). The mode of delivery includes spontaneous vaginal delivery, assisted vaginal deliveries, i.e. vacuum and forceps deliveries, and CS deliveries, either performed as an emergency or an elective procedure.

Agrawal et al (10) showed that there were no significant statistical ($p=0.758$) differences in the CS rates between their GMP study group (33.3%) and the multiparous control group (34.9%). Goldman et al (6), however, found that there were fewer CSs in the GM group when compared to multiparous and primiparous women (6.8%, 16.6% and 11.3% respectively). In their discussion they suggested that the lower CS rate is a function of GM

women's choices, believing that having a CS after five successful normal vaginal deliveries is 'humiliating'.

In 1990 Hughes et al (9) and in 1996 Bugg et al (18) documented a lower occurrence of elective CSs than emergency CSs in the GM group. Four studies observed an overall reduction in the rate of CSs (4, 6, 15, 16). Nordin et al (22) found the CS rate was the highest in the great grand multiparous group and accounted for 12% of their CSs for macrosomic babies (>4500grams). The results showed that emergency CSs occurred more frequently compared to elective CSs (22).

Across the studies reviewed by Yves et al (2), the incidence of instrumental vaginal deliveries was significantly lower for GM women when compared to multiparous women, 1.8% and 7.3% respectively.

The University of the Witwatersrand Department of Obstetrics and Gynaecology contraindicates induction of labour for parity ≥ 5 (35). As a result there is a low threshold to book grand multiparas for elective CS at term if elective delivery is indicated. It is notable that the Cochrane database, the American College of Obstetrics and Gynaecology and the Royal College of Obstetrics and Gynaecology guidelines do not provide specific protocols for managing the modes of delivery in GMP.

Tarik et al (36) performed a study between 1991 and 2001 at King Abdul-Aziz University Hospital with a study group of 405 GM women who had one previous CS. In the community being observed it was reported that CSs were frowned upon because large families were favoured as it was the social culture and a CS was considered limiting and not an acceptable option for the family. According to the University of the Witwatersrand Department of Obstetrics and Gynaecology, GMP is a relative contraindication to VBAC (35). Tarik et al

(36) aimed to determine the rate, delivery outcome and safety of VBAC in GMP. They found a 54% rate of successful VBAC in GM women. Sixteen percent of the women needed and received labour augmentation with oxytocin. Seventy-three percent of the study group had a previous successful VBAC, excluding the index pregnancy. No major maternal morbidities such as uterine rupture or uterine dehiscence were reported. The overall findings showed VBAC in GMP to be safe and effective.

Kugler et al (37) conducted research between 1988 and 2006 at the Soroka University Medical Centre in Israel. The study aimed to assess the risks of maternal and neonatal complications associated with VBAC compared to those of repeated CSs in GM women. Seventy percent of the study population chose to have a VBAC, of which 56% were successful. The remaining 14% of the total population underwent a trial of labour and 30% had an elective CS. Thirty percent of women chose to have an elective repeat CS. There were no significant maternal morbidities in the VBAC group and only one uterine rupture was reported, from the elective CS group. There were no statistical differences in the outcomes across the two groups. The authors concluded that trial of scar in GMP is not associated with higher maternal adverse effects as compared with elective repeated CSs.

Tarik et al (36) and Kugler et al (37) stated that further studies are needed to confirm their findings, as the numbers examined were relatively small.

2.4 Use of oxytocin and misoprostol in GMP

Prostaglandins are used for IOL for obstetric and medical reasons in low parity women (38). Tarik et al (38) compared IOL with vaginal PG-E₂ with the onset of spontaneous labour in GMP in a retrospective case-control study. Induction of labour, like VBAC in GMP, is a relative contraindication as per the University of the Witwatersrand Obstetrics and

Gynaecology protocol and the fear of uterine rupture has long been a concern in the administration of uterine stimulants in GMP (35). The indications in the study by Tarik et al (38) for IOL were gestational DM, DM, chronic HPT, gestational HPT and post-dates, among others. The work by Tarik et al further mentions that studies they reviewed relating to the use of PGs in GMP are limited and very few support the use of oxytocin and misoprostol in GMP owing to the lack of data regarding safe outcomes of IOL in GMP (38). CSs were performed on 6.9% of the induction group, indicating failure of PG-E₂ as these women did not go into labour, compared to 3.0% in the control group who delivered vaginally. One uterine rupture (0.5%) occurred after the use of two doses of 1.5 mg of vaginal PG-E₂: this was diagnosed at CS for fetal distress (prolonged decelerations were present) and the baby was born alive at 4830g, with low Apgar scores, and died thereafter. Despite this poor outcome, the study concluded that IOL with vaginal PG-E₂ was relatively safe in GMP and quoted the 1995 bulletin of the American College of Obstetrics and Gynaecology that suggested that IOL in GMP required caution but was not contra-indicated (39). No further update to this bulletin has been made to date.

In 1999 the Scandinavian Journal, *Acta Obstetrica et Gynecologica Scandinavica*, published an article on labour induction using vaginal misoprostol in GM Mozambican women (40). In their work, Bique et al (40) compared 134 GM women with the fetus alive, with 31 women who shared the same profile, but with a late IUFD, in a low income setting. Both groups had labour induced with vaginal misoprostol, 50µg and 100µg respectively, and no oxytocin was used in either group. The time to delivery for women with a live fetus was shortened compared with the women who had an IUFD. Quicker labours were seen in women who presented with pre-labour rupture of membranes than those who presented with intact membranes. There were no maternal adverse effects noted for both groups. Additionally, no adverse fetal effects were noted for GM women who had a live fetus. In contrast to the work

by Tarik et al (38), there were no uterine ruptures in the study population. However, the sample size was small, restricting any comment on rare but severe maternal outcomes, such as fatal haemorrhage from uterine rupture.

Induction of labour in great grand multiparas with misoprostol versus oxytocin has been explored in Turkey by Zeteroglu et al (41). Special ethical approval for the use of misoprostol was obtained from the local university's research ethics committee as the use of inducing agents in great grand multiparas was not usual practice. This randomised controlled trial divided 64 women into two groups: 32 women were induced with misoprostol and 32 with oxytocin. There were no women with failed induction. The CS rates were significantly higher ($p=0.072$) 15.6% in the misoprostol, and 12.5% in the oxytocin group. The indications for CS in the misoprostol group were fetal distress ($n=3$) and placental abruption ($n=2$). Obstructed labour ($n=1$), fetal distress ($n=2$) and abruptio placentae ($n=1$) were indications for CS in the oxytocin group. Uterine contraction abnormalities, e.g. tachysystole and hypertonus, were reported in 3.1% ($n=1$) of the misoprostol cases who went on to NVD without complication. No statistical significance was found for differences in placental abruption and PPH between the two groups. There were no cases of uterine rupture. This study suggested that misoprostol and oxytocin were safe to use, and that misoprostol was the superior choice for induction amongst these women as it was easy to use and cost effective. It was also noted that more work could provide further clarification. Again, however, the small sample size made it difficult to comment on safety with respect to rare but catastrophic complications.

2.5 The acceptance of contraceptive practice

Sigmund Freud made an important forecast about fertility control: 'one of the greatest technological triumphs would be the ability for humans to plan procreation and separate it from the natural desire of sexual satisfaction' (42). Contraception is effectively practised in

industrialised countries while developing countries still experience high fertility rates and exponential population growth (42). In a few developed countries, although well-equipped, high fertility rates are common because of cultural and religious beliefs (2).

Omu et al (42) conducted a study in Nigeria focussing on the response to contraception in GMP. Medical personnel interviewed a total of 560 women and a questionnaire was completed. Most of the women were from low socio-economic backgrounds and were married at a young age, some as early as 11 years. There appeared to be a high level of awareness, with 65% being aware of contraception, although only 27% reported contraceptive use. The oral contraceptive pill was the most preferred method of contraception. The intrauterine contraceptive device was more commonly used after the final pregnancy. The factors that influenced contraceptive usage included:

- Spacing between pregnancies;
- Families that were completed;
- To prevent an unwanted pregnancy;
- To further education and career prospects;
- Financial support of these large families was taxing; and
- Fear of a CS or a complicated labour and prolonged hospital stay.

Reasons for declining contraception were opposition from the family (husband and in-laws), religious beliefs and traditional culture, the sex of the existing children (too few girls or boys), a new husband, and adverse effects experienced with the previous method of contraception. Education increased the use of contraception after the index pregnancy as there seemed to be a better understanding and availability of contraceptive techniques (42).

2.6 Fetal Complications

Reports on fetal outcomes in GMP have differed across studies. Baskett et al (12) found the stillbirth incidence, neonatal mortality and perinatal mortality of grand multiparas to be much higher when compared with multigravidas and primigravidas. Data from 1973 in Winnipeg, Canada showed a perinatal mortality rate of 47/1000 for grand multiparas and a perinatal mortality rate of 22/1000 in the combined multipara and primigravida group. The authors pointed out that in half of these poor outcomes there were avoidable factors and that perinatal outcome was related to antenatal care (12). Neonatal deaths were five times greater in the unbooked group (five cases) compared to the booked group (one case). The increase of low birth weights and stillbirths were statistically significantly different when the unbooked and booked groups of the grand multipara were compared. In contrast to Baskett et al's (12) finding of unfavourable fetal outcomes, King et al (43) in 1991 reported the perinatal mortality rate to be zero from an examination of the obstetric outcomes of GM women over a five year period in low socio-economic settings. Some type of antenatal care was received by 98% of women with only four unbooked. The obstetric risks traditionally associated with GMP can be mitigated through access to modern medical care (43). In 2002, Bai et al (17) showed that neonatal morbidity and perinatal death increased from the fourth pregnancy and suggested that the threshold for risk may begin with GMP.

Arad et al (44) looked specifically at the relationship between the neonatal outcome of very low birth weight infants and parity. The hypothesis being tested was that preterm deliveries occur in GMP due to a multitude of medical conditions that women of advanced maternal age experience (44). The result of these maternal complications, e.g. severe PE and abruptio placentae, is a high frequency of induced preterm deliveries. Often these inductions or CSs are done as emergencies, allowing little time to improve lung maturation, and this could

account for the higher perinatal morbidity and mortality rates (44). The authors noted high rates of intraventricular haemorrhage and bronchopulmonary dysplasia in the GMP group (44). Babies who experienced severe respiratory distress syndrome were shown to have poor outcomes that were often fatal after the first 24 hours of life. This study was conducted in a neonatal intensive care unit in Jerusalem, a setting that did not allow for a control group. The authors therefore encouraged further work elsewhere to confirm their findings. In South Africa, spontaneous preterm birth is the most common cause of perinatal death in babies 500g or more. Mortality owing to hypertension specific complications is prevalent in patients who are referred to higher levels of care (45).

Low birth weight babies (those weighing less than 2.5kg) face a greatly increased risk of dying during their early months and years. (46) An estimated 18 million LBW babies are born worldwide every year. Sub-Saharan Africa has the second highest (next to South Asia) LBWR in the world, with close to 3.1 million babies born below 2.5kg. Weight at birth is a good indicator not only of the mother's health and nutritional status but also of the newborn's chances of survival, growth, long-term health and psychosocial development. The higher the LBWR in a community, the higher the perinatal mortality as low birth weight babies have greater mortality rates (46). The LBWR in 2010-2011 indicated by the Saving babies report was 13.99% for the Johannesburg metro region, 4.06% for Gauteng Province and 14.17% total for South Africa (45). These findings are not specific to GMP but reflect on the socio-economics of a community in which GMP is prevalent. Omole-Ohonsi et al (11) investigated GMP in a developing setting and when compared to multiparous women found a lower LBWR in the GM group. In a developed setting The LBWRs were similar amongst the multiparous and GM groups but lowest in the great grand multiparous group (25).

It is well accepted that the birth weight increases with increased parity and that macrosomia is far more common amongst GM women (24). Babinszki et al (16) showed an increasing frequency of macrosomia: 14.3% in multiparas, 19.5% in grand multiparas and 21.2% in great grand multiparas. They also showed that this increase in neonatal weight did not contribute to the overall complications associated with GMP, nor did it influence the CS rates (16). Goldman et al (6) and Hughes et al (9) also reported macrosomia, which did not contribute to adverse outcomes in GMP.

Low 5-minute Apgar scores have been noted as more frequent with GMP. Bugg et al (18) and Yves et al (2) showed a high incidence of 5-minute Apgar scores less than seven, but these increases were not statistically significant in either study. Fetal distress was isolated to those deliveries that needed assistance either with PG induction or oxytocin stimulation. This was often a finding in postdates pregnancies that warranted medical induction.

Abnormal liquor volumes have been associated with maternal illness, such as polyhydramnios being a feature of DM and oligohydramnios a feature of pre-labour rupture of membranes or severe gestational HPT (16). These features are not directly related to GMP. Meconium stained liquor has been mentioned as a feature of deliveries in GMP (2, 16). However, the review by Yves et al (2) reported no difference in MSL between the GM group and multiparous group.

King et al (43) concluded that GMP itself appears to show little or no risk for poor fetal outcomes, provided these pregnancies are attended to early in health care centres that are well equipped with well trained staff.

3 PROBLEM STATEMENT

GM women have historically been expected to have more antepartum, intrapartum and postpartum complications as compared to multiparous women. They have been considered to be at risk for maternal and fetal complications resulting in poor outcomes. Over the years, the poor outcomes have been attributed to physiological changes as a result of high parity, maternal age and age-related medical conditions, socioeconomic status, and religious and cultural beliefs. There appears to be a relationship between access to health care, especially in the antenatal period, and outcomes, in both the South African and international contexts.

In the modern setting, GM women in Soweto, Johannesburg, are afforded access to adequate health care facilities and hence should have good outcomes. This research aimed to determine current obstetric management and outcomes of GMP in this South African setting. It is hoped that the study would inform local protocols to manage GMP.

4 OBJECTIVES OF THIS STUDY

- i. To describe maternal, obstetric and fetal complications occurring in GM women in Soweto, Johannesburg, giving birth from May 2011 to August 2011.
- ii. To determine the proportion of GM women who attended antenatal clinic at least once (booked for antenatal care).
- iii. To determine the frequencies of modes of delivery in GM women.
- iv. To identify any demographic characteristics related to GMP.

5 METHODS

5.1 Study design

This was a prospective, cross-sectional descriptive study using medical record review and a short interview.

5.2 Study population

The study included all births to GM women at CHBAH and its seven satellite MOUs.

Women with babies BBA, either at home or in transit, were included. Also, down-referred women from Chris Hani Baragwanath having elective caesarean sections at South Rand Hospital were included in the study. The International Federation of Gynaecology and Obstetrics (FIGO) defined in 1993, GMP as five or more deliveries (16). Women who were currently in their 5th viable pregnancy (reaching the third trimester for the 5th time) were included in the study. Frequently, women in their 5th pregnancy are referred from the MOUs to CHBAH, for antenatal care and delivery.

5.3 Setting

Chris Hani Baragwanath Academic Hospital is a tertiary and regional hospital situated in Soweto that serves approximately two million people. Over 23 000 deliveries are performed each year. Its labour ward attends mostly to high-risk women and approximately 20% low-risk walk-ins. Another 10 000 low risk women give birth at seven MOUs in Soweto and nearby townships. The population is urban and mostly working to middle class, with the majority dependent on state services for their health care. As there are no secondary hospitals or any other public hospitals in Soweto, the MOUs refer high-risk pregnant women to deliver in the hospital. Routine antenatal care for GM women is conducted by midwives at community clinics especially for those women who have no co-morbidities. Women who are

para 5 (about to have their sixth child) are considered high-risk and transferred to the hospital for delivery.

Chris Hani Baragwanath Academic Hospital also utilises the resources of South Rand Hospital, a district hospital in Rosettenville, Johannesburg, for elective CS. A number of women presenting at CHBAH who require elective CSs have these performed at South Rand Hospital.

Chris Hani Baragwanath Academic Hospital adheres to protocols regarding GMP, which have been drawn up by the Department of Obstetrics and Gynaecology of the University of the Witwatersrand. While there is no specific section on grand multiparity, there are two areas where grand multiparity is mentioned:

- Women with parity of five or more after delivery are given additional oxytocin (20 units drip) in the third stage of labour; and
- Women of parity five or more must not receive oxytocin or prostaglandin for induction or augmentation of labour.

5.4 Inclusion criteria

Women who had five or more pregnancies reaching viability, including the index pregnancy, were included.

This study included all grand multiparas with their fifth viable pregnancy (≥ 26 weeks), who gave birth at CHBAH and the seven MOUs (Chiawelo, Dobsonville, Lenasia South, Lillian Ngoyi, Mofolo, Stretford, and Zola clinics). Multiple pregnancies, intrauterine deaths, and major fetal congenital abnormalities were included in this study.

5.5 Exclusion criteria

Women that had families of five children consisting of high order pregnancies, i.e. sets of twins or triplets, were to be excluded, as they were not truly grand multiparas. For example, a woman may present as a 'para 5' but gravida 3 as she may have delivered a set of triplets and therefore did not fit the requirement of GMP for this study.

5.6 Sampling and sample size

Deliveries of grand multiparas were included in a period sample from 1 May to 31 August 2011. The hospital registers were reviewed every 4th day, the only day out of her 4-day registrar rotation that the researcher was available to collect data. Only those GM women who had delivered within the 24 hours before data was collected were included in the study. GM women who delivered at the MOUs and at South Rand Hospital were included if they delivered on the same day as the hospital deliveries.

The study intended to include at least 100 women based on the advice from the supervisor. Experience of work and examination of birth registers at CHBAH and the MOUs suggested this would take about three months.

5.7 Data collection

The delivery registers in the admissions area, labour ward and CS theatre were reviewed at about 07:00 every 4th morning to find GM women who had delivered the day before (from 06:00 to 06:00). The delivery register in the admissions area recorded those women who had arrived at the hospital as BBA, the labour ward register recorded spontaneous NVDs as well as assisted vaginal deliveries, and the CS theatre register recorded women who had emergency CSs or elective CSs. The women who had delivered were then found in their respective postnatal wards where a short interview was conducted and medical records

reviewed, after written informed consent to use their clinical information in the study was obtained.

Grand multiparas that delivered at the MOUs on the same days as the grand multiparas delivered at CHBAH were also included. The deliveries at the MOUs included those women who had spontaneous vaginal deliveries and BBA births. Information regarding grand multiparas was taken periodically from the MOU birth registers, although there were no medical records for review and no opportunity to interview these women. According to the clinical protocols, grand multiparas treated at the MOUs would have no co-morbidities because only low-risk uncomplicated births are completed at the MOUs.

Elective CSs from CHBAH are performed at South Rand Hospital, and so grand multiparas who underwent CSs at South Rand hospital were included in the study sample. The South Rand Hospital CS theatre register was reviewed from 1 May to 31 August and those CSs that took place on the same day as the deliveries recorded at CHBAH were used. These women also did not have full medical records and could not be interviewed.

All data was collected on a data sheet. The data capture sheet and interview questionnaire are attached as Appendix 1 and 2 respectively.

5.7.1 Data collection categories

Data was collected under the following variables (Appendix 1):

Demographics and Antenatal Clinical data:

- Age
- Parity
- Gravidity

- Booked/unbooked
- Booking haemoglobin
- HIV status
- CD4 count
- Antiretroviral drug use
- Race
- Gestational age
- Singleton/multiple pregnancy

Existing medical illness at antenatal care:

- Anaemia
- Cardiac disease
- Diabetes
- Epilepsy
- Aids defining illness / non-Aids defining illness
- Hypertension
- Other illness

Intrapartum complication:

- Pre-labour rupture of membranes
- Antepartum haemorrhage
- Intrauterine growth restriction
- Placenta praevia
- Chorioamnionitis

Progress of labour:

- Duration of 1st stage, 2nd stage and 3rd stage of labour
- Induction of labour
- Augmentation of labour
- Spontaneous rupture of membranes
- Artificial rupture of membranes
- Meconium staining of the liquor
- Perineal trauma
- Intensive care unit admission
- Hysterectomy
- Uterine rupture
- Blood loss
- Blood transfusion
- Death

Delivery:

- Caesarean section
 - Tubal ligation at caesarean section
 - Indication for caesarean section
- Vaginal delivery
 - Spontaneous
 - Assisted

Fetal outcomes:

- Live birth
- Macerated or fresh stillbirth
- Birth weight
- Apgar score at 5-minutes
- Prematurity
- Early neonatal death

5.8 Interview

The women in hospital underwent a brief interview. Written consent was obtained after the nature of the study was explained to the women in a manner and in a language that they would understand, and an interpreter was used from the postnatal wards to communicate with women who did not speak English. Women were interviewed by the primary researcher who then recorded the answers on the data sheet.

Data from the interview was collected under the following variables (Appendix 2):

- Marital status
- Level of education
- Employment
- Monthly income
- Access to water and electricity
- Number and ages of previous children
- Contraception awareness and use
- Failed sterilisation
- Reasons for a big family

5.9 Data analysis

The data was tabulated in a Microsoft Excel spread sheet, and then exported for analysis into Stata 11 (Stata Corp, College Station, Texas) software. Descriptive statistics were used. Frequencies were expressed as proportions and percentages. Frequency distributions were described using means with standard deviations, medians with ranges, and modes.

5.10 Ethics approval

The study received approval from the University of the Witwatersrand's Human Research Ethics Committee, approval number M110110 (Appendix 3).

6 RESULTS

6.1 Place of birth

A total of 122 women were included during the study period, with 124 deliveries, as there were two twin pregnancies. Ninety nine (81.14%) of the women delivered in hospital: 95 (77.87%) at CHBAH and four (3.28%) at South Rand Hospital. MOUs contributed 15 (12.30%) of the deliveries while the remaining eight (6.56%) were BBAs (Table 6.1).

Detailed data were available for 98 women, of whom 95 delivered at CHBAH and three were BBAs that presented to CHBAH. Partial data were available for the women that had elective CSs at South Rand Hospital (n=4) and for those that delivered at the MOUs (n=15) and the remaining BBAs (n=5).

Table 6.1 Place of birth (n=122)

CHBAH	95 (77.87%)
BBA	8 (6.56%)
MOU	15 (12.30%)
South Rand Hospital	4 (3.28%)

6.2 Antepartum results

The mean age of the women (n=122) was 37 years with the youngest being 25 years and the oldest being 50 years old. Ninety two (75.40%) were aged ≥ 35 years, and 36 years was found to be the most frequent age (Table 6.2).

Table 6.2 Age in years (n=122)

Mean age	37.2 ± 4.6
Median	37
Interquartile range	35 – 41
Range	25 – 50

The highest parity after delivery was 13 (n=1) with five being the most prevalent (n=70) as well as the median (Table 6.3).

Table 6.3 Frequency distribution of parity after delivery (n=122)

5	70 (57.38%)
6	36 (29.51%)
7	9 (7.38%)
8	4 (3.28%)
9	1 (0.82%)
11	1 (0.82%)
13	1 (0.82%)

Antenatal booking data were available for 104 women. Ninety five (91.35%) were booked and nine had no attendance at an antenatal care facility (unbooked). Of the 96 available haemoglobin observations, 34 women (35.42%) had haemoglobin values less than 11.0 g/dL. HIV results were available for 104 women, of whom 41 (39.42%) tested positive, with 27

(65.85% of positive woman) on antiretroviral treatment (Table 6.4). Seven (7.14%) of the 98 women, where data was available, had a CD4 count <200 cells/mm³.

Table 6.4 Demographics and antenatal care of GM women

Ethnic origin (n=98)	
African	84 (85.71%)
Coloured	13 (13.27%)
Indian	1 (1.02%)
Booked at antenatal clinic (n=104)	95 (91.35%)
Mean haemoglobin level (n=95)	11.96 g/dL±3.41
Anaemia (Haemoglobin < 11.0 g/dL)	34 (34.69%)
HIV infected (n=104)	41 (39.42%)
Twin pregnancy (n=122)	2 (1.64%)
Previous CS (n=122)	13 (10.66%)

Of the 98 women with available data, 24 (24.48%) had hypertensive disease of which 17 (17.35%) had a history of chronic HPT. Of these 17 women with chronic HPT, five (29.41%) had superimposed PE. Of the remaining group, two (11.76%) women developed PE in the current pregnancy and one (5.88%) had unclassified HPT. Overall, there were four (23.53%) women with gestational HPT. There were no women with diabetes mellitus (DM) based on medical history, placental abruption or placenta praevia. Seven women (7.14%) gave a history of asthma and one woman (1.02%) presented with pulmonary tuberculosis and tested HIV negative (Table 6.5).

Table 6.5 Medical disorders of pregnancy in GM women (n=98)

Chronic hypertension	17 (17.35%)
Gestational hypertension	4 (23.53%)
Pre-eclampsia	2 (11.76 %)
Superimposed pre-eclampsia	5 (29.41%)
Unclassified hypertension	1 (5.88%)
Epilepsy	1 (1.02%)
Asthma	7 (7.14%)
Pulmonary tuberculosis	1 (1.02%)

There were 98 recorded gestational ages at delivery. The mean gestational age at delivery was 37.8 weeks (n=91). Twenty five women (25.51%) delivered before 37 completed weeks. The delivery with the shortest gestational period was 28 weeks. Thirteen women (13.26%) were postdates (≥ 41 weeks). The longest pregnancy duration was found to be 43 weeks. Two sets of twins were born. The first set was born to a 42 year old para 6 gravida 5 at 37 weeks gestation. The second set of twins was born to a 29 year old para 4 gravida 5 at 40 weeks.

6.3 Intrapartum complications

Of the 98 cases where data were available, one woman (1.02%) had antepartum haemorrhage (APH) of unknown origin. Ten (10.20%) presented with pre-labour rupture of membranes, six of which (6.12%) went into spontaneous labour and delivered vaginally. The remaining four women (4.08%) had CSs; three (3.06%) as a result of fetal distress and one (1.02%) as a result of prolonged rupture of membranes.

There were seven cases (7.14%) of PE. Of the seven women with PE, six had CSs, two of the six for fetal distress and three for PE itself. Labour was induced in one woman (1.02%) although the induction failed and the fetus developed fetal distress and was delivered by CS (Table 6.6).

Table 6.6 Intrapartum period for GM women (n=98)

Induction of labour	3 (3.06%)
Pre-labour rupture of membranes	10 (10.20%)
Antepartum haemorrhage	1 (1.02%)
Breech presentation	2 (2.04%)

6.4 Modes of Delivery

NVDs accounted for 66.12% (n=82) of the 124 deliveries. . Nine (7.25%) women delivered vaginally after being booked for a CS. The reasons these women being booked for elective CS were pre-labour rupture of membranes (n=1), breech presentation (n=1), previous CS (n=1), previous CS and postdates (n=1), PE (n=1) and chronic HPT (n=2) and GMP (n=2).

The CS rate was 32.25% (n=40) (Table 6.7). In the entire population of deliveries (n=124), 28 emergency caesarean sections were performed (22.58%): for fetal distress (n=17); no progress (n=3); PE (n=2); breech presentation (n=2); twin pregnancy (n=1); GMP and poor obstetric history (n=1); prolonged rupture of membranes (n=1); and for one woman who had two previous CSs presenting in spontaneous labour.

There were 12 elective CSs booked (9.67%), eight of the 12 (6.66%) were conducted at CHBAH and the remaining four of the 12 (3.33%) at South Rand Hospital. Six CSs were

booked, two for GMP associated with PE, one for prolonged rupture of membranes, two for postdates and one for twin pregnancy. The remaining six (5.00%) elective CSs were booked for women who had previous CSs. No instrumental deliveries were recorded.

Of the 40 CSs performed, 14 of the 40 (35.00%) women gave consent for bilateral tubal ligation. Fourteen women are known to have had previous CSs of which six (4.28%) had spontaneous VBAC deliveries while the remaining eight (57.14%) delivered by CS.

Table 6.7 Modes of Delivery (n=122)

CS	40 (32.25%)
NVD	82 (66.12%)

6.5 Postpartum complications

Ninety eight women had detailed postpartum clinical information. Two women (2.04%) had PPH, both of whom delivered vaginally. The cause of PPH was uterine atony and both patients responded well to uterotonics. No PPH was observed in those that had CSs. One woman received a blood transfusion. Her blood loss was 800mL after delivering twins vaginally. Perineal trauma (first degree tear) was sustained by seven women (7.14%). There were three cases (3.06%) of RPOC, all of which underwent evacuation of the uterus in theatre (Table 6.8).

In the total sample of 122 women, there were no intensive care unit admissions, no woman had uterine rupture, none underwent a hysterectomy and there were no maternal deaths.

Table 6.8 Postpartum complications in GM women (n=98)

Retained products of conception	3 (3.06%)
Perineal tears	7 (7.14%)
Blood transfusion	1 (1.02%)
Blood loss >500 mL at vaginal delivery	2 (2.04%)
Blood loss >1000 mL at caesarean section	0 (0%)

6.6 Fetal Outcomes

Out of 124 babies, 120 (96.77%) were born alive (Table 6.9). There was one fresh stillbirth: the woman presented as a 50 year old with spontaneous rupture of membranes and was HIV positive, not on ARVs. The baby had a birth weight of 2430 g and was born before arrival at the hospital. The cause of death was unexplained. There were three macerated stillbirths (2.42%). The first was born weighing 3460 g to a 43 year old woman who had chronic hypertension with superimposed PE and was HIV positive with a CD4 count of 696 cells/mm³, not on ARVs. The second was born weighing 3710 g to a 42 year old woman who had asthma and was HIV positive with a CD4 count of 200 cells/mm³, using ARVs (regimen B). The third was born weighing 2125 g to a 39 year old woman who reported no fetal movements for a few days, had no co-morbidities and but was not tested for HIV.

The mean birth weight of the total deliveries (n=124) was 2993g and ranged from 1065 g to 4395 g. Twenty five (20.16%) weighed less than 2500 g and nine (7.26%) were born weighing less than 2000 g. One hundred 5-minute Apgar scores were available. The lowest score was six. The mode of the Apgar scores at five minutes was 10. There were no early neonatal deaths.

Table 6.9. Fetal outcomes in GMP (n=124 except where there is missing data)

Alive	120 (96.77%)
Fresh stillbirth	1 (0.81%)
Macerated stillbirth	3 (2.42%)
Stillbirth rate per 1000 births	32.3
5-minute Apgar score < 7 (n=100)	2 (2.00%)
Mode of 5-minute Apgar scores (n=100)	10
Mean birth weight	2993±628
Early neonatal death	0 (0%)
Low Birth weight rate <2500 g	25 (20.16%)

6.7 Interview responses

Interviews were conducted with 98 women. Forty seven women (47.96%) were married, and 41 (41.84%) lived together with their partners but were not married. Seven (7.14%) were single, one (1.02%) divorced and two (2.04%) married but separated from their partner.

Forty nine women (50.00%) had attended secondary school as the highest qualification and 42 (42.86%) had been to primary school or less. Seven women (7.14%) had a tertiary education.

Forty three women (43.88%) were on a grant to financially support their large families, while 37 (37.76%) were earning less than R2 500 per month. Ten (10.20%) earned between R2 500

and R5 000 per month, while 7 (7.14%) earned more than R5000 per month. One (1.02%) declined to respond to the question. Eighty two women (83.67%) had access to basic water and electricity.

Oral or injectable contraception were used previously by 67 women (68.37%) while 31 (31.63%) did not use contraception. Fifty one women (52.04%) indicated that the reason they had large families was a personal choice. Fifty five women (56.12%) had unplanned pregnancies. One woman (1.02%) attributed her big family to cultural reasons and one desired a big family (Table 6.10).

Table 6.10 Interview responses of GM women (n=98)

Secondary education or more	56 (57.14%)
Income < R2500 pm	20 (20.41%)
Access to basic utilities	82 (83.67%)
Use contraception	67 (68.37%)

7 DISCUSSION

The study revealed that pregnancies in GM women had generally good outcomes for the mother and baby where no extenuating circumstances existed. This conclusion agrees with various other works reviewed that conclude that GM women are not at an increased risk of having pregnancy-related complications (8, 9, 14, 16, 20, 21, 22, 33, 44) especially when ANC attendance rates are high.

7.1 Antepartum findings

The majority of the women in this study were older than 35 years of age (75.40%) with the mean age being 37 years. This is aligned with the expectation of advanced maternal age (>35 years) in the GM group, which has been evident in many studies (4, 6, 9, 10, 11, 17, 21, 23, 26, 33). Agarwal et al (10) noted that their sample of GMP (mean age = 32) was older than the control group of multiparous women (mean age 27), although this is younger than in our study.

Goldman et al (6) have discussed the age-related risks factors faced by GM women and various studies have isolated these medical conditions to HPT and DM (2, 5, 8, 13, 16). This idea was supported by Yves et al (2) who related the contribution of obesity to HPT and DM as resulting from GM women finding it difficult to lose weight gained from repeated pregnancies. In the studies performed by Nordin et al (22) and Hughes et al (9) it was indicated that the difference in the prevalence of HPT between GM women and multiparous women was not statistically significant. Forty-seven percent of Hughes et al's (9) study group of GM women were under 35 years, and they noted that there was an increased prevalence of DM found in the GM group of advanced age. Goldman et al (6) found a higher prevalence of HPT and DM among older GM when compared to the control groups in their study. No

women in our study were found to have existing DM. Oral glucose tolerant tests were not recorded to exclude gestational DM.

Seventeen percent of the women in our study had chronic HPT and five of the 17 (29.41%) were observed to have superimposed PE. Hypertension accounts for one of the five major causes of maternal deaths in South Africa (32). The sample size of our study population was small but still supports that HPT is prevalent in the South African setting. While chronic HPT is found more frequently in the older GM woman (6), PE is conspicuously rarely mentioned in the literature related to GM women. In our results, however, PE, superimposed on chronic HPT and new onset PE, occurred in 7% of the women surveyed.

The relationship between antenatal care and poor pregnancy outcome is well described in various articles. Akwuruoha et al (23) specifically describe the higher prevalence of perinatal mortality in unbooked GM women in relation to booked GM women. Baskett et al (12) noted significant differences in occurrence of low birth weight, neonatal death and in still birth rate between women that attended an antenatal facility and those that did not get antenatal care. In this study there appeared to be an awareness of the importance of booking with 91.35% of women attending antenatal clinics. Previous rationales for poor attendance at antenatal facilities, such as disinclination resulting from previous successful pregnancies without antenatal care (2), and time constraints due to large families (23), did not hold seem to hold true.

Anaemia is universally recognised as a complication of pregnancy and this is expected to be evident in GMP. High parity is associated with iron deficiency, which contributes to anaemia, considered to be of major concern among GM women (18). Bugg et al (18) showed an increased incidence of antenatal anaemia in GM women (22%) compared to multiparous women (16%). The nutritional impact upon, and the contribution to anaemia in, women by

prolonged repeated lactation events is well accepted (31). Of the women in our study, 34.69% presented with anaemia. Information around previous breast-feeding was not collected, yet the study group may have been impacted by iron loss as a result of high parity.

The Department of Health in South Africa has published recent statistics showing a 0.7% decline in HIV prevalence in the antenatal population from 2010 to 2011 (30.2% to 29.5%) (47). However, in the antenatal population aged between 35 years and 39 years, there has been an increase of 1.1% in the prevalence of HIV nationally, from 38.4% to 39.5%. The prevalence of HIV in the antenatal population of Gauteng Province is reported at 28.7%. The prevalence of HIV found in our study was 48.93%, was higher than the national HIV prevalence for the age group (35 years to 39 years). This is notably higher than the prevalence of HIV in the national antenatal population (19.4% greater) and that of the antenatal population of Gauteng Province (20.2% greater). It is more likely to be related to greater exposure to sexual activity and number of sexual partners.

The Saving Mothers 2008 - 2010 reported that the commonest cause of death amongst HIV positive pregnant women was respiratory complications from pulmonary tuberculosis. Our study had a 1.02% rate of tuberculosis with only one patient out of 98 with a definitive diagnosis of pulmonary tuberculosis. Almost 4 out of 5 women who die in pregnancy, at childbirth or in the puerperium are tested for HIV, 70% of which are positive (32).

7.2 Intrapartum findings

In the article by Simonsen et al (20), GMP is not noted to be an independent risk factor for intrapartum complications for young (18 - 34 years) multiparas. Benecke et al (12) found no statistically significant differences when comparing the incidence of abruptio placentae,

placenta praevia, malpresentation and uterine rupture between GM women and multiparous women. This is aligned with Abu-heija et al's (33) study conducted in Jordan. No cases of abruptio placentae or placenta praevia were observed in our study. There was one woman with an antepartum haemorrhage. Hughes et al (9) showed no statistically significant differences in prevalence of overall APH in GM women compared to multiparous women, although Bai et al (17) found the occurrence of APH in GMP (5.8%) was higher than in the total obstetric population they studied (2.3%).

Baskett et al (12) highlighted the point that malpresentations were common in GMP (9%) when compared to the overall hospital incidence (5%). Bai et al's (17) study findings agreed with this. In our study, the incidence of malpresentation was low, with only two women (2%) presenting with breech presentation, no more than one would expect in an obstetric population that includes all groups.

7.3 Modes of delivery

The proportion of NVDs in our study was 66.12%, with none requiring instrumental assistance.

The CS rate in our study was calculated at 32.79% (n=40). This agrees closely with Agrawal et al (7) who quoted a CS rate of 33.3% and stated that there was no significant difference in the CS rate between the GM group and a multiparous control group. In 2011 the CS rate for the Soweto area was 24.79%, with 33000 deliveries including CHBAH and surrounding clinics, and 8179 of them by CS (CHBAH departmental statistics 2011). Goldman et al (6) reported a CS rate of 6.8% for GM women and found that this was significantly less than multiparous women (16.6%). Goldman et al suggested in their discussion that GM women would consider CS as 'humiliating' after five vaginal deliveries. That attitude does not seem

to be shared by the GM women in our study. The CS rate would have been higher if the additional nine women who were booked for CS did not deliver vaginally during the wait for a CS.

Twenty eight (70.00%) of the CSs were emergency CSs, primarily for fetal distress. Nordin et al (22), Hughes et al (9) and Bugg et al (18) found similar results in that the rate of emergency CSs exceeded the rate of elective CS. None of the women who chose elective CSs delivered prior to the CS being performed in our study.

Two studies have investigated the safety of trial of labour and VBAC (36, 37) in GM women. Tarik et al (36) found the outcomes to be positive for the mother and baby. Kugler et al (37) did not find any significant differences in the risks for GM women when compared to the control group. Both studies concluded that VBAC was 'safe and effective' (36). Our study had six women that had successful VBAC deliveries with no maternal or fetal complications.

Yves et al (2) and Gurewitsch et al (27) indicated that augmentation of labour in GMP should be common owing to slow progress of labour. As per protocol, no labours were augmented in our study. Labour was only induced in 3.06% (n=3) of the women in our study, two for postdates and one for PE. Two of these women underwent CSs due to fetal distress while the third, who had an induction for postdates, delivered vaginally. The low prevalence of induction is aligned with the University of the Witwatersrand protocol that contraindicates induction in GM women (35), although this contraindication applies to women of parity ≥ 5 before the current pregnancy. The three women that underwent induction of labour all had a parity of four. In Tarik et al's (27) comparison of IOL with vaginal PG-E₂ with the onset of spontaneous labour in GMP, the authors concluded that 'induction of labour in grand multiparity required caution but was not a contra-indication'. Both Bique et al (40) and Zeteroglu et al (41) conducted similar research and concluded that IOL was 'relatively' safe.

7.4 Postpartum outcomes

Yves et al's (2) review suggested that PPH was associated with GMP owing to physiological changes. There is a risk of uterine rupture as a result of uterine muscle loss associated with repeated stretching of the uterus in high parity. Solomons (5) also highlighted physiological changes (thinning) of uterus as a risk for PPH in multiparous women. He supported this hypothesis by highlighting the fact that he had observed 148 cases of accidental haemorrhage, 130 of which were in multiparous women. Goldman et al (6) saw a significantly higher prevalence of PPH when comparing GM women with multiparous and primiparous women.

Our study showed a low prevalence of PPH (2.04%), and no women suffered uterine rupture. Further, there were no intensive care unit admissions, no woman underwent a hysterectomy and there were no maternal deaths. In Akwuruoha et al's (23) study, two of the three maternal deaths were as a result of PPH. In their discussion, however, they suggested that the deaths were rather a function of lack of access to medical care than pregnancy complications.

7.5 Fetal outcomes

The relationship between fetal outcomes and antenatal care is well known and discussed in various studies. Baskett et al (12) showed a perinatal mortality rate of 47/1000 for grand multiparas compared to 22/1000 for a combined multipara and primigravida group. They went on to demonstrate that these poor outcomes were related to a lack of antenatal care. Neonatal deaths were five times greater in the unbooked group (five cases) compared to the booked group (one case). King et al (43) aimed to reappraise the risks of GMP enumerated by Solomons (5). In their study of 168 GM women, they reported a zero perinatal mortality rate. The women in their study were of low socio-economic status, although they highlighted the fact that there was a 98% attendance rate at antenatal facilities.

In our study, 96.77% of the babies were born alive, however a stillbirth rate of 32/1000 was observed which is considered to be unfavourable (45). It cannot be assumed that GMP was a cause of these stillbirths. Amongst the women that delivered stillborn babies, all four were over the age of 35. Three of them were HIV positive and the HIV status of the fourth woman was unknown.

Baskett et al (12) remarked that a higher prevalence of low birth weight existed when the unbooked and booked groups of the grand multipara were compared (23.9% and 9.4% respectively). For all babies, our results showed a mean birth weight of 2993 g, however the proportion of low birth weight babies was 20.16%, higher than the 14% for South Africa quoted in the Saving Babies 2010-2011 report (45). However, when compared on provincial tertiary level, the proportions of low birth weight babies were similar. As expected, more low birth weight babies are delivered at higher levels of care. Chris Hani Baragwanath Academic Hospital is a provincial tertiary institution and the percentage of low birth weight babies (20.16%) compares almost equally to the 22.1% for provincial tertiary institutions in the country (45).

Congenital abnormalities as a consequence of advancing maternal age are considered a threat to GM women yet there are no findings in the literature regarding such a relationship. There were no findings of congenital abnormalities in this study.

7.6 Socio-economic status

South Africa has a diverse population from which arises a multitude of cultural and religious beliefs. Soweto as a community also includes people from different socio-economic backgrounds. Most of the women in this study had attended school, with 57.14% attending secondary school or higher. The availability of electricity and running water was available in

83.67% of homes but there are still many women who live in areas with limited resources. There was a large group of women (56.14%) with unplanned pregnancies. Fifty one (51.04%) women attributed their large families to personal reasons, either they were in a new relationship or had previously lost children from their earlier pregnancies. Contraception strategies need to be reinforced and these women need to be enlightened about the different methods of contraception. Thirty five percent of women had a bilateral tubal ligation done at the time of CS in this study. Previous studies on GMP have not elaborated on the rates of bilateral tubal ligations at CS.

7.7 Limitations

The sample size was too small to detect any rare but serious outcomes, such as catastrophic blood loss leading to hysterectomy and massive transfusion, and uterine rupture. It was not possible to assemble a control group of low-risk multiparous women for comparing pregnancy risks and outcomes because CHBAH has many high-risk medical and complicated obstetric cases that would be unsuitable as controls.

Data on home births and delivery at private facilities were not available for this study; hence it is not possible to establish whether this is a fully representative sample of Soweto women.

8 CONCLUSION

Since Solomons's 1934 study (5), where he introduced the risks related to multiparity, many studies have explored the issue of whether GM women are at risk for maternal and fetal complications with resulting poor outcomes.

This study has shown good maternal and mostly positive fetal outcomes in a group of GM women who had access to and who largely attended antenatal care facilities. There were few occurrences of obstetric complications observed. The results do not support traditional views that GM women are at risk of poor outcomes owing to advanced maternal age or to physiological changes as a result of high parity or low socioeconomic status.

GM women who are generally healthy and who are afforded access to adequate health care facilities should have good outcomes, as should their babies. This makes it all the more important to educate women, including women who have had many previous successful deliveries, about the benefits of attending antenatal health care facilities.

Appendix 1: Data Collection Sheet

Study no.: ____

Demographics and History			
Age:			
Parity:			
Gravidity:			
Booked:	1 - Y	Race:	1 - African
	2 - N		2 - Coloured
Booking Hb:			3 - Indian
			4 - White
		Gest age:	
		# of fetuses	
RVD:	1 - Pos		
	2 - Neg		
	3 - Not tested		
CD4:			
ARVs:	1 - Y		
	2 - N		
Regimen #:	1 - A		
	2 - B		
	3 - DT		

Medical		Preg Cx	
Cardiac	1	PROM	1
Diabetes	2	APH	2
Epilepsy	3	IUGR	3
Aids Def	4	Placenta Praevia	4
Hypertension	5	Chorioamnionitis	5
Non Aids infxn	6	anaemia	6
Other		Other	

Progress of Labour		
1 st stage:	2 nd stage:	3 rd stage:
Hrs:	Hrs:	Min:
IOL	1 - Y	
	2 - N	
AOL	1 - Y	
	2 - N	
SROM	1 - Y	
	2 - N	
AROM	1 - Y	
	2 - N	
MSL	1 - Thin	
	2 - Thick	
	3 - Clear	
Perineum trauma	1 - Y	
	2 - N	
ICU admission	1 – Y	
	2 – N	
Death	1 – Y	
	2 – N	
Hysterectomy	1 – Y	
	2 – N	
Uterine rupture	1 – Y	
	2 – N	
Blood transfusion	1 – Y	
	2 – N	
Blood loss		
Modes of Delivery		
Caesar: Indication		
FD	1	
CPD	2	
No Progress	3	
Malpresentation	4	
Placenta praevia	5	
Abruptio placenta	6	
Other		
Vaginal:	1 – Normal	
	2 – Vacuum	
	3 – Forceps	
Sterilisation	1 – Y	
	2 – N	
	3 – Refused	

Fetal Outcome

Alive	1 - Y
	2 - FSB
	3 - MSB
Weight:	
Apgar: 1 min	
5 min	
Prematurity	
END	1 - Y
	2 - N

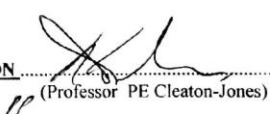
Appendix 2: Interview Sheet

Study no.: ____

Marital Status	1- Single
	2 - Married
	3 - Divorced
	4 - Married but separated
Level of Education	1 - None
	2 - Primary
	3 - Secondary
	4 - Tertiary
Employment	1 - Unemployed
	2 - Full time employed
	3 - Part time employed
	4 - Self employed
Income (pm)	1 - R0
	2 - R0 to R2500
	3 - R2500 - R5000
	4 - >R5000

Water and Electricity	1 – Y
	2 – N
Number and ages of children	
Contraception	1 – Use
	2 - Don't use
If don't use contraception, why?	1 – Personal
	2 - Cultural / Religious
	3 – Unaware
Failed sterilisation	1 – Y
	2 – N
Why a big family?	1 – Personal
	2 - Cultural / Religious
	3 – Unplanned
	Other

Appendix 3: Ethics Approval Letter from the University of the Witwatersrand Ethics Committee

<u>UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG</u> Division of the Deputy Registrar (Research)	
<u>HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)</u> R14/49 Dr Shastra Avendra Bhoora	
<u>CLEARANCE CERTIFICATE</u>	<u>M110110</u>
<u>PROJECT</u>	Obstetric Management and Outcomes of Grand Multiparous Women
<u>INVESTIGATORS</u>	Dr Shastra Avendra Bhoora.
<u>DEPARTMENT</u>	Department of Obstetrics & Gynaecology
<u>DATE CONSIDERED</u>	28/01/2011
<u>DECISION OF THE COMMITTEE*</u>	Approved unconditionally
<u>Unless otherwise specified this ethical clearance is valid for 5 years and may be renewed upon application.</u>	
<u>DATE</u>	28/01/2011
<u>CHAIRPERSON</u>	 (Professor PE Cleaton-Jones)
*Guidelines for written 'informed consent' attached where applicable cc: Supervisor : Professor E Buchmann	
<u>DECLARATION OF INVESTIGATOR(S)</u>	
To be completed in duplicate and ONE COPY returned to the Secretary at Room 10004, 10th Floor, Senate House, University. I/We fully understand the conditions under which I am/we are authorized to carry out the abovementioned research and I/we guarantee to ensure compliance with these conditions. Should any departure to be contemplated from the research procedure as approved I/we undertake to resubmit the protocol to the Committee. I agree to a completion of a yearly progress report. PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES...	

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