Research Report

A comparison of booked and unbooked pregnant women presenting in labour at three health facilities in Region F, Inner City of Johannesburg

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Medicine in partial fulfilment of the requirements for the degree of Master of Science in

Community Paediatrics

Candidate's declaration

I, Siphamandla Bonga Ziphozonke Gumede declare that this research report is my own work. It is being submitted for the degree of Masters of Science in Community Paediatrics (Child Health) in the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at this point or any other University.

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day of	, 2015

Abstract

Background

Antenatal attendance is important for ensuring good pregnancy and birth outcomes therefore booking for care in the antenatal period remains an important gateway to accessing life-saving services and benefits. There is limited evidence on the impact of antenatal booking on birth outcomes in the inner city, Johannesburg. This study aimed to determine the 1) prevalence of antenatal booking and 2) the risk factors for being unbooked and consequences of being unbooked.

Methods

We reviewed birth registers of deliveries between January 2008 and December 2009 from three labour wards within the inner city of Johannesburg. Summary statistics, inferential analysis and logistic regression were conducted using STATA version 12.

Results

Of 12,455 deliveries reviewed, 897 (10.8%) were adolescents. Of total deliveries, 23.8% were HIV positive, 52.2% HIV negative and 24.0% had unknown HIV status. Of women presenting in labour, 14.6% were unbooked. Being unbooked was associated with poor viability (p<0.001), HIV status (p<0.001) and adolescent age (p=0.02), but not pre-term delivery. Also, independent of booking status, having an unknown HIV status was a predictor of poor viability.

Conclusion

The inner city has a significantly lower booking rate than the 95% reported for the country. Being an adolescent or HIV positive was associated with a lower booking rate, raising the

concern that stigma may hinder antenatal attendance. Unbooked women had significantly worse birth outcomes than women who attended antenatal care. The risk of perinatal mortality was associated with an unknown HIV status. Strategies to increase antenatal care particularly for adolescents and HIV positive pregnant women in this region are needed. Further research should be conducted to understand barriers and facilitators of antenatal attendance during pregnancy.

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Acronyms

ANC Antenatal Care

AIDS Acquired Immunodeficiency Syndrome

ART Antiretroviral Treatment
AZT Azidothymidine/Zidovudine

BANC Basic Antenatal Care
BBA Born Before Arrival
C/S Caesarean Section

CCMT Comprehensive Care Management and Treatment

CI Confidence Interval

CMJAH Charlotte Maxeke Johannesburg Academic Hospital COMMIC Committee On Morbidity and Mortality In Children

DHIS District Health Information System

DoH Department of Health GP General Practitioner

HCHC Hillbrow Community Health Centre

HCT HIV Counselling and Testing
HIV Human Immunodeficiency Virus
LMIC Lower and Middle Income Countries

M&E Monitoring and EvaluationMDG Millennium Development GoalMTCT Mother-to-Child TransmissionNVD Normal Vaginal Delivery

PEPFAR President's Emergency Plan for AIDS Relief

PHC Primary Health Care

PMTCT Prevention of Mother-to-Child Transmission of HIV

SD Standard deviation sdNVP Single Dose Nevirapine SRH South Rand Hospital

STIs Sexually Transmitted Infections
WHO World Health Organization

Wits RHI Wits Reproductive Health and HIV Institute

Definitions

Adolescent

For this report, defined (WHO definition) as women between 10-

19 years old

Adult

For this report, defined (WHO definition) as women above 19

years old.

Early-mid

For this report, early-mid adolescents were defined as women

adolescent

between 10-16 years.

Late adolescent

For this report, late adolescents were defined as women between

17-19 years.

Booked women

In this report, booked women refer to all women who presented for

antenatal care (ANC) services for their current pregnancy at

primary, secondary or tertiary health care facilities, including those

referred from private partners and general practitioners (GPs).

Booking status was measured in the labour ward.

Unbooked women

In this report, unbooked women refer to all women who did not

present for any ANC services during their current pregnancy and

presented to a health care facility for the first time during their

pregnancy at the time of labour or delivery.

Term Term is defined as infants born between 37 and 41 weeks of

pregnancy (259 to 293 days) of gestation (1).

Pre-term Pre-term is defined as infants born before 37 weeks of pregnancy

are completed (less than 259 days of gestation) (1).

Post-term Post-term is defined as infants born at forty-two or more weeks

(294 days or more) of gestation (1).

BBA BBA is defined as deliveries that occur before a woman arrives in

labour ward. For this study, we assumed that all these women

delivered by NVD as no interventions could be provided as no

health care workers were present at the time of delivery.

Chapter 1: Introduction

1.1 Background and rationale

1.1.1 Global Maternal Health: Programme implementation and Outcomes

The global health care strategy is driven by the Millennium Development Goals (MGDs) of which the child and maternal health (MDG 4 and 5) and HIV prevention related goals (MDG 6) emphasize the need to reduce child and maternal mortality and reduction of deaths from HIV by 2015. Specifically MDG 4 highlights the importance of reducing child mortality by two thirds, MDG 5 emphasizes the improvement of maternal health by reducing maternal mortality by three quarters and MDG 6 emphasizes reduction of deaths, combating and reversing of spread of HIV/AIDS, malaria and other diseases (2). However, many countries around the world have struggled to implement effective strategies to reduce maternal and child mortality. A review conducted on progress made towards achieving MDGs 4 and 5 report that although there has been progress, due to various challenges the global targets for these goals are unlikely to be reached (3). For example, although confirmed that child mortality has been reduced, the majority of child mortality cases are still concentrated in lower and middle income countries, particularly in sub-Saharan Africa and South Asia. It is for this reason that significant political will and resources have been diverted towards strengthening maternal and child health services.

HIV remains a significant contributing factor towards high child and maternal mortality (4). South African reports have consistently shown that around 30% of pregnant women test HIV positive and of those women, under 5% of infants test HIV positive (5, 6). Research shows that HIV contributes to more than 40% of all maternal deaths and about 35% of infant mortality (6, 7). Consequently, initiatives to strengthen maternal and child health services have included integration of HIV counselling and testing (HCT) and prevention of mother-to-

child transmission of HIV (PMTCT) into the standard of care offered. This package of care has been endorsed by the South African Department of Health and is considered as part of the basic antenatal care (BANC) services to be offered to all pregnant women with the aim of ensuring good health outcomes for both pregnant women and their infants (8). The BANC guidelines promote utilization of antenatal care services and reiterate that all pregnant women are entitled to and receive quality antenatal care services. These services comprise of both counselling and clinical activities where counselling includes provision of information on nutrition, discussion of socio-cultural barriers in the context of antenatal attendance and HIV testing, avoidance of risk factors such as drug and alcohol use, recognition of potential danger signs in pregnancy and future family planning (8, 9). Clinical services include monitoring of pregnancy, early screening of adverse events and screening of STIs (including HIV).

The World Health Organization (WHO) has encouraged development of policies and guidelines that emphasize the importance of antenatal care and ensuring integration of antenatal, PMTCT and maternal services within antenatal care (10). Therefore it is not surprising that integration of PMTCT services with BANC has received global endorsement particularly in countries situated in sub-Saharan Africa, despite their low income status. Understandably, developed countries have emerged strong in implementing and developing policies and guidelines that ensures integration of services within antenatal care services (such as family planning and PMTCT), largely due to strong political buy in which has played a vital role in sustaining health systems and also ensuring accessibility of services by pregnant women as early as possible. The high socio-economic status in developed countries also allows feasibility of implementation of new interventions. This is mainly due to availability of operational resources and access to health services (11).

In contrast, low and middle income countries (LMIC) such as those located in sub-Saharan Africa have taken longer to implement global policies and guidelines, particularly those addressing the importance of integration of services in antenatal clinics (11). Although health care services have been oriented towards the delivery of integrated patient care, booking and antenatal attendance remains poor. In LMIC unbooked women account for 17% to 29% of births (12). To further confirm challenges associated with antenatal booking, the WHO (11) and Demographic and Health Survey (13) reported that out of all pregnant women attending antenatal care during their pregnancy, globally only 53% of women are able to attend four antenatal visits and markedly fewer (36%) in LMIC. Reasons for such low service utilisation have been the lack or no availability of resources for health services which impacts adequate staffing and drug supply thereby leading to delays in service provision, poor political will to support and implement effective strategies and interventions, few skilled health care workers and poor administration including poor patient booking system and inflexible operating times resulting in low utilisation of antenatal services (12, 14). In order for women to receive interventions to improve pregnancy outcomes they need to attend antenatal care. This low level of ANC attendance in LMIC shows that there is a large amount of work still to be done in meeting the MDGs 4, 5 and 6 by 2015 in LMICs (15).

1.1.2 Maternal and Child Health in South Africa

South Africa, like many other sub-Saharan African countries, has not shown much improvement towards achieving targets set for MDGs 4, 5 and 6. In 2005, the South African government produced its first report on progress towards achieving the MDGs (16). It was in this report that early evidence emerged that South Africa was not on target to meet the health related goals. Another worrying factor contained in this 2005 report was the steady increasing trend of HIV prevalence and associated deaths (16). Subsequent progress reports were released in 2007 and 2010 and reported similar findings to that reported in 2005 (16).

Specifically, high HIV prevalence, unemployment, gender inequality and poor living conditions were documented as barriers to reaching country targets.

Worryingly, while child and maternal mortality showed a decline globally, this was not the case with South Africa and most of sub-Saharan Africa. In an interim report of the Committee on Morbidity and Mortality in Children (COMMIC) in 2012, the South African government reported that the under-five mortality was 50.7 per 1000 which has remained over two times higher than the MDG target of 20 deaths per 1000 live births to be achieved by 2015 (17). The report also showed that the maternal mortality ratio was 269/100 000 live births which was significantly higher than the MDG target of 38 maternal deaths per 100 000 live births (17, 18).

Contributing factors to failure in achieving these targets in South Africa has been HIV, late or no health seeking behaviour especially antenatal care, poor quality of services offered due to poor implementation of policies and guidelines, staff attitude, poor integration and linkages to care, and poor or no community involvement or awareness regarding services offered within the public health setting. In addition, social determinants such as poverty, cultural beliefs and attitudes towards health services have also played a critical role in poor antenatal attendance (19, 20). To reduce the impact of these barriers on maternal and child health outcomes, the South African government has encouraged antenatal attendance and consistent implementation of strategies to improve antenatal attendance. These strategies included changes to policy to improve access for all pregnant women including; pregnant women to be seen the first day a woman presents to a clinic and clinics to attend new antenatal clients on a daily basis (4).

There have been various studies (4, 8, 21) examining the impact of missed opportunities in antenatal care, consequences of poor antenatal attendance and the importance of linkage to care between antenatal care and delivery units or labour wards. These studies highlight that community awareness and mobilisation to increase linkage to care is a gap. According to a study conducted in southwest Nigeria, creating community awareness towards antenatal care services is crucial and feasible and would increase early access to antenatal care for pregnant women (12) with appropriate and timely referrals to primary health care facilities. This finding is supported by a study conducted by Fanata and Worku (8) who emphasized the importance of linking communities to the health facilities in order to improve access to health care and reduce stigma. This linkage has recently been observed in South Africa through the introduction of a Primary Health Care (PHC) re-engineering model.

The Primary Health Care re-engineering (PHC re-engineering) model was introduced in South Africa in late 2012 with the aim of mobilizing communities and creating community awareness around health services which included early access to health care services (22). The PHC re-engineering plan introduces a ward based outreach team component which consists of community health workers supervised by professional nurses. Community health workers are assigned to visit households to identify individuals who may require immediate care and ensure referral to a health facility is made immediately (22). Included in this role is identification and referral of all pregnant women to antenatal care timeously for access to quality health care such as early screening and assessments and other relevant antenatal services. Based on evidence from Brazil, the effectiveness of this model in other settings promises to yield good health outcomes for maternal and child health (22). In evidence from Brazil, the implementation of the PHC re-engineering model showed significant success; with

its implementation maternal mortality dropped from 70.3/100 000 live births in 2009 to 60.8 in 2011 while antenatal attendance improved from 80.9% in 2006 to 98.7% in 2014 (23, 24).

1.2 Literature Review

1.2.1 Antenatal Attendance

In South Africa, between 5-10% of women fail to attend any antenatal services for various reasons including the high cost of travelling to facilities, poor booking system (fear of being turned away), inconvenient operating times, the clinic being far from where they live and poor staff attitude (4, 12). Unfortunately, failure to attend antenatal care has consequences to both women and the unborn infant. For the woman, late diagnosis and identification of infections and diseases such as diabetes and hypertension, and possible birth abnormalities are real concerns, (25) which contribute to the poor infant outcomes including low birth weight, prematurity and still birth (26). It is therefore very important to develop strategies that will promote antenatal attendance with these facts in mind.

Antenatal booking or attendance is an important predictor of good pregnancy and infant birth outcomes. This has been confirmed by Hussain, et al. (27) which highlighted that antenatal care provides an opportunity to identify and intervene in high risk pregnancies and is important to improve pregnancy related outcomes. According to a study conducted by Joshi, et al. (28), completing all recommended antenatal visits reduces chances of suffering from pregnancy induced hypertension and pre-term labour. Ideally, a minimum of four antenatal visits are important in ensuring that the pregnancy is well monitored throughout and that all diagnostic assessments are completed under supervision of skilled health care workers.

Despite the overwhelming evidence regarding the importance of antenatal care attendance, a South African study by Wabiri, et al. (13) reported that less than 40% of women attend antenatal care before 20 weeks. The same study also showed that only between 36-53% pregnant women attended four antenatal visits.

Studies have emphasized that antenatal care is important for screening for high risk pregnancies including those with diabetes, hypertension, multiple gestation and other medical conditions that could adversely affect pregnancy outcomes (29, 30). Screening at antenatal care includes vital blood tests such as HIV testing and screening for other STIs that could affect pregnancy. A South African study conducted in the Northern Cape and Gauteng by Dinh, et al. (31) pointed out that poor antenatal booking and lack of testing for HIV and syphilis at antenatal care increased chances of HIV transmission from a mother to her child and resulted in other poor birth outcomes and neonatal death.

Beyond medical assessments and evaluations, antenatal care also plays a vital role in preparing women for labour and motherhood. This is usually achieved through health information and counselling sessions offered at the antenatal clinic. Birdthistle, et al. (32) showed in a study among people in Swaziland that failure to attend antenatal care enhanced the chances of women missing family planning counselling. Therefore, counselling and provision of information during pregnancy should be provided on a regular basis, particularly at every antenatal visit to ensure women understand the importance of antenatal care and family planning such that these opportunities for comprehensive management are not missed.

1.2.2 Factors contributing to poor antenatal attendance

According to the WHO framework outlining the social determinants of maternal health [figure 1], the consideration and implementation of maternal and child interventions should not neglect possible factors causing poor antenatal attendance. Using the social determinants of health for maternal health as a conceptual framework, various factors associated with poor maternal and child health outcomes are clearly outlined.



Figure 1: The Social Determinants of Maternal Health. Adapted from WHO (2011)

The framework highlights individual attributes, family and peer influences, and community context and health services as intermediary social determinants of health while governance, policies, culture and social values are classified as structural social determinants of health inequities. Some of these factors are individually oriented while some affect the entire community. Tomlinson, et al. (33) showed in a South African population that underlying factors leading to poor birth outcomes are not due to clinical complications but rather due to

non-clinical barriers. Non-clinical factors causing poor antenatal attendance in low and middle income countries include poor socio-economic status such as poverty, poor living conditions, poor knowledge and lack of education for most women (34)

1.2.2.1 Individual attributes

According to the framework a woman's age, knowledge of health services, number of children and birthing experience can influence antenatal attendance. Age has been noted to affect utilisation of health services; therefore it is important to understand how age impacts uptake particularly of maternal health services. Literature indicates that perceptions and attitudes towards pregnancy and health services, particularly antenatal care, differ between adults and adolescents (35). According to a study conducted in Ethiopia by Gatta and Thupayagale-Tshweneagae (35) on adolescents' knowledge regarding health care, it appeared that most adolescents would prefer health services to be offered outside health facilities due to stigma and discrimination towards adolescents by health care workers. Adolescent's failure to attend antenatal clinic also signals missed opportunities for health information offered at antenatal care, counselling and preparation for motherhood. There are very few studies that have described risk factors or predictors of poor birth outcome associated with adolescents (36-38). Therefore, these studies recommend a focus on improving care for adolescents during pregnancy. (39).

Individual attributes also consider previous birthing experience as a factor to antenatal attendance. Women falling pregnant for the first time may be more anxious and are likely to attend antenatal care due to less antenatal experience and pregnancy awareness. In contrast women who have had previous pregnancies and attended antenatal care may delay antenatal

attendance due to their prior birthing experience which did not require any medical attention or due to facility and health worker interaction (40, 41)

Knowledge and education has been modelled to be one of the key factors in antenatal booking not only for pregnant women but also for all women intending to conceive (42). A study conducted in Italy showed that women who were informed or educated around antenatal or reproductive stages were more likely to attend antenatal care as compared to those who were not informed (43). The study recommended that efforts should therefore be invested in provision of information around antenatal care and reproductive health for all women at reproductive age (43). Additionally, a study conducted by Mashuda, et al. (44) recommends that feasible and cost effective interventions such as education and provision of information to pregnant women in low and middle income countries should be explored in order to reduce poor birth outcomes (44).

1.2.2.2 Family Influences and Community Context

Part of successful and cost-effective approaches to improving antenatal attendance and birth outcomes is the increasing family and community involvement and integration of other health programmes within antenatal care services (45). A study conducted in Burkina Faso which looked at factors affecting antenatal booking, highlighted that communities with no health facilities in their close proximity were more likely to deliver at home instead of a hospital (29). The same article also highlighted financial and socio-economic barriers within families. Families with poor socio-economic status or low income may struggle to attend health facilities. (29). In addition, most families have only one member who provides means of income especially in poor communities which makes it more difficult to access health services especially if there is transportation required. It is therefore important to consider

families or community socio-economic status and distance to facilities when assessing barriers to antenatal care attendance/access.

1.2.2.3 Provision and Accessibility of Health Services

Health services provided within antenatal care aim to provide optimum basic antenatal care services. Adequate health service delivery depends on staff skills and technical competencies, acceptability of services and user associated with care. The focus of these services should aim and concentrate on screening and treating pregnancy related conditions, health education and maximise health systems strategies for improving antenatal services and pregnancy outcomes.

Booking times have been one of the major concerns within the South African public health setting. A South African study examining reasons for women's failure to attend antenatal care early highlighted that women fail to attend antenatal care due to poor facility booking systems and inflexible operating times (4). The study indicates that facilities turned away women because they had presented too early in their pregnancy. Rigid booking systems meant the majority of pregnant women would not be seen early in their pregnancy and some would likely be turned away until the last trimester (4). Patients or pregnant women being turned away from care have been associated with staff attitude, stigma and discrimination from health care workers and have consequences such as failure to test and treat HIV and other STIs at antenatal clinic.

HIV counselling and testing and ART initiation within antenatal clinics is considered an effective intervention for most sub-Saharan countries as HIV has been the major cause of maternal and infant mortality in the region (46). In most high income countries, HIV testing

at antenatal care has been made mandatory while most low and middle income countries have kept it as a voluntary option.

A study conducted by Clark (47) in Botswana suggested that mandatory HIV testing for all pregnant women would be effective in preventing HIV transmission from mother to child. A study conducted on scaling up of health services highlighted that women of reproductive age should be educated on HIV in pregnancy and also be provided with options that would ensure access to antenatal clinics as early as possible and eventually improve birth outcomes (48).

Provision of HIV and ART care during antenatal care is critical to both mother and infant and therefore should be prioritised as early as 14 weeks (49, 50) to ensure increased chances of preventing HIV transmission from mother to child (31, 32). However, DHIS data suggests that around 60% of pregnant women infected with HIV are initiated onto ART within public health settings. This is insufficient considering the consequences of HIV in pregnancy (49). This is also in consideration that antenatal HIV prevalence has remained around 30% in the South African public health setting (5). Ideally, countries with high HIV prevalence, such as South Africa, should have high ART initiation.

1.2.2.4 Governance and Policies

Development of policies and guidelines associated with antenatal services, maternal and child health should aim to support and improve clinical outcomes within antenatal care settings. These documents should focus on reproductive health and rights, law, social protection and education. Various policies and guidelines have been developed by the South African government, however the implementation for some of these policies and guidelines has not been consistent or effective.

Basic antenatal care (BANC) guidelines are one of the important guides that were adopted and well implemented by the South African government. BANC sets standards and recommendations of antenatal services that should be offered to all pregnant women. BANC also highlights the importance of attending all antenatal services in order to receive optimum care throughout pregnancy. This eventually is important in preparing women for motherhood and parenting (51).

In addition, initiatives such as Campaign on Accelerated Reduction of Maternal and child Mortality in Africa (CARMMA) emphasises antenatal coverage in the African continent. CARMMA was an African Union initiative which aimed at providing a plan of action for reducing maternal mortality and achieving MDG 5. This campaign listed antenatal care coverage as an important strategy that should be adopted in addressing maternal mortality in the continent (52). Furthermore, CARMMA emphasizes universal access to reproductive health services. Services regarded as important under reproductive health included family planning, screening of HIV and other STIs and youth friendly services especially towards sexual reproductive health which is also noted as a key strategy for youth empowerment, development and wellbeing (52).

HIV and ART related guidelines have been reviewed several times since 2004. Through research, guidelines and policies, recommendations to intensify and improve prevention of mother-to-child transmission were explored. The South African government has continuously improved its PMTCT guidelines which emphasized provision of ART to most pregnant women who are HIV positive. Without any ART intervention to a mother or the infant chances of HIV transmission from mother-to-child are between 15%-45% (53). The latest

South African guidelines on prevention of mother-to-child transmission emphasized that initiation of ART as triple therapy to HIV positive pregnant women immediately without waiting for CD4 cell count results and should reduce mother-to-child HIV transmission to less than 3.4% and also result in better maternal and perinatal outcomes (6).

Transmission of HIV from mother-to-child occurs during the antenatal period, labour and delivery and the post natal period through breast feeding. Transmission is linked to maternal viral load and the earlier in pregnancy one initiates ART the lower the risk of MTCT transmission of HIV at time of HIV exposure. (47). Consequently the earlier in pregnancy women book and receive care, the lower the risk of mother-to-child transmission of HIV. A study conducted in Johannesburg by Hoffman, et al. (54) on effects of highly active antiretroviral therapy duration and regimen on risk of MTCT showed that the longer a women was on ART during pregnancy the lower the transmission rate of HIV from mother-to-child (54).

While guidelines and clinical procedure have emphasized the importance of clinical diagnosis and treatment, it is unfortunate that barriers around culture and social norms have been continuously neglected. Cultural and social values have a visible role towards antenatal attendance and are indirectly linked to pregnancy and birth outcomes.

1.2.2.5 Culture and social values

In South Africa, cultural and social values may support and improve access to antenatal care. There are different behaviours associated with culture and religion that affect antenatal attendance during pregnancy within the South African population. Ngomane and Mulaudzi (20) conducted a study that focused on barriers to antenatal attendance and findings showed

that most women were not attending antenatal care early in their pregnancy due to cultural beliefs.

Ngomane and Mulaudzi (20) also highlighted that women who were more religious were more likely to attend antenatal care during pregnancy than those who were not, while the same study highlighted that women who have cultural beliefs were likely to delay antenatal attendance until the third trimester for cultural reasons (20). Cultural norms further highlight roles of men in decision making especially towards health seeking behaviours. Ngomane showed that pregnant women were likely to follow their husbands' instructions towards health seeking behaviour (20). This means any cultural intervention that aims to improve antenatal care attendance should also focus on social determinants such as gender norms which would allow and emphasise involvement of men within antenatal care. Overall, it is important to emphasise and pay attention to cultural, traditional and religious roles within communities and how these affect antenatal care attendance.

1.3 Rationale for the study

Although multiple studies have been conducted showing that unbooked women presenting in labour have more risk factors than booked women (12, 55), not many have been conducted in a mobile community with a high antenatal HIV prevalence (29.6%) (5) living in an area with a high unemployment rate and poor socio-economic status as that found in Region F of the inner-city of Johannesburg. Literature indicates that there have not been many studies adopting a secondary data analysis approach of labour ward records to determine the prevalence of unbooked women and compare birth outcomes among booked and unbooked women. There have been limited studies assessing booking patterns and birth outcomes amongst adolescents and adults.

Therefore, this study aimed to determine the prevalence of women who did not attend antenatal care clinic during their current pregnancy (unbooked women). This study also aimed to compare birth outcomes for the booked group of women to the unbooked group. The study also allowed comparison of birth outcomes for booked and unbooked women separated into categories including adolescents and adults. This comparison will assist in supporting existing evidence highlighting the importance of antenatal attendance for good birth outcome (56). This study also aims to provide evidence to guide appropriate decisions and effective interventions in the region to improve antenatal care.

1.4 Study Aims and Objectives

This research study aimed to:

- 1.4.1. Determine the prevalence of unbooked women;
- 1.4.2 Describe birth characteristics of women at the different facilities
- 1.4.3. Compare birth outcomes between booked and unbooked women;
- 1.4.4. Compare the demographics of, and risk factors associated with booking status, birth outcome and delivery method.

Chapter 2: Methodology

2.1 Study design

We conducted a cross sectional study using a secondary data analysis approach on data collected between January 2008 and December 2009 to determine the prevalence of antenatal booking status during pregnancy and to explore the relationship of booking status with multiple outcomes including birth outcomes (dead or alive) and delivery method among women accessing care at three health care facilities in the region F sub-district (innercity) of Johannesburg Metro Municipality. Primary data collection was done by Wits Reproductive Health and HIV Institute (Wits RHI) to assess the birth outcomes amongst HIV positive unbooked women presenting in labour for delivery. Due to unanswered questions around the prevalence of unbooked patients and factors associated with booking status at facilities, it was deemed appropriate to use the current database for secondary data analysis to answer the above questions.

2.2 Study Setting

The primary data was collected in the labour wards of Charlotte Maxeke Johannesburg Academic Hospital (CMJAH), South Rand Hospital (SRH) and Hillbrow Community Health Centre (HCHC). These three facilities provide services to the population of the inner city of Johannesburg (region F) and outlying areas. As part of Wits RHI's health system strengthening objectives, these facilities receive technical assistance for improving service delivery. Therefore, the facility sampling frame comprised of purposeful selection based on existing relationships between Wits RHI and the Department of Health (DoH) within the region. The above facilities are the only three facilities providing birthing services (labour ward services) in region F. However, CMJAH and SRH are referral facilities therefore providing services to patients from many regions within and outside of the country, for

example data suggests that these facilities provide antenatal, maternal and obstetric services to patients from Zimbabwe, Swaziland, Lesotho and Mozambique. A more detailed description of each site is found below.

Charlotte Maxeke Johannesburg Hospital (CMJAH), located in Parktown (north of the innercity of Johannesburg) is one of two large tertiary hospitals in Gauteng Province providing an array of diagnostic and curative services to patients. CMJAH also provides comprehensive obstetric services for any complicated maternal cases ranging from hypertension, diabetes mellitus, previous caesarean section and other chronic conditions. The hospital has a specialised unit for pregnant women which provides all antenatal care services including screening of STIs, counselling for HIV testing, PMTCT services and genetic counselling (for mothers at risk of having an infant with a birth defect or where a genetic disorder has been identified). This includes provision of information, genetic testing and provision of treatment and other options available. District Health Information System (DHIS) data shows over 7,000 women attend antenatal care services in CMJAH every year. Over 95% of those are screened and tested for syphilis and HIV. An average of 30% women are diagnosed HIV positive at antenatal clinics (5). Identified HIV positive pregnant women are started on ART treatment at the antenatal clinic as opposed to the previous procedure of referral to a separate ART initiation unit. DHIS data shows that public health facilities initiate ART to over 60% of HIV positive pregnant women. About 8,000 deliveries from CMJAH are reported to the DHIS which includes referrals from other satellites clinics. The hospitals and community centres that have delivery or labour ward units are linked with primary health care clinics to ensure strong referral for pregnant women between antenatal care at PHC level and hospitals thus ensuring most pregnant women are effectively referred to labour ward for delivery.

South Rand Hospital (SRH) is a district hospital located to the south of the inner-city of Johannesburg and provides services to the community of three suburbs i.e. Rosettenville, South Hills and Turfontein and one municipality i.e. Ekurhuleni Metro. The antenatal clinic provides all antenatal care services as recommended through Basic Antenatal Care (BANC) which includes health education, assessment of pregnancy complications, screening of STIs, counselling for HIV testing and PMTCT services. SRH also provides obstetric services to maternal complicated cases but also refer complicated cases to CMJAH. DHIS data shows that over 5,000 women attend antenatal care services in SRH every year including referrals. Over 95% of those are screened and tested for syphilis and HIV and about 30% of those are diagnosed as HIV positive at antenatal clinic with 70% of HIV newly diagnosed started on ART. According to the DHIS, over 6,000 deliveries are reported at South Rand Hospital every year. After delivery, all HIV positive women are referred either to the nearest primary health care clinics (PHC) or Virology clinic (ART service point within the hospital) for continued care.

Hillbrow Community Health Centre (HCHC) is the only community health centre located in the inner city of Johannesburg providing services to a mobile community of the inner city. HCHC provides antenatal services to pregnant women from the inner city which consists of a large proportion of migrants mobile from other provinces and countries such as Zimbabwe, Mozambique and Swaziland. HCHC also provides obstetric services to maternal cases but similarly to SRH refers any complicated cases to CMJAH. According to DHIS data, more than 5,000 women are seen at the antenatal clinic every year and more than 95% of those are screened and tested for syphilis and HIV. About 30% of women are diagnosed as HIV positive and 70% are started on ART at the antenatal clinic. DHIS has reported an average of 7,000 deliveries observed every year in HCHC. This includes women who attended antenatal

care in the facility and those who presented for delivery at the facility without any previous antenatal visit.

These facilities have a clear flow or movement of pregnant women between antenatal, maternal-obstetric, postnatal and adult ART service points. This allows all booked HIV positive pregnant women to be followed up from antenatal care until referred into an adult ART clinic after delivery. The provision of integrated antenatal and postnatal HIV care ensures improved child survival through adequate provision of PMTCT services (31). Beside antenatal care services and labour ward services, these facilities also provide postnatal care services for all new mothers.

2.3 Study population

The study population consisted of women who were pregnant and delivered in one of three facilities in City of Johannesburg, Region F (Charlotte Maxeke Johannesburg Academic Hospital, Hillbrow Community Health Centre and South Rand Hospital).

2.4 Study sample

Primary data was collected through review of labour ward registers and information was collected as part of a labour ward birth audit that was conducted by Wits RHI at Charlotte Maxeke Johannesburg Academic Hospital, Hillbrow Community Health Centre and South Rand Hospital. Not all registers were reviewed as some of the birth registers were missing. Availability of registers has been an ongoing challenge for most region F facilities not only in labour wards but across all service points. A sample of registers from CMJAH for 2008-2009 was collected. Because of sampling, CMJAH provided fewer data entries compared to HCHC and SRH i.e. only 799 records were reviewed.

2.4.1 Sampling Frame and Method

All data collected from the three facilities were used to determine the HIV prevalence of unbooked women and compare infant birth outcomes and delivery method between booked and unbooked women. The original data was collected on all pregnant women who were recorded in labour ward registers from January 2008 to December 2009 from HCHC and SRH. A sample of registers from CMJAH was reviewed.

2.4.2 Inclusion criteria

All births recorded at CMJAH, SRH and HCHC between January 2008 and December 2009 was included. This included all deliveries at the facility and BBAs that were subsequently managed at the facility and recorded in the birth register

2.4.3 Exclusion criteria

There were no records excluded during collection and analysis for this study.

2.5 Sample size

A total of 12,455 records over a two year period i.e. between January 2008-December 2009 from the three maternal and obstetric units were included in the sample for analysis. Of 12,455 records collected; 7,543 patients were from HCHC, 4,113 records were from SRH and only 799 records were from CMJAH. Out of all three facilities; only 8,342 records from CMJAH and HCHC provided data on age as this variable was not collected in SRH. Furthermore, data on parity and gravida was only collected for CMJAH. The sample for CMJAH was smaller than the other sites due to sampling of data in the original data collection. The original data were collected for two different studies.

Routine monitoring data obtained from the DHIS for sub-district Region F indicated that in 2008 the unbooked rate was approximately 5%. DHIS also reported 26,792 deliveries from region F in 2008-2009 period and we recorded 12,455 (46.5%) births. The lower number we have compared to DHIS is due to a combination of sampling data at CMJAH and missing records at HCHC and SRH.

2.6 Data collection

Using a structured data collection tool, labour ward birth registers were reviewed for the following information:

- Clinic Number: The unique number assigned to each patient within the facility;
- Booking status: In a South African public health context, booking status is defined in the context of booked or unbooked. Specifically, a woman with a booked status is someone presenting in labour at a delivery ward having attended one or more antenatal care appointments during pregnancy services before delivery. In contrast, unbooked status is a woman who failed to attend antenatal care during her pregnancy and presented for delivery.
- Age of mother age of women presenting for delivery at labour ward in years. Age was described as both a continuous and categorical variable where appropriate. For this study; adolescents were defined (WHO definition) as women between 10-19 years old. Adults were defined (WHO definition) as women above 19 years old (57). For this study, early-mid adolescents were defined as women between 10-16 years and late adolescents were defined as women between 17-19 years.
- **Gravida** (WHO definition): Defined as the total number of pregnancies, regardless of birth outcome i.e. abortion, still born, alive.

- Parity (WHO definition): Defined as the total number of deliveries after 28 weeks gestation.
- **Duration of pregnancy** (in weeks): to classify if delivery is Term or Pre-term.
- **Gender of infant**: defined as male or female.
- **Birth outcome/Viability:** for the purpose of this study, refers to whether an infant is born alive or dead. For those classified as dead, the definition also included miscarriages, stillbirths and those who were born alive but died shortly thereafter.
- **Pregnancy outcome:** For the purpose of this study pregnancy outcome is reported as a combination of both viability (infant born alive, dead or unknown) and duration of pregnancy at delivery (pre-term and term deliveries).
- **Method of delivery**: Delivery performed through normal vaginal delivery (NVD), Caesarean Section (C/S) or classified as unknown delivery method.
- **HIV status:** Defined as HIV positive, negative or unknown. Unknown HIV status referred to a case where sero-positive or negative status was not recorded or confirmed in the delivery record or HIV test was not conducted or where it is written as refused an HIV test.

Data was entered into Microsoft Excel worksheet. Only women who delivered at a facility or came to one of these facilities shortly after delivery are registered or recorded in facility birth registers.

2.7 Data Analysis

For analysis, data was coded and analysed using STATA version 12 (STATA Corporation, College Station, Texas, USA). Variables analysed included booking status, age, birth outcomes (infant born alive or not), delivery method and HIV status. Both descriptive and inferential statistics were performed. Descriptive and summary statistics are presented with the 95% confidence interval (CI). Descriptive analysis included determining the frequencies and means with 95% confidence interval and or standard deviation of unbooked women accessing all three facilities in region F. Chi squared test or Fischer Exact test (for observations below 5) were used for analysing categorical variables. Inferential statistics included logistic regression to determine factors associated with booking status, delivery method and infant birth outcome. A p-value indicating significance of ≤0.05 was also used. Lastly, logistic regression analyses were conducted for all factors associated with birth outcomes.

2.8 Ethical Considerations

Ethics clearance for the study was obtained from the Human Research Ethics Committee of the University of the Witwatersrand (M121148). Patients' names or any information linking to patient identities were not collected.

2.9 Funding

Primary analysis was part of operational research for health systems strengthening grant within Wits RHI funded by President's Emergency Plan for AIDS Relief (PEPFAR).

Chapter 3: Results

This chapter reports on the prevalence of antenatal booking status and factors associated with booking status i.e. birth outcomes, delivery method and age for all women who delivered in Charlotte Maxeke Johannesburg Academic Hospital, Hillbrow Community Health Centre and South Rand Hospital between January 2008 and December 2009.

Results are outlined to show characteristics of the study population and factors associated with each of the following variables; booking status, birth outcome and delivery method. Specifically, table 1 describes key study variables, particularly prevalence of unbooked status, by facility. Factors associated with booking status, birth outcome, delivery method and other variables are presented in tables 2-6. Therefore, the results chapter is structured as follows: 1) characteristics of study population, factors associated with 2) booking status, 3) pregnancy outcomes (viability and duration of pregnancy at delivery), and 4-6) delivery method. Table 7 and 8 shows the logistic regression analyses assessing the risk of mortality (poor viability outcome) and unbooking status to the following variables; 1) booking status, 2) maternal HIV status, 3) age of women and 4) duration of pregnancy at delivery.

3.1 Characteristics of the study population

Of the total 12,455 records, 7,543 (60.6%) were from HCHC, 4,113 (33.0%) were from SRH and 799 (6.4%) records were from CMJAH. Of 8,342 records that documented maternal age; 7,396 (88.7%) were adults, 897 (10.8%) were adolescents and 49 (0.6%) records in CMJAH and HCHC did not provide age information. The mean age was 25 years [SD~5.2, range 10-48 years]. Overall, 2,968 (23.8%) women were HIV positive, 6,498 (52.2%) were HIV negative and 2,989 (24.0%) of women reported for delivery with an unknown HIV status.

There was little variation observed with duration of pregnancy at delivery across all facilities. Of the 12,455 records; 12,168 (97.7%) had term delivery, 264 (2.1%) had pre-term delivery (less than 37 weeks) and 23 (0.2%) women had a post-term delivery (42 weeks and above). There was a higher proportion (72.3%) of pre-term deliveries in CMJAH as compared to HCHC and SRH. Data on parity and gravida (only recorded by CMJAH) indicated that the mean gravida was just above two 2.3 (SD~1.3) while the mean parity was 1.1 (SD~1.2).

Data on delivery method indicated that 11,391 (91.5%) women had normal vaginal delivery (NVD) and 1,060 (8.5%) had caesarean section (C/S). There were four stillbirths recorded from CMJAH. HCHC, as a maternal obstetric unit (MOU), does not perform caesarean section deliveries therefore no caesarean section deliveries were recorded in HCHC therefor all 7,543 deliveries recorded in HCHC were NVD. A comprehensive review of outcomes along with facility specific variation is found in Table 1 below.

Table 1: Characteristics of the study population by study site¹

Characteristics	СМЈАН	НСНС	SRH	TOTAL 1	p-value (0.05; 95% CI)
Number of records, n (%)	799 (6.4)	7,543 (60.6)	4,113 (33.0)	12,455	-
Age of mother, mean (SD)	26.75 (5.8)	25.32 (5.1)	NOT COLLECTED	8342, 25.46 (5.2)	-
^Age category, n (%, CI)	799 (9.6)	7,543 (90.4)	NOT COLLECTED	8,342	
Adolescents (10-19)	78 (9.8)	819 (10.9)	NOT COLLECTED	897 (10.8, 10.1-11.4)	n= 8,342
Adults (>19)	714 (89.4)	6,682 (88.6)	NOT COLLECTED	7,396 (88.7, 88.0-89.3)	p= 0.348
Missing/unknown	7 (0.9)	42 (0.6)	NOT COLLECTED	49 (0.6, 0.4-0.8)	<u>-</u>
Parity mean (SD)	1.07 (1.17)	NOT COLLECTED	NOT COLLECTED	1.07 (1.17)	-
Gravida mean (SD)	2.26 (1.26)	NOT COLLECTED	NOT COLLECTED	2.26 (1.26)	-
Maternal HIV status, n (%, CI)					
HIV Negative	474 (59.3)	3,270 (43.4)	2,754 (67.0)	6,498 (52.2, 51.3-53.1)	
HIV Positive	204 (25.5)	1,897 (25.1)	867 (21.1)	2,968 (23.8, 23.1-24.6)	N=12,455
HIV Unknown	121 (15.1)	2,376 (31.5)	492 (12.0)	2,989 (24.0, 23.3-24.8)	p<0.001
Booking status, n (%, CI)				1	1

¹ For variables where "n" was less than total number of records (12,455); causes were either missing records or registers, facility not recording or collecting the variable or sampling for example SRH did not record age of women presenting for delivery. Instead of all registers, a sample of registers from CMJAH for 2008-2009 was collected and used for the study. All variables except for age category, used number of records as a denominator

Booked	736 (92.1)	5,813 (77.1)	3,661 (89.0)	10,210 (82.0, 81.3-82.6)	N=12,455
Unbooked	57 (7.1)	1,728 (22.9)	32 (0.8)	1,817 (14.6, 14.0-15.2)	
Unknown	6 (0.8)	2 (0.03)	420 (10.2)	428 (3.4, 3.1-3.8)	p<0.001
Duration of Pregnancy, n (%,	CI)				
Term deliveries	593 (74.2)	7,517 (99.7)	4,058 (98.7)	12,168 (97.7, 97.4-98.0)	N=12,455
Pre-term deliveries	191 (23.9)	26 (0.3)	47 (1.1)	264 (2.1, 1.9-2.4)	p<0.001
Post-term deliveries	15 (1.9)	0 (0)	8 (0.2)	23 (0.2, 0.1-0.3)	p<0.001
Delivery method ² , n (%, CI)		1			
NVD method	719 (90.0)	7,543 (100)	3,129 (76.1)	11,391 (91.5,91.0-91.9)	N=12,451
C/S method	76 (9.5)	0 (0)	984 (23.9)	1,060 (8.5, 8.0-9.0)	p<0.001
Viability ³ , n (%, CI)					
Alive	611 (76.5)	7,514 (99.6)	4,093 (99.5)	12,218 (99.5, 99.4-99.6)	N=12,277
Dead	15 (1.9)	28 (0.4)	16 (0.4)	59 (0.5, 0.4-0.6)	p<0.001
Gender of infant, n (%, CI)					
Male	148 (18.5)	3,687 (48.9)	2,079 (50.5)	5,914 (47.5, 46.6-48.4)	N 12 455
Female	141 (17.6)	3,833 (50.8)	2,031 (49.4)	6,005 (48.2, 47.3-49.1)	N=12,455
Unknown	510 (63.8)	23 (0.3)	3 (0.07)	536 (4.3, 4.0-4.7)	p<0.001

² Delivery method variable excluded "other delivery method" and still births (only included NVD and C/S method) ³ Viability variable excluded unknown viability outcome

3.2 Prevalence of booking status i.e. booked vs. unbooked

Overall, the majority, 82.0%, (95% CI 79.5%-84.2%) of women had been booked and seen for antenatal care during their pregnancy whilst 1,817 (14.6%)) were unbooked. Booking prevalence varied by facility; CMJAH had the highest booking rate (92.1%) whilst HCHC had the lowest booking prevalence at 77.0%. HCHC had the highest proportion of women who were unbooked (n=1728, 22.9%, p<0.001). Although there was a high booking rate at SRH, a booking status could not be determined for 420 (10.2%) of women presenting for delivery due to missing information in the registers.

3.3 Viability (infant alive or dead)

There were 12,218 (99.5%), records showing infants who were born alive, while just less than one percent (n=59) of infants died i.e. still born or died immediately after birth.

The number of dead or stillborn babies varied between sites. CMJAH recorded the highest proportion of dead infants compared to HCHC and SRH i.e. CMJAH reported 15 (1.9%) dead infants while HCHC recorded 28 (0.4%) and SRH recorded 16 (0.4%) (p<0.001).

3.4 Factors associated with booking status

The following results show the relationship of the following variables with booking status i.e.

1) birth outcome, 2) duration of pregnancy, 3) maternal HIV status, and 4) age.

Table 2: Factors associated with booking status

	В	ooking status	
Variables n (%, CI)	Booked, (n=10,210, 84.9, 84.2-85.5)	Unbooked, (n=1,817, 15.1, 14.5-15.8)	p value, N (%)
Viability, n (%, CI)			
Alive	10,010 (98.0, 97.8-98.3)	1,786 (98.3, 97.6-98.8)	n=12,027
Dead	37 (0.4, 0.3-0.5)	20 (1.1, 0.7-1.7)	p<0.001
Unknown	163 (1.6, 1.4-1.9)	11 (0.6, 0.3-1.1)	
Duration of pregnancy,	n (%, CI)		
Term	9,978 (97.7, 97.4-98.8)	1,771 (97.5, 96.6-98.1)	n=12,027
Pre-term	211 (2.1, 1.8-2.4)	46 (2.5, 1.9-3.4)	p=0.070
Post-term	21 (0.2, 0.1-0.3)	0	
HIV status, n (%, CI)			
Negative	6,241 (61.1, 60.2-62.1)	63 (3.5, 2.7-4.4)	n=12,027
Positive	2,800 (27.4, 26.6-28.3)	101 (5.6, 4.6-6.7)	p<0.001
Unknown	1,169 (11.4, 10.8-12.1)	1,653 (91.0, 89.6-92.3)	
Age category, n (%, CI)	6,518 (78.6, 77.8-79.6)	1,767 (21.3, 20.4-22.2)	n=8,285
Adolescent (10-19 years)	680 (10.4, 9.7-11.2)	217 (12.3, 10.8-13.9)	p=0.027
Adult (>19)	5,838 (89.6, 88.8-90.3)	1,550 (87.7, 86.1-89.2)	
	, , , , ,	,	
Adolescents, n (%, CI)	680 (75.8, 72.9-78.6)	217 (24.2, 21.4-27.1)	
Early-mid adolescent (10-16 years)	78 (11.5, 9.2-14.1)	23 (10.6, 6.8-15.5)	n=897 p=0.724
Late adolescent (17-19 years)	602 (88.5, 85.9-90.8)	194 (89.4, 84.5-93.2)	

3.4.1 Booking status and viability or birth outcomes

Our study showed that birth outcome was associated with booking status (p<0.001). From the total 10,210 women booked; 10,010 (98.0%) infants were recorded as alive, 37 (0.4%) were recorded as dead and 163 (1.6%) had unknown viability or birth outcome. Out of the 1,817 total unbooked women, 1,786 (98.3%) were recorded as alive, 20 (1.1%) were recorded as dead and 11 (0.6%) had unknown viability or birth outcome.

3.4.2 Booking status and duration of pregnancy

Our study showed no association between duration of pregnancy and booking status (p=0.070).

Of the 10,210 total women booked, 9,978 (97.7%) had term deliveries (n= 9,978, 97.7%), 211 (2.1%) were pre-term deliveries and 21 (0.2%) recorded as post-term. Out of the total 1,817 unbooked women; 1,771 (97.5%) were term deliveries, 46 (2.5%) were pre-term deliveries.

3.4.3 Booking status and maternal HIV status

Our study showed a significant association between HIV status and booking status (p<0.001).

From the total 10,210 women booked; 6,241 (61.1%) were HIV negative, 2,800 (27.4%) were HIV positive which was in line with existing routine DHIS data within antenatal care in the public health setting. However, a high proportion of women with unknown HIV status within the category of booked women was also observed (n=1,169, 11.4%).

From the total of unbooked women (1,817); the majority had an unknown HIV status (n=1,653, 91.0%) in comparison to 63 (3.5%) with a HIV negative status and 101 (5.6%) who were recorded as HIV positive.

3.4.4 Booking status and age (adults vs. adolescents)

Our study showed a significant association between booking status and age category (p=0.027).

Of 6,518 (78.7%) booked women with recorded age; 680 (10.4%) were adolescents and 5,838 (89.6%) were adults. Out of all 1,767 (21.3%) unbooked women with recorded age; 217 (12.3%) were adolescents while 1,550 (87.7%) were adults. Data showed that there were more adolescents who were recorded as unbooked as compared to those recorded as booked (12.3% unbooked adolescents versus 10.4% booked adolescents, p=0.027). Out of all 680 (75.8%) booked adolescents, 78 (11.5%) were early-mid adolescents and 602 (88.5%) were late adolescents. Out of all 217 (24.2%) unbooked adolescents, 23 (10.6%) were early-mid adolescents and 194 (89.4%) were late adolescents. This was not significant (p=0.724).

3.5 Factors associated with pregnancy outcome

The following results show the relationship of the following variables with pregnancy outcome (viability and duration of pregnancy at delivery); 1) duration of pregnancy at delivery (only compared to viability), 2) age category (adolescent and adult), 3) mother HIV status, and 4) delivery method.

Table 3: Factors associated with pregnancy outcome (viability and duration of pregnancy)

				Pregnancy	outcome					
		Viability			Duration of pregnancy at delivery					
Variables	Alive	Dead TOTAL p-valu		p-value	Pre-term delivery	Term delivery TOTAL		p-value		
Duration of pregnancy, n (%, CI)	12,218 (99.5, 99.4-99.6)	59 (0.5, 0.3-0.6)	12,027 (98.0, 97.3- 98.2) n=12,277		12,277		-	-	-	
Term	11,988 (98.1, 97.9-98.4)	39 (66.1, 52.6- 77.9)			-	-	-			
Pre-term	212 (1.7, 1.5-2.0)	20 (33.9, 22.1- 47.4)	232 (1.9, 1.7-2.1)	p<0.001	-	-	-	-		
Post-term	18 (0.1, 0.08-0.2)	0	18 (0.1, 0.08-0.2)		-	-	-			
Age category, n (%, CI)	8,077 (99.5, 99.3-99.6)	43 (0.5, 0.3-0.7)	8,120		216 (2.6, 2.3-3.0)	8,062 (97.4, 97.0- 97.7)	8,278			
Adolescent (10-19)	875 (10.8, 102-11.5)	5 (11.6, 3.9-25.1)	880 (10.8, 10.1-11.5)	n=8,120 p=0.867	26 (12.0, 8.0- 17.1)	869 (10.8, 10.1-11.5)	895 (10.8, 10.2-11.5)	n=8,278 p=0.557		
Adult (> 19)	7,202 (89.2, 88.5-89.8)	38 (88.4, 74.9- 96.1)	7,240 (89.2, 88.5- 89.8)		190 (88.0, 82.9- 92.0)	7,193 (89.2, 88.5- 98.9)	7,383 (89.2, 87.3-88.7)			
Maternal HIV status, n (%, CI)	12,218 (99.5, 99.4-99.6)	59 (0.5, 0.3-0.6)	12,277		264 (2.1, 1.9-2.4)	12,168 (97.9, 96.6- 98.1)	12,432			
Negative	6,372 (52.2, 51.3-53.0)	19 (32.2, 20.6- 45.6)	6,391 (52.1, 51.2- 52.9)	n=12,277	120 (45.5, 39.3- 51.7)	6,362 (52.3, 51.4- 53.2)	6,482 (52.1, 51.3-53.0)	n=12,432 p=0.05		
Positive	2,911 (23.8, 23.1-24.6)	13 (22.0, 12.3- 34.7)	2,924 (23.8, 23.4- 24.6)	p<0.001	66 (25.0, 19.9- 30.7)	2,896 (23.8, 23.0- 24.6)	2,962 (23.8, 23.1-24.6)			
Unknown	2,935 (24.0, 23.3-24.8)	27 (45.8, 32.7- 59.2)	2,962 (24.1, 23.4- 24.9)	, , ,		2,910 (23.9, 23.2- 24.9)	2,988 (24.0, 23.3-24.8)			
Delivery Method, n (%, CI)	12,218 (99.6, 99.4-99.7)	55 (0.4, 0.3-0.6)	12,273	12.252	260 (2.1, 1.8-2.4)	12,168 (97.9, 97.6- 98.2)	12,428	10.400		
NVD	11,238 (92.0, 91.5-92.5)	50 (90.9, 80.0- 97.0)	11,288 (92.0, 91.5- 92.4)	n=12,273 p=0.771	250 (96.2, 93.0- 98.1)	11,123 (91.4, 90.9- 91.9)	11,373 (91.5, 91.0- 92.0)	n=12,428 p=0.007		
C/S	980 (8.0, 7.5-8.5)	5 (9.1, 3.9-20.0)	985 (8.0, 7.6-8.5)	1	10 (3.8, 1.9-7.0)	1,045 (8.6, 8.1-9.1)	1,055 (8.5, 8.0-9.0)			

3.5.1 Viability and duration of pregnancy at delivery

There was a significant association between viability and duration of pregnancy at delivery (p<0.001).

There were 12,218 (99.5%) alive deliveries of whom 11,988 (98.1%) were term deliveries, 212 (1.7%) were pre-term deliveries and 18 (0.1%) were post-term. Out of 59 total deliveries recorded as dead, 39 (66.1%) were term deliveries and 20 (33.9%) were pre-term deliveries.

Pre-term deliveries reported a higher proportion of infants recorded as dead compared to term deliveries.

3.5.2 Pregnancy outcome and age

Results from our study indicated no significant difference between viability (alive or dead) and age category (adolescents and adults) (p=0.867). Furthermore there was no difference between viability and early-mid adolescents and late adolescents (p=0.513). Out of all 8,077 (99.5%) alive deliveries with recorded age, 875 (10.8%) were adolescents and 7,202 (89.2%) were adults. Out of all 43 (0.5%) deliveries recorded as dead, five (11.6%) were adolescents and 38 (88.4%) were adults.

Findings also indicated that there was no association between duration of pregnancy at delivery and age category (p=0.557). There was also no difference between duration of pregnancy at delivery and early-mid adolescents and late adolescents (p=0.967). There were 216 (2.6%) pre-term deliveries with recorded of whom 26 (12.0%) were adolescents and 190 (88.0%). Out of all 8,062 term deliveries with recorded age, 869 (10.8%) were adolescents and 7,193 (89.2%) were adults.

3.5.3 Pregnancy outcome and maternal HIV status

HIV status of a mother has been identified as a risk factor for poor birth outcomes of infants (4). There was a significant association between unknown maternal HIV status and viability (p<0.001).

Findings showed that out of all 12,218 (99.5%) alive deliveries, 6,372 (52.2%) were from HIV negative women, 2,911 (23.8%) were from HIV positive women and 2,935 (24.0%) women had unknown HIV status. Out of all 59 (0.5%) deliveries recorded as dead, 19 (32.2%) were from HIV negative women, 13 (22.0%) were from HIV positive women and 27 (45.8%) women had unknown HIV status which was higher than HIV negative and positive women (p<0.001).

Findings also showed a significant association between HIV status of women and duration of pregnancy at delivery (p=0.05). HIV status demonstrated a similar trend in terms of term deliveries while there was slight variation in terms of pre-term deliveries. Out of 264 (2.1%) pre-term deliveries, 120 (45.5%) were from HIV negative women, 66 (25.0%) were from HIV positive women and 78 (29.5%) had unknown HIV status. From the total 12,168 (97.9%) term deliveries, 6,362 (52.3%) were from HIV negative women, 2,896 (23.8%) were from HIV positive women and 2,910 (23.9%) had unknown HIV status (p=0.05).

3.5.4 Pregnancy outcome and delivery method

Pregnancy outcome (viability and duration of pregnancy) was compared with delivery method. Results from our study showed no association between viability and delivery method (p=0.771) while there was observed association between duration of pregnancy at delivery and delivery method (p=0.007).

Out of 12,218 alive deliveries, there were 11,238 (92.0%) had NVD while 980 (8.0%) had caesarean section deliveries. Out of all 55 (0.4%) deliveries recorded as dead, 50 (90.9%) had NVD and five (9.1%) had caesarean section deliveries. This was not significant (p=0.771).

Out of 260 (2.1%) pre-term deliveries, 250 (96.2%) had NVD while 10 (3.8%) had caesarean section deliveries. From the total of 12,168 (97.9%) term deliveries, there 11,123 (91.4%) NVD and 1,045 (8.6%) caesarean section deliveries (p=0.007).

3.6 Factors associated with delivery method

The following results show the relationship of the following variables with delivery method i.e. 1) Mother HIV status, and 2) age category (adolescent and adult)

Table 4: Comparison between delivery method and maternal HIV status

	HIV Negative	HIV Positive	HIV unknown	Total	p-value
	n (%, CI)	n (%, CI)	n (%, CI)	n (%, CI)	
Normal Vaginal	5,771	2,694	2,926	11,391	p<0.001
Delivery (NVD)	(88.9, 88.0-89.6)	(90.8, 89.7-91.8)	(98.0, 97.4-98.4)	(91.5, 91.0-92.0)	
Caesarean Section	725	274	61	1,060	
	(11.2, 10.4-12.0)	(9.2, 8.2-10.3)	(2.0, 1.6-2.6)	(8.5, 8.0-9.0)	
Total	6,496	2,968	2,987	12,451	
	(52.0, 51.3-53.1)	(23.8, 23.1-24.6)	(24.0, 23.2-24.8	(100)	

3.6.1 Delivery method and maternal HIV status

The study showed an association between HIV status of women and delivery method (p<0.001).

Out of 6,496 HIV negative women; 5,771 (88.9%) were NVD and 724 (11.2%) caesarean section deliveries. Out of 2,968 HIV positive women; 2,694 (90.8%) were NVD and 274 (9.2%) were caesarean section deliveries. Women with HIV unknown status showed higher proportion of NVD compared to HIV negative and positive groups. Out 2,987 (24.0%) women with unknown HIV status; 2,926 (98.0%) were NVD and 61 (2.0%) were caesarean section deliveries which was significantly lower than HIV positive and negative.

Table 5: Comparison between delivery method and age category

	Adult, n (%, CI)	Adolescent, n (%, CI)	Total (%, CI)	p-value
NVD	7,322 (99.0, 98.8-99.2)	891 (99.4, 98.7-99.8)	8,213 (99.1, 98.9-99.3)	p=0.233
Caesarean Section	71 (1.0, 0.8-1.2)	5 (0.6, 0.2-1.3)	76 (0.9, 0.7-1.1)	
Total	7,393 (89.2, 88.5-89.9)	896 (10.8, 10.1-11.5)	8,289 (100)	

Table 6: Comparison of delivery methods between early-mid and late adolescent groups

	Adolescent (10-16 years	Adolescent (17-19	Total (%, CI)	p-value
	old), n (%, CI)	years old), n (%, CI)		
NVD	99 (98.0, 93.0-99.8)	792 (99.6, 98.9-99.9)	891 (99.4, 98.7-99.8)	p=0.042
Caesarean	2 (2.0, 0.2-7.0)	3 (0.3, 0.08-1.1)	5 (0.6, 0.2-1.3)	
Section	2 (2.0, 0.2 7.0)	3 (0.3, 0.00 1.1)	3 (0.0, 0.2 1.3)	
Total	101 (11.3, 9.3-13.5)	795 (88.7, 86.5-90.7)	896 (100)	

3.6.2 Delivery method and age category

Our study showed that there was no difference in delivery methods (NVD and caesarean section) between adolescents and adults (p=0.233).

Out of 896 adolescents recorded; 891 (99.4%) had NVD while five (0.6%) had caesarean section deliveries. A similar trend was also observed with adults; out of 7,393 adults, 7,322 (99.0%) had NVD and 71 (1.0%) had caesarean section deliveries which was higher than observed for adolescents but not statistically different. Comparison between early-mid adolescent (10-16 years) and late adolescent (17-19 years) groups showed an association in terms of delivery methods (p=0.042). Out of all early-mid adolescents (n=101, 11.3%); 99 (98.0%) had NVD while two (2.0%) had caesarean section. Furthermore, out of all 795 (88.7%) late adolescents, 792 (99.6%) had NVD while three (0.3%) had caesarean section.

3.7 Factors associated with birth outcomes

Logistic regression analyses assessed and compared the risk of mortality (poor viability outcome-Table 7) and booking status (Table 8) to the following variables; 1) booking status, 2) maternal HIV status, 3) age of women and 4) duration of pregnancy at delivery

Table 7: Logistic regression assessing risk factors for mortality

	Logistic regression					
		Risk of mortality				
Characteristics	N (%)	OR [CI]	p-value			
Booking status	57					
Booked	37 (64.9%)	1	-			
Unbooked	20 (35.1%)	3.06[1.77-5.28]	p<0.001			
HIV status of mother	59					
HIV negative	19 (32.2%)	1	-			
HIV positive	13 (22.0%)	1.50[0.74-3.04]	p=0.261			
HIV unknown	29 (49.2%)	3.11[1.73-5.60]	p<0.001			
Age	43					
Adolescent	5 (11.6%)	1	-			
Adult	38 (88.4%)	0.92[0.36-2.35]	p=0.864			
Adolescents	5					
Early-mid adolescent (10-16 years)	1 (20.0%)	1	-			
Late adolescent (17-19 years)	4 (80.0%)	0.51[0.056-4.56]	p=0.543			
Duration of						
pregnancy at	59					
delivery						
Term	39 (66.1%)	1	-			
Pre term	20 (33.9%)	25.49[14.65-44.45]	p<0.001			

Table 8: Logistics regression assessing factors associated with booking status

	Logistic regression					
		Risk of being unbook	ed			
Characteristics	N	OR [CI]	p-value			
HIV status of mother	1,817					
HIV negative	63 (3.5%)	1	-			
HIV positive	101 (5.6%)	3.60[2.62-4.94]	p<0.001			
HIV unknown	1,653 (91.0%)	126.38[97.60-163.64]	p<0.001			
Age	1,767					
Adolescent	217 (12.3%)	1	-			
Adult	1,550 (87.8%)	0.83[0.71-0.98]	p=0.026			
Adolescents	217					
Early-mid adolescent	23 (10.6%)	1	_			
(10-16 years)	23 (10.070)	1	-			
Late adolescent (17-19 years)	194 (89.4%)	1.09[0.67-1.79]	p=0.724			

Our study showed that there were three times greater odds or increased risk of mortality in the unbooked group as compared to the booked group of women [OR=3.06, (1.77-5.28), p<0.001]. HIV positive women had 50% greater odds of increased risk of mortality compared to HIV negative women, though this was not significant [OR=1.50, (0.74-3.04), p=0.261].

There was a three times greater odds of mortality in women who had unknown HIV status [OR=3.11, (1.73-5.60), p<0.001]. Our study showed that there was no significant difference in risk of mortality between adolescent and adult pregnancies [OR=0.92, (0.36-2.35), p=0.864]. Furthermore our study showed that there was a 0.51 lesser odds of mortality in late adolescents compared to early-mid adolescents though this was not significant [OR=0.51, (0.056-4.56), p=0.543]. There was a 25 times greater odds of mortality in pre-term deliveries as compared to term deliveries [OR=25.49, (14.65-44.35), p<0.001].

Our study showed that there was a 3.6 times greater odds of HIV positive women to be unbooked [OR=3.60, (2.62-4.94), p<0.001]. Results from our study further showed that there was a 126 times greater odds of women with unknown HIV status to be unbooked [OR=126.38, (97.60-163.64), p<0.001]. Our study further showed that there was a 0.83 less odds of adults to be unbooked as compared to adolescents [OR=0.83, (0.71-0.98), p=0.026]. Lastly, there was no difference between early-mid adolescents and late adolescents in terms of booking status [OR=1.09, (0.67-1.79), p=0.724].

Chapter 4: Discussion

The study focused on determining the prevalence of unbooked pregnant women presenting for labour or delivery and also comparing birth outcomes between booked and unbooked women presenting in labour wards. The study referred to the literature highlighting factors associated with booking status and factors associated with poor birth outcomes. It is important to highlight that results obtained from this study may be more relevant to the population of region F, Inner city of Johannesburg but cannot rule out the relevance of these results to other populations with similar demographics and characteristics as the population sampled.

The discussion of the results followed the objectives of the study and is structured to discuss;

1) prevalence of unbooked women and 2) factors associated with booking status, birth outcome and delivery method.

4.1 Prevalence of unbooked women in labour

This study showed an unbooked rate of 15% within region F. This proportion of those being unbooked was higher than expected. South African Millennium Development Goals country report showed that more 95% of women attend antenatal care at least once and 73% women attend antenatal care four times or more (4, 16), yet in the inner city only 85% of pregnant women attend antenatal care. The reasons for this were not explored in this study, however the inner city is known for its highly migrant population and high number of foreigners. Some studies have suggested that xenophobia (real or perceived) within the health system deters foreigners from attending health care facilities (58). Additionally a study by Solarin and Black showed that women without valid South African identity documents are often turned away from ANC. Furthermore previous studies in central Johannesburg have shown

barriers to accessing antenatal care linked to booking systems and health care administration (31, 59). The same study by Solarin and Black found that half of women were not seen at their first visit to an ANC, but were turned away for variety of reasons to return later. This study also showed that some women deliberately attended ANC late for the first time as they expected being turned away. These factors may contribute to the high levels of pregnant women not being booked. Further research into reasons why pregnant women in the inner city do not attend ANC need to be developed and strategies to increase ANC attendance implemented.

4.2 Booking status and birth outcomes as key measures of antenatal care

Our study showed an association between booking status and birth outcomes (infant born alive or dead) which was consistent with evidence from previous studies which also showed an association between these two variables (12, 60-62). This further confirms the importance of antenatal booking and early access to antenatal care.

Our study showed no association between booking status and duration of pregnancy at delivery. Though there have not been many studies showing an association between the two variables it is important to note that women attending antenatal clinics have a greater chance of being assessed for any possible risks that could cause any adverse event during pregnancy which includes pre-term birth. Unbooked women do not have such advantages.

While our study was unable to prove an association between booking status and duration of pregnancy at delivery, it would be important to acknowledge previous reports and encourage antenatal care booking to minimize the possibility of pre-term delivery which could

subsequently lead to poor birth outcomes (56, 63). There were too few post-term deliveries to provide meaningful analyses.

The finding that this population has a high unbooked rate coupled with showing a poor pregnancy outcomes highlights the importance of strategies needed to improve access to antenatal care within this population.

4.3 HIV as a risk factor

Our study showed an association between booking status and HIV status of women presenting in labour. Expectedly more booked women knew their HIV status than unbooked women and evidently from this study and previous studies (46, 64) failure to attend antenatal care has consequences of missing important blood tests such as an HIV test.

Interestingly women with an unknown HIV status at the time of delivery had worse birth outcomes than HIV positive women. Previous studies have shown HIV positivity to be associated with poor birth outcomes yet this study showed similar outcomes for HIV positive and negative women and significant poorer birth outcomes for women of unknown HIV status. This study also showed that an unknown HIV status is associated with being unbooked and this may be the reason why women of unknown HIV status show worse pregnancy outcomes than HIV positive women. A South African report from 2009 on saving mothers and babies includes non-attendance of pregnant women for antenatal care as one of the five avoidable causes of perinatal mortality (61, 62). The surprising result showing similar birth outcomes for HIV positive and negative women may reflect the excellent PMTCT programme services available within ANC. Women of unknown HIV status may include a large number of HIV positive women who are not receiving PMTCT interventions and

consequently their outcomes are similar to HIV positive women prior to the introduction of combination ART for PMTCT interventions.

4.4 Antenatal booking and birth outcomes between adults and adolescents

Our study showed that there was an association between booking status and age (adults and adolescents) suggesting the differences in antenatal care seeking behaviour between adolescents and adults. This study showed a higher unbooking rate within adolescents as compared to adults which supported previous literature and existing knowledge which has indicated that adolescents perceive health services as non-friendly because of stigma and discrimination (39). Our study showed that adolescents and HIV positive women were more likely to be unbooked. Both being pregnant as an adolescent and being HIV positive are associated with stigma and discrimination and this may contribute to their higher unbooked rate. Further studies aimed to understand barriers to accessing antenatal care amongst HIV positive adolescents are needed.

Our study was unable to show any association between birth outcome, delivery method and age category. However there was an association observed in adolescents between 10-16 years and late adolescents (17-19 years) in terms of delivery methods. Our study showed that there were more adolescents between 10-16 years who had caesarean section deliveries as compared to late adolescents. This could be due to adolescent pregnancy being more complex and likely to have complications that may require caesarean section or assisted deliveries. It is evidently worse for adolescents between 10-16 years. This could be due to various factors such as anatomic complications observed in early adolescence, pregnancy experience and level of knowledge regarding pregnancy from adolescents (65, 66).

Hoque and Hoque (67) recommended that strategies and interventions for antenatal care should be explored with adolescent health in mind (67). In the same study, Hoque recommended the implementation of adolescent friendly clinics as part of the improvement of adolescent health care and integration of services within antenatal care (67). Such integration would improve adolescent antenatal attendance and overall behavioural patterns of adolescents in terms of health seeking behaviour at a community level.

4.5 Effect of delivery methods and birth outcomes

This study showed an association between birth outcome and delivery method. This finding is not surprising as complicated pregnancies are more likely to be delivered by caesarean section. Complicated pregnancies by their very nature will be associated with worse birth outcomes. Though there has been limited research to demonstrate such association before, it is important to note that results from this study may be demonstrating the true reflection observed in the public health setting.

Our study did not consider other factors such as community roles; social norms and skills of health care worker providing the delivery service that may influence and affect delivery method choices and birth outcomes. Therefore these factors should be considered to accurately assess the association between delivery method and birth outcomes.

Our results further showed that normal vaginal delivery was the most common delivery method for pregnant women within the public health setting. The caesarean section rate was 8.5%. An acceptable caesarean section rate is between 10-15% in order to indicate acceptable levels of access to essential obstetric care (68). The District Health Barometer report suggests that Johannesburg Metro Municipality has a caesarean section rate higher than 15% (68). Our

low finding may reflect the proportionally higher number of delivery method data elements contributed by HCHC, an MOU which does not perform caesarean section deliveries. Additionally SRH refers pregnant women for caesarean section to Chris Hani Baragwanath Hospital after hours and during weekends. This finding therefore probably represents sampling rather than a true finding for the inner city. Findings from our study showed that HIV negative women were more likely to undergo caesarean section. The reasons for this were not explored in this study, but warrants further investigation in a separate study.

4.6 Limitations of the study

Owing to data being collected retrospectively from birth registers, poor data quality was the main challenge i.e. incomplete recording of data within the birth register. There was also a possibility that amongst the three facilities that were studied; information collected was not collected in a standardized and systematic manner. From Wits RHI Health Systems Strengthening project, there has been evidence from baseline assessments conducted by Wits RHI that health facilities do not use standardized registers and are collecting different information using different tools.

HCHC labour ward reports showed that the facility missed lots of information or data elements because of usage of incorrect registers and no availability of standardized registers. There were variables that were recorded in CMJAH registers that were not recorded in HCHC and SRH i.e. gravida and parity. This could have affected analysis of the study. Another limitation was missing information or data from women who delivered at the defined facilities but were not recorded in the birth register.

Data was collected at a health care facility level and consequently do not reflect women who delivered at home and do not subsequently attend a health care facility.

Chapter 5: Conclusions and Recommendations

Our study of registers of women who delivered in the inner city of Johannesburg found an unbooking prevalence of 15% which is significantly higher than the country average of 5% of pregnant women not attending antenatal care prior to delivery. Our study found that being an adolescent or HIV positive was associated with a lower booking rate. Furthermore, unbooked women had significantly worse birth outcomes than booked women. Our study also showed that the risk of perinatal mortality was associated with an HIV unknown status.

Our study points to the need for further studies to understand reasons why women do not book in the inner city as well as develop strategies to increase antenatal care access, particularly those which minimize stigma and discrimination of adolescent and HIV positive pregnant women in this region are also needed.

Recommendations

As part of the recommendations, it is important to encourage antenatal booking for all pregnant women and ensure all antenatal services are accessible to all pregnant women. Community involvement and awareness has been noted as one of the best strategies to improve antenatal booking during pregnancy. It would therefore be important to implement and strengthen strategies that would ensure women are identified and easily linked to health facilities during pregnancy. Research studies that will focus on barriers to accessing antenatal care should be considered in order to provide adequate health services.

It is important to assess level of knowledge from adolescents and strive to improve adolescent access into care while discouraging adolescent or teenage pregnancy. Government should promote adolescent friendly services in order to improve adolescent access into care and by

doing so government and all stakeholders should discourage stigma and discrimination directed to adolescents.

More studies around perceptions and birth outcomes in adolescents should be conducted and emphasis should focus on perceptions and behavioural patterns towards access of antenatal care services in adolescents. As part of interventions, sexual and reproductive education, family planning, antenatal and maternal knowledge should be prioritized for adolescents.

Continuous education of all women on the importance of antenatal care services and sensitization on antenatal booking would improve antenatal attendance. Government should continue implementation of MomConnect at all health facilities, a new strategy employed by National Department of Health which aims to improve knowledge and antenatal attendance through use of mobile text messaging and pregnancy registry to improve access to health care for pregnant women while providing knowledge and education through mobile health technology (mHealth).

Maternal HIV testing during both antenatal visits as well as at delivery where the status is unknown (if the mother was unbooked) should be emphasized and facilitated as much as possible.

As a component of health systems strengthening within antenatal care, policies and guidelines should be constantly and systematically reviewed and amended using evidence based outputs to ensure good practice and attitudes which will promote antenatal attendance.

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Annexures

Annexure A: Study questionnaire/ Information Collection Form

Unique Number	Booking status	Age (years)	Parity	Gravida	Duration of Preg (weeks)	Gender of infant (male or female)	Alive/Dead	Mode of Delivery (NVD, C/S, Other)	HIV Status (Negative, Positive, unknown)

Codes: Booking Status (booked/unbooked), Age (years), Duration of pregnancy (weeks), Gender of child (male or female), Mode of delivery (NVD, C/S, Other), HIV status (Negative, Positive, Unknown)

Annexure B: Ethics clearance certificate



UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

Division of the Deputy Registrar (Research)

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

R14/49 Mr Siphamandla Gumede

CLEARANCE CERTIFICATE

M121148

PROJECT

A Comparison of Booked and Unbooked Pregnant Women Presenting in Labour at Three Health Facilities in Region F, Inner City

of Johannesburg

INVESTIGATORS

Mr Siphamandla Gumede.

DEPARTMENT

Wits Reproductive Health & HIV Res Unit

DATE CONSIDERED

30/11/2011

DECISION OF THE COMMITTEE*

Approved unconditionally

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

DATE

29/05/2013

CHAIRPERSON

*Guidelines for written 'informed consent' attached where applicable

cc: Supervisor:

Dr Vivian Black

DECLARATION OF INVESTIGATOR(S)

To be completed in duplicate and **ONE COPY** returned to the Secretary at Room 10004, 10th Floor, Senate House, University.

I/We fully understand the conditions under which I am/we are authorized to carry out the abovementioned research and I/we guarantee to ensure compliance with these conditions. Should any departure to be contemplated from the research procedure as approved I/we undertake to resubmit the protocol to the

Committee. <u>I agree to a completion of a yearly progress report.</u>

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES...