

EVALUATION OF THE NEW OPTION B+ PMTCT PROGRAM

EVALUATION OF THE NEW OPTION B+ PREGNANT MOTHER TO CHILD
TRANSMISSION (PMTCT) PROGRAM FOR HIV INFECTED WOMEN AT
HOSPITAL FACILITIES:

CASE STUDY AT THE RAHIMA MOOSA MOTHER AND CHILD HOSPITAL,
JOHANNESBURG, SOUTH AFRICA

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ABSTRACT

Background. South Africa's National Department of Health has adopted World Health Organization's (WHO) 2013 consolidated guidelines on the use of ARVs for treatment and prevention of HIV infection. The guidelines include changes for prevention of mother to child transmission (PMTCT) through Option B+. Option B+ aims to reduce the HIV prevalence rate amongst these women by placing them on ART for life, no matter their CD4 count. As a result, in January 2015, these guidelines were implemented for the PMTCT programme at RMMCH. Little is known about the impact of these new guidelines on the work of healthcare professionals in state hospitals. Most importantly, no research has focused on how these changes have affected adherence for the patients.

Purpose. The purpose of this research project is (1) to explore the impact of the Option B+ PMTCT programme on the work of healthcare professionals, and (2) to understand pregnant HIV-positive women views and experiences with ART for life, as a way to better manage the Option B+ PMTCT programme.

Methods. A qualitative study design is used with a phenomenological approach. The methodology uses demographic questionnaires and semi-structured interviews with healthcare professionals and patients. The study is situated in Johannesburg, South Africa.

Findings. The findings demonstrate that work has changed and become difficult to manage for all healthcare professionals because of (1) the need for strengthening indicators for tracking to decrease loss to follow-up (LTFU); (2) inconsistency in delivery of counseling and support services and the need for communication across clinical departments; and (3) the lack of compassion and understanding by service providers. The

difficult healthcare environment has affected overall views and experiences of pregnant HIV-positive women going on ART for life. All 55 patient participants responded that they chose to take the fixed-dose combination (FDC) for life to protect the health of the baby and felt ART for life can be stopped after giving birth.

Conclusion. Implications for future research include the need to address changes within the healthcare system at both clinical and management levels. It is crucial to incorporate *the perspective of patients* in policy implementation; uptake and adherence are key indicators in informing whether the Option B+ PMTCT programme is being adapted into state hospitals effectively. There needs to be extensive research on how to strengthen indicators for long term scalability and sustainability of the programme. Future evaluations need to address, will interdisciplinary collaboration within hospitals improve the management and understanding of Option B+?

Dedication

This master's thesis is dedicated to the late Kevin Jonathan Bisnauth, my loving brother and health activist. To my grandmother, Gail and Nkosi Johnson, your stories will always live on, and the staff at Rahima Moosa Mother and Child Hospital for your endless dedication to the cause.

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ABBREVIATIONS AND SYMBOLS

3TC	Lamivudine
AIDS	Acquired immune deficiency syndrome
ANC	Antenatal clinic
ART	Antiretroviral therapy
ARV	Antiretroviral
AZT	Zidovudine
BD	Twice-daily
CD4	T-lymphocyte cell bearing CD4 receptor
DoH	Department of Health
d4T	Stavudine
EFV	Efavirenz
ELISA	Enzyme-linked immunosorbent assay
FDC	Fixed dose combination
FTC/3TC	Lamivudine
HCT	HIV counseling and testing
HIV	Human immunodeficiency virus
LPV	Lopinavir
LTFU	Loss to follow-up
MNCH	Maternal, newborn and child health
MTCT	Mother-to-child transmission of HIV
NVP	Nevirapine
PMTCT	Prevention of mother-to-child transmission of HIV

RMMCH	Rahima Moosa Mother and Child Hospital
TDF	Tenofovir
VL	Viral load (HIV)
WHO	World Health Organization

DECLARATION OF ACADEMIC ACHEIVEMENT

The following is a declaration that the content of the research in this document has been completed by Melanie A. Bisnauth and recognizes the contributions of Dr. Stephen Birch, Dr. Ashraf Coovadia, Dr. Michael G. Wilson, and Dr. Lawrence Mbuagbaw in both the research process and the completion of the thesis.

Chapter I: Introduction

Statement of Problem

The World Health Organization (WHO) stated that prevention of mother to child transmission (PMTCT) of human immunodeficiency virus (HIV) is a major issue in South Africa. The WHO states the prevalence of HIV infection among pregnant women in South Africa is likely to remain high for at least the next two decades (WHO, 2015). The number of people receiving life-long antiretroviral therapy (ART) is still increasing and predicted to plateau at around 3 million in 2016 (WHO, 2015).

An estimated 70.4% of maternal deaths in South Africa were associated with HIV infection, half being children younger than 5 years old (WHO, 2015). Consequently, the success of programmes for PMTCT of HIV is critical for reducing maternal and child mortality and morbidity rates (WHO, 2015).

Existing Policy

Countries had the option to choose between two prophylaxis regimens for pregnant women living with HIV with a CD4 count greater than 350 cells/mm³. Option A, pregnant women received either intrapartum antiretroviral (ARV) prophylaxis or lifelong ART based on their CD4 count of 350 during pregnancy. Option B, on the other hand, has a simpler clinical flow in which *all* pregnant women with HIV are offered ART beginning in the antenatal period and continuing throughout the duration of breastfeeding. At the end of breastfeeding those women who do not yet require ART for their own health would discontinue the prophylaxis and continue to monitor their CD4 count, eventually re-starting ART when the CD4 falls below 350 cells/mm³ (see Appendix A).

World Health Organizations' New Policy

In January 2015, South Africa's National Department of Health (DoH) adopted WHO's 2013 consolidated guidelines on the use of ARVs for treatment and prevention of HIV infection across all age groups and populations, based on providing a broad continuum of HIV care across the country (WHO, 2015). The guidelines were named, *'National consolidated guidelines for the prevention of mother-to-child transmission of HIV (PMTCT) and the management of HIV in children, adolescents and adults'*.

The Government of South Africa had adopted these guidelines as a rapid approach to help reach WHO's objectives outlined in the Negotiated Service Delivery Agreement for the health sector in South Africa (Kieffer et al., 2014). These objectives consisted of ambitious goals advised from The Global Plan, a national consultative process that aims to reduce new HIV infections among children by 90% in 2015, and reduce the number of HIV related maternal deaths by 50% (Kieffer et al, 2014; UNICEF, 2012). The goal is to strengthen the existing national healthcare system of Africa and improve its effectiveness. This had resulted in more than 2.6 million people being initiated on antiretroviral therapy (ART) by mid 2014 (Department of Health [DOH], 2014).

The 2013 guidelines included changes for PMTCT through the implementation of Option B+ (Department of Health [DOH], 2014). Option B+ aims to reduce the HIV prevalence rate amongst pregnant women by placing all pregnant women on ART for the rest of their lives. Option B+ is an approach where triple ARV drugs in the form of a fixed dose combination (FDC) pill start the same day as the patient is diagnosed as HIV-positive and treatment is continued for life. A fixed dose combination pill (FDC) was

introduced, made up of the regular three drugs, tenofovir (TDF), lamivudine (FTC/3TC), and efavirenz (EFV) used in the first-line regimen.

The decision was made by South Africa's DoH to adopt FDC because it was simpler, more effective and cheaper by having women take only one pill once a day instead of three or more ARVs multiple times a day (Fried et al., 2013). The goal was to improve adherence, retention on treatment, and for patients to have fewer side effects. Adherence is defined as the extent in which a patient continues an agreed-on mode of treatment without close supervision from a healthcare professional, whereas retention is the ability for the patient to persevere and stay on FDC for life no matter the circumstances (DoH, 2014).

In July 2014, the Minister of Health, announced the threshold for initiation of ART will rise to CD4 count $\leq 500/\mu\text{l}$ for pregnant women and that the Option B+ approach will be adopted at the clinical level for PMTCT programs. This change entitles every pregnant HIV-positive and breastfeeding woman to lifelong ART regardless of CD4 count or clinical staging (DoH, 2014).

Coverage of HIV testing of pregnant women is now close to 100% with PMTCT offered in almost all healthcare facilities in South Africa. The percentage of HIV-positive pregnant women receiving ART to reduce MTCT has steadily increased from 83% in 2009 to 87.1% in 2012 (DoH, 2014). The DoH adopted new 2030 targets of having 90% of mothers tested for HIV and 90% of those eligible for treatment on treatment, with at least 90% of those on treatment virally suppressed (DoH, 2014). The 2013 guidelines would assist in providing the necessary guidance towards improved management of HIV through Option B+ PMTCT programme in state hospitals.

Issues have emerged with the new guidelines for PMTCT including the need to strengthen the educational component of Option B+ to promote awareness and increase comprehension of the FDC one pill a day regimen (UNICEF, 2012).

Education and training programs that are provided at health clinics across South Africa are a crucial component of patients understanding the benefits of taking the new one pill regimen. However, the lack of resources and manpower at each healthcare facility persists as an important implementation barrier (UNICEF, 2012). In high HIV prevalence settings, the integration of PMTCT and ART services can emphasize the importance of Option B+ benefits through educational workshops to patients (UNICEF, 2012).

Little is known about the impact of these new guidelines in state hospitals or on the work of healthcare professionals and on the adherence of the patient population.

Purpose of Study

The purpose of this study is to inform policy and decision makers about the perception of pregnant HIV-positive women on the Option B+ PMTCT programme and the implications of their views for adherence. The purpose of this research project is to; (1) explore the impact of the national consolidated guidelines on the work of healthcare professionals, including nurses, physicians and management and (2) to understand pregnant HIV-positive women views and experiences with ART for life, as a way to better manage the Option B+ PMTCT programme within state hospitals.

Option B+ states that all pregnant women living with HIV are offered life-long ART, regardless of their CD4 count. ART is a regimen of combined ARV drugs used to slow the rate at which HIV/AIDS makes copies of itself and multiplies in the body. In

addition to this drug regimen, counseling and support services are provided for at risk and vulnerable populations, such as HIV-positive pregnant women who are unaware about the risk of HIV transmission to the baby.

There are the implications for pregnant HIV-positive women's perceptions for access to effective care under the Option B+ programme in terms of the availability, affordability, acceptability, and *adaptability* of care. Women may not fully understand the Option B+ programme in ways which affect uptake, adherence, retention and hence policy implementation.

This study provides important evidence on barriers to adoption of the policy in state hospitals that can be applied to healthcare facilities across South Africa and sub-Saharan African countries.

Option B+ was developed by WHO, however introduced by the South African ministry of health as a one-size-fits-all solution without necessarily catering towards the different contexts of South African communities and healthcare infrastructures. This research will contribute to the HIV/AIDS prevention programme literature in the health and policy field. In our increasingly globalized world, it is important to determine how WHO's processes and policies in one country, or setting (i.e. South Africa) could be successfully applied to another country.

Study Objective

The objectives of this study are:

- (1) to explore the impact of the national consolidated guidelines for Option B+ PMTCT on the work of healthcare professionals at both clinical and management levels (including nurses, physicians and management)

(2) to understand pregnant HIV-positive women views and experiences with ART for life, as a way to better manage the Option B+ PMTCT programme within state hospitals

Research Questions

The following research questions will be used to explore both perceptions of healthcare professionals and patients:

1. How have the national consolidated guidelines for Option B+ PMTCT affected the work of healthcare professionals?
2. What are pregnant HIV-positive women's views and experiences about going on lifetime treatment with ARVs?

Theoretical Framework

The lens that will be used to analyze whether South Africa will undergo similar issues as Malawi is McIntyre et al. (2009) Accessibility Framework. McIntyre et al. (2009) '*Access as a policy-relevant concept in low and middle income countries*' along with several studies have identified three dimensions of access to health care, availability, affordability and acceptability.

However, an important aspect added to the three dimensions of access by the investigator for this research study is the concept of *adaptability*. It is important to explore the concept of adaptability because there is a literature gap that exists when determining whether Option B+ is successful in policy implementation in terms of scalability and sustainability. Adaptability determines whether the programme can be transferred between different population settings. For example, some studies emphasize the importance of evaluating the Option B+ PMTCT programme in South Africa since

there is not enough research for the long-term outcomes of this programme (Keehn & Karfakis, 2014). Many healthcare professionals have highlighted in key informant interviews that they cannot say whether it is effective in the long term (Keehn & Karfakis, 2014).

McIntyre et al. (2009) presented an Accessibility Framework as a basis for “understanding the opportunities and constraints that influence health care seeking behaviour of different individuals in different settings in a systemic and integrated way” (p.180) (see Appendix B). This framework will be used in this case for a pregnant HIV-positive woman located in Johannesburg, South Africa.

Recommendations and policy development responses are often limited to decisions about programme implementation without fully understanding the levels and types of use and even the non-use of services (McIntyre et al, 2009). It is important to consider how the guidelines for Option B+ interact with different individuals and communities across various contexts, all with the same aim of reducing the transmission rate of HIV (McIntyre et al, 2009).

Availability (Physical Access)

Availability can create differences in access to services. At the distribution level it is a policy choice to have specific services available for clients. In some settings the provision of counselling and support services for the Option B+ PMTCT programme may be sacrificed as a result of resource constraints (McIntyre et al., 2009).

How does one evaluate whether the needs of the population targeted is met? Stakeholders and policymakers can actively empower pregnant HIV-positive women in a participatory process in order to better inform decision making. Stakeholders and

policymakers could involve the perspective of the patient who utilizes the services available to them in order to better inform what services should be available and are most needed.

It is important to consider individual choices and how that empowers them to utilize the Option B+ PMTCT programme. For example, if a pregnant HIV-positive woman prefers to practice traditional medicine, she may refrain from using ARVs and accessing any type of therapy offered with Option B+. Thus, cultural and religious beliefs may influence her level of empowerment and her utilization of services being offered to her. It is crucial to retain the patient in the system because of the time where infection could occur.

Availability is concerned with whether appropriate health care providers or services are supplied in the right place and time to meet the needs of these HIV-positive pregnant women (McIntyre et al., 2009). This includes distribution of facilities, hours of operation, drug supply of ARVs, willingness of service providers, information, degree of fit with hours of service, treatment effectiveness and the quality of health care for the individual (McIntyre et al., 2009).

Affordability (Financial Access)

Affordability is concerned with the individual's ability and willingness to pay in order to access healthcare services (McIntyre et al., 2009). HIV-positive pregnant women may not be able to afford transport costs to and from the hospital as well as additional medicine charges, diagnostic tests, special diets, child care costs, etc (UNICEF, 2012).

Affordability of the Option B+ PMTCT programme can be measured by opportunity costs, what the patient has to forego in order to meet the costs of using the

programme. This can include forgone earning as time is taken off work as well as reductions in other aspects of household consumption (McIntyre et al., 2009). In this way, while the effects of the programme might be similar across patients, the opportunity costs may be very different and dependent on the context in which the costs are incurred (McIntyre et al., 2009).

Acceptability (Cultural Access)

Acceptability is concerned with the fit between provider and patient perception towards and expectations of each other (McIntyre et al., 2009). This includes perceptions toward characteristics of age, gender, ‘race’ or ethnicity, and language which impacts the relationship of delivery and recipient of care (McIntyre et al., 2009). Respect and the ability to listen to symptom descriptions, undertake a thorough examination, explain illness and discuss treatment alternatives conducted by the healthcare provider are very important, especially at the first point of contact with the patient (McIntyre et al., 2009). The ability to create a comfortable environment no matter what resources there are, minimize burden and avoid stigmatization will affect adherence and the willingness of the woman to follow the Option B+ PMTCT programme. Perceptions and beliefs can influence acceptance and the effectiveness of health care services. Acceptability also “may be affected by the healthcare provider’s willingness to involve an individual in decision making around those options” (McIntyre et al., 2009, p.187-8).

Study Gaps

Women participating in the Option B+ programme are sources of valuable information that can help inform the Option B+ policy.

However, there is failure across the current literature specifically in South Africa to involve patient perspectives. Research has found that the aspirations of increasing adherence may be more difficult than expected by key stakeholders (UNICEF, 2012). This may be a sign that the adaptability of a policy is dependent on all actors involved in Option B+ including the perceptions of the healthcare workforce, and the HIV-positive pregnant women.

Addressing Adaptability (Contextual Access)

Adaptability is a concept that McIntyre et al (2009) Accessibility Framework failed to address. It is crucial in understanding barriers to the short and long term scalability and sustainability of the Option B+ programme. Understanding the environment in which a PMTCT programme operates can address policy implementation and programme issues and hence inform how adaptable Option B+ PMTCT programming is on a larger scale. Adaptability considers the patient's perspective of their experience with the Option B+ PMTCT programme and whether or not that experience extends outside of RMMCH. The Option B+ PMTCT programme is in its early implementation stage and there may not be enough long-term data to analyze whether the programme is adaptable to healthcare facilities outside of RMMCH, i.e. local health clinics or other state hospitals in Johannesburg. The national guidelines have been developed but adaptability may remain problematic to successful roll out of the Option B+ programme outside of RMMCH.

Chapter II: Literature Review

Geographical Setting

The South African Government faces pressure to provide ARVs to the large HIV-infected resident population of more than 837,000 HIV-positive individuals. Yet only 21% of women have access to such treatment in public clinics and state hospitals (WHO, 2014). An estimated 3.5 million South Africans would have died of AIDS-related infections by 2010, and this number continues to increase (WHO, 2014).

On, December 1st, 2009, President Zuma announced interventions to improve ART access to special groups, which included pregnant women that were HIV infected and have a CD4 count less than or equal to 350 cells/ μ l (DoH, 2014).

South Africa's government decided to adopt the new guidelines by providing a free FDC regimen for all HIV-positive pregnant women. However, the country is experiencing some difficulty with implementation of the new guidelines due to limited manpower, resources and infrastructure in healthcare (Besada et al., 2012; WHO, 2015).

Where is it Implemented?

An implementation science study analyzed data from eleven African countries to describe experiences of implementing Option B+ (Kieffer et al., 2014). Countries had different approaches in adopting the Option B+ policy. Review of implementation plans showed that countries chose models of scale-up to fit their context (Kieffer et al., 2014). Malawi had chosen rapid expansion of Option B+ across the country. Whereas, the country of Uganda used a national rollout of Option B+ to facilities already offering PMTCT services (Kieffer et al., 2014). Other countries in Africa are using a phased approach based on HIV prevalence and healthcare facility capabilities of providing ART

(Kieffer et al., 2014). The advantage of a phased approach allows Option B+ to strengthen the MCH platform to deliver ART, providing enough qualified staff to manage the programme and integrate Option B+ PMTCT on all levels of healthcare (Kieffer et al., 2014). Implementation can occur first for facilities that have the capacity to implement Option B+, and then lower-level facilities can address their capacity gaps to meet quality standards to initiate the programme (Kieffer et al., 2014). This can contribute to overall strengthening of the healthcare system and its support of the programme nationally.

Why use Malawi as a Model?

South Africa has adopted the rapid expansion model like Malawi for WHO's guidelines and Option B+ PMTCT programming. Malawi implemented Option B+ three years ago because of WHO's claim that it was cost-effective (Keehn & Karfakis, 2014). A literature gap exists, excluding the voices of those impacted by the policy, including both pregnant women and healthcare professionals.

In 2011, Malawi became one of the first countries in the world to adopt Option B+ as part of the HIV policy, the decision was made in response to WHO 2013 guidelines. The rationale behind Malawi's adoption and implementation of Option B+ PMTCT was to increase access to ART for HIV-positive pregnant or breastfeeding women in a setting that has limited access to CD4 testing (WHO, 2014). Malawi's low uptake of PMTCT at 39%, with a high fertility rate of 5.7 births per woman, slowed progress of the 2015 Millennium Development Goals in MCH (Kamuyango et al., 2014). The Malawi Ministry of Health reported that Malawi has a retention rate of 77% for pregnant women under Option B+ and that most lost to follow-up occurs within the first

three months of ART initiation for a pregnant woman (Kamuyango et al., 2014). Malawi serves as one of the earliest implementers of Option B+ and therefore is a useful source of data for retention over a long term.

Malawi utilized an equity based approach where the country was able to rapidly expand access to ART for HIV-positive pregnant women in hard-to-reach areas (UNICEF, 2012). After three years of adopting Option B+, the country is undergoing issues with LTFU, uptake by pregnant HIV-positive women, and lack of indicators to monitor adherence of patients on Option B+. These may be issues SA will experience.

Therefore, the model of Malawi was chosen because this experience can inform the health and policymaking in Johannesburg for the initiation of Option B+ PMTCT.

Availability

Malawi underwent frequent stock out of HIV test kits and ARVs due to rapid expansion of Option B+ PMTCT. There was insufficient strategic information for management, incomplete training and tools for the use of PMTCT programming. The issue of same-day testing and initiation of FDC was controversial and some healthcare workers refused to cooperate (WHO, 2014). This caused a problem with the quality of laboratory testing as well.

A focus group discussion of HIV-infected pregnant women participants in Malawi expressed views that public health facilities are the most important source of health care but that there were not enough healthcare workers in the facilities (Silal et al., 2012; WHO, 2014). These women felt that the service provision, including the performance of clinical examinations, was better in public facilities than in private clinics they attended (WHO, 2014). Low availability of ART at MNCH sites resulted in poor access to ART

for the most vulnerable women, i.e. those travelling long distances from their homes to access ART at higher level facilities (UNICEF, 2012). These women felt that public health facilities offered them all the antenatal care services they need, including HIV testing and ARVs.

South Africa may undergo similar issues with availability of healthcare facilities and services that affect access to Option B+ PMTCT. Women who have to travel long distances from remote and rural areas to attend the healthcare facility may not be as inclined to which can impact their overall adherence to the Option B+ PMTCT programme, becoming loss to follow-up (LTFU) (Larsson et al., 2012).

Affordability: Opportunity Costs

Though ARVs are free of charge, pregnant HIV-positive women on Option B+ incur many costs that impact their adherence (McIntyre et al, 2009). Pregnant HIV-positive women observed that in a private hospital, services were faster than public facilities but they had to pay a fee that most of them could not afford (WHO, 2014; Cleary et al., 2013). In Malawi, women reported the most common barrier to ARV adherence is low income and food insecurity (Sibanda et al, 2013). The ability for a HIV-positive pregnant woman to have nutritional support and food security led to better adherence (Sibanda et al, 2013). Many women may not be able to afford both food and transportation to pick up ARVs from local healthcare facilities. These women often sacrifice treatment which leads to poor adherence for Option B+.

Is Option B+ PMTCT Improving Adherence and Retention?

Analysis has revealed clear benefits of the rapid approach towards PMTCT in Malawi in terms of increasing access to ART. Despite this success, progress has been

stagnated due to significant challenges with uptake, retention in care, and adherence to treatment.

Kamuyango et al. (2014) performed a retrospective study at three locations, one of which included the Thyolo District Hospital in Malawi, a healthcare facility that provided antenatal care for HIV-positive pregnant women. The study compared maternal outcomes from one year after starting ART in pregnancy in the pre-Option B+ era to outcomes in the Option B+ era. Results revealed that women in the Option B+ cohort had lower CD4 counts and started ART at a lower clinical stage but “would be more likely to have low adherence and most likely to default from care” (Kamuyango et al., 2014, p.333).

Acceptability

Challenges are compounded by the personal, interpersonal, social and cultural barriers that contribute to a woman’s ability to fully participate in the Option B+ PMTCT programme (McIntyre et al., 2009). Many pregnant HIV-positive women in South Africa and Malawi start ARV treatment for life the day they discover their HIV-positive status. Many of these women attend the healthcare facility, like RMMCH, for reasons unrelated to HIV, but are told by their physician to take this medication, while they may ‘feel’ healthy and symptom-free (Keehn & Karfakis, 2014).

The use of the same-day initiation may be contributing to the inadequate uptake of treatment under Option B+, which points to the need to identify alternatives or enhancements to this rapid approach. In countries that used a rapid approach, “Young women requested better counseling and psychological support” to make decisions about

accepting treatment and the need for information at an earlier stage, especially those starting ARVs for the first time (Webb & Culler, 2013, p.9).

Furthermore, symptom free HIV-positive pregnant women may not see the need to continue ART long-term because they do not have a clear understanding of the benefits for their health after delivery and breastfeeding. A misconception existed among some HIV-infected pregnant women about the treatment being aimed primarily at reducing risks for the child (for prevention of MTCT) with less focus on concurrent benefits to the mother (Kamuyango et al., 2014; Webb & Culler, 2013). HIV-positive pregnant women were confused by the name 'Option' B+ when there were no other therapeutic choices offered for PMTCT, feeling pressured to initiate ART in a rushed manner without any support around decision making (Kamuyango et al., 2014, p.335).

In March 2012, research found that 17% of pregnant HIV-positive women in Malawi were loss to follow-up (LTFU) six months after ART initiation and that most losses occurred in the first 3 months of therapy (WHO, 2014). Pregnant HIV-positive women who did not start ART on the day of diagnosis and who received additional counseling had better retention than women who started treatment the day they were diagnosed (WHO, 2014). Women who started ART during pregnancy were five times more likely to never return after their initial clinic visit than women who started in a later clinical stage of 3 or 4 according to WHO with a CD4 count of 350 or less (see Appendix C) (WHO, 2014; Keehn & Karfakis, 2014). The clinical stages of 3 or 4 indicate that the woman shows severe symptoms (i.e. fever, diarrhea, weight loss) of HIV and requires medical attention. The issue remains, that many pregnant HIV-positive women may not

have started taking ART and healthcare workers will not be able to follow-up these patients and their soon-to-be born babies.

As nearly half of infants born in South Africa are LTFU at 24 months, retention rates for HIV-exposed children present a serious challenge (Sibanda et al., 2013). According to a systematic review of mostly sub-Saharan African countries, about one-third of HIV-exposed children in standard PMTCT programs fall out of care in their first 3 months after delivery, while 45% stop care after their first HIV test (Sibanda et al., 2013).

Adaptability

Rapid adoption of Option B+ has led to large increases in approximately 50% of HIV-positive pregnant women accessing ART in antenatal care (Kieffer et al., 2014). Countries within the continent of Africa have used different approaches to implementation of Option B+ in order to scale up the programme and expand PMTCT services (Kieffer et al, 2014). However, rapid adaptation showed that countries chose models of scale-up to national implementation to fit their context (Kieffer et al, 2014). Malawi's approach to implementation was for rapid expansion whereas other countries such as Kenya used a phased approach. A phased approach is based on HIV prevalence and facility capabilities, including healthcare facilities that already provide ART services (Kieffer et al, 2014). The slower pace of Option B+ scale up to other healthcare facilities can allow for time and the ability to strengthen service delivery, providing qualified staff to manage Option B+ PMTCT, and the integration of the programme into any existing ART, PMTCT or MCH services (Kieffer et al, 2014). Adaptability is dependent on many factors such as leadership, integration on all healthcare levels, and collaboration between

ART and PMTCT services. This is not solely dependent on how many HIV-positive pregnant women are put on FDC, but how long are they able to remain on Option B+. The implementation of Option B+ in Malawi extended beyond a change in ARV regimen. Kenya's ART and PMTCT programs were fully integrated to strengthen support services that were sustainable in the long term for women to better understand Option B+ (Kieffer et al., 2012).

Malawi's approach to implementing Option B+ PMTCT has indicated that there are challenges that remain after three years, the biggest being the lack of indicators for system planning, monitoring and evaluation. This has made it difficult to determine whether the PMTCT guidelines are scalable and sustainable to the context of Malawi. It is crucial to understand if these are barriers that will impact the long term adaptability of Option B+ PMTCT in South Africa.

Following in Similar Footsteps?

The current practices in Malawi address issues of retention and adherence through WHO's 'one size fits all' policy of Option B+. Malawi's rapid approach to PMTCT service delivery and management of healthcare facilities, both public and private face some challenges that the RMMCH in Johannesburg can better prepare for. Evidence from Malawi may be far from definitive in some areas. Research has presented that there is still work that needs to be done with increasing adherence for HIV-positive pregnant women by providing better services, especially in state hospitals. Malawi underwent similar health care system issues with stock-outs, lack of human resources and internal communication issues that South Africa is experiencing.

South African Government's Reasons for Promoting Option B+ PMTCT

Easier to Manage

The DoH states the benefits of the changeover for FDC would be ordering, storage and managing one ARV compared to the current regimen. The DoH claims that healthcare workers will have simpler training and curriculum for daily work and relationships with patients may improve with a regimen that is easier explain and manage (Fried et al., 2013). There is a significant drop in the retention rate that is occurring nation-wide, which explains the dire need for international institutions, such as the WHO to intervene. Fewer adults have remained on ART between the years of 2004 to 2013. The graph indicates that only 60% of adults remain on ART at 60 months versus 94% of adults who remain on ART at 12 months (see Appendix D).

In November 2014, training on monitoring and evaluating was done in Pretoria, South Africa for the consolidated guidelines. The purpose of the training was essential to; monitor clinical care; patient outcome improvement; logistical appropriateness; programme cost-effectiveness; performance measures and improvement; and monitor effectiveness and the quality of services provided.

The monitoring and evaluation cycle was discussed in order to provide proper training on how to implement policy changes most effectively in healthcare (see Appendix E). The challenges that were highlighted included incomplete data collection between pre-ART registers and clinical folders, and the level of accuracy and completion with registers. There were many data collection tools listed in order to discuss ways on which a patient can be tracked, many of which include; patient held/maternal health

cards, pre-ART registers, ANC and birth registers, clinical HIV stationery, labour record and delivery register, post natal care register, etc.

However a request was made to all programme managers to remove any unnecessary indicators and to focus on the most essential ones. Gauteng was the only province with the most pediatric information district system (PIDS) indicators, however it was determined that the benefits of reducing indicators would not only improve the data quality and make it easier to manage data and analyze it but allow a clean audit outcome.

Most importantly, resources and capacity were two crucial factors to consider at an operational level when discussing indicators between provincial and National DoH. The indicators that are used at RMMCH follow the Gauteng Department of Health criteria (see Appendix F).

Safety: Taking Precaution

The UN claims that Option B+ will improve maternal and infant health, and increase ARV coverage. In South Africa, there are major social implications associated with pregnant HIV-positive women that can affect her ability to adhere to ART (Coutsodis et al., 2013). How safe is it to put a HIV-positive pregnant woman on treatment for life that may not necessarily need it? Is it ethical to do so if she doesn't fully understand the long-term benefits and risks? The FDC that was used in South Africa is a single tablet which contains a combination of the TDF, 3TC/ FTC and EFV. Research has shown that increased exposure to TDF may also increase renal toxicity in mothers and poor growth outcomes in infants (Siberry et al., 2012).

Cost Effective

The United Nations (UN) claims Option B+ is more cost-effective than Option A and B (Coutsodis et al., 2013). However, this claim is unsubstantiated because there is not enough evidence on programme performance and economic benefits of Option B+ (Fasawe et al., 2013). Many questions remain about operational effectiveness, processes and policies surrounding the initiation and roll out of Option B+ for programme planning (UNICEF 2012). The percentage of HIV positive pregnant women receiving ARVs for PMTCT increased from 9% in 2004 to 48% in 2010 in low and middle income countries (UNICEF, 2012). Furthermore, Option B+ is claimed to be less costly because of only one pill, less laboratory tests, less human resources and health-system expenditures (UNICEF, 2012). However, there may still be a high demand for human resources to assist with much needed adherence counseling and support services required to help HIV-positive pregnant women understand the benefits of FDC.

UNICEF (2012) completed a study using a deterministic model of pregnant HIV-positive women aged 15 to 49. They estimated the total PMTCT costs and new child infections under Options A, B, and B+ as well as cost-effectiveness ratios. The study included adult sexual transmissions averted from ART, corresponding costs saved, and estimated the total incremental cost per transmission (child and adult) averted. Option B+ was estimated to be the most cost-effective strategy with an average cost per additional transmission averted of between R60 000 and R230 000 (UNICEF, 2012; O'Brien et al., 2014). In addition, to cost differences between Option B+ and A/B,

“Option B+ generates a set of financial benefits such as lower MTCT rates due to protection from ART initiated in the previous pregnancy, reduced transmission

to HIV negative male sexual partners due to the impact of treatment as prevention, improved maternal health and associated productivity gains, lower morbidity and associated secondary and tertiary care costs and potentially lower non-drug direct and indirect costs of delivery (including cost of fewer CD4 counts and from switching on and off treatment over time)” (UNICEF, 2012, p.21).

There estimated cost difference depends largely on the willingness of the patient to accept Option B+. If their feelings of women differ from what is assumed by stakeholders such as UNICEF and WHO, then uptake and adherence will be less than that assumed.

“A critical component for how well an intervention will work is how acceptable it is to its recipients. In choosing antiretroviral regimens for PMTCT, the efficacy of a regimen has typically been a much more important criterion than its acceptability, given that it has been justifiably assumed that women will want to use the most effective regimen. However, in cases where two options may have similar efficacy for an individual woman, understanding the relative acceptability of the options becomes especially critical from a human rights perspective. Therefore, in comparing Options A, B, and B+ it is important to hear from women living with HIV themselves regarding which option they would prefer, and also whether they would like to have the opportunity to choose between the two options” (UNICEF, 2012, p.16).

The WHO states that if options A, B and B+ are comparable in preventing new infant infections, yielding cost effectiveness ratios between R370 and R690 per disability adjusted life year averted in children (Fasawe et al, 2013). However, Option B+ increased women’s survival rates by ten-years in total and an additional 250,000 maternal life years

(Fasawe et al., 2013). Therefore, Option B+ represented a cost effective programme for a policy option even if it required more financial resources for service provision in the longer term.

Stock-Outs: A Challenge to Overcome

The National DoH of South Africa managed to negotiate R89.37 per month for FDC treatment which they claim is a significant saving from the old drug tenders for triple ARVs (Fried et al., 2013). Stock outs of ARVs occur frequently in South Africa and the changeover to FDC will require better communication between healthcare facilities and the National DOH (Fried et al., 2013).

Therefore a one-pill regimen may be more feasible in avoiding stock-outs of drug supply at healthcare facilities. The FDC has been approved to be used for all adult populations by the U.S. Food and Drug Administration (FDA) in 2009 along with permissions for generic supply (UNICEF, 2012).

Stock-outs occur across Johannesburg, South Africa at healthcare facilities, because they are largely dependent on the state for provision of antiretroviral medication. U.S. Government agencies which implement the President's Emergency Plan for AIDS Relief (PEPFAR) committed resources in 2013 to support operational plans for countries such as South Africa, who wished to adopt Option B+. However, reallocation of unspent resources and cost efficiency strategies has proven to be difficult due to national government involvement (UNICEF, 2012).

Save Money or Mothers?

A huge driver for Option B+ from the National DoH has been the cost-effectiveness of the programme for Johannesburg. Only two studies have presented

similar views for this, Malawi and Zimbabwe. The results from these studies would imply that South Africa would be impacted the most in comparison to other African countries because it has high fertility rates and short average birth intervals (Gopalappa et al., 2014). Effectiveness in the long term depends on management of Option B+ programme in healthcare facilities. If there are no changes in the South African environment in terms of, culture, stigma and resources, then the Option B+ programme could fail in reducing infections and improving health benefits in the long term.

In order for long term sustainability and scalability of Option B+, each healthcare facility must be able to manage the programme. Hence experience of Option B+ in Malawi is insufficient to measure universal feasibility of the programme (Coutsodis et al, 2013). The recommendation of Option B+ to be adopted universally is based on an untested assumption that it will be initiated successfully across the world, no matter the differences in each enabling environment.

Challenge of Integrating Option B+ in Hospitals

Making the Option B+ PMTCT programme available and accessible to HIV-positive pregnant women can be a challenge with the requirement that all healthcare facilities are on the same page. Often, PMTCT and ART services function separately and are inconsistently depending on the hospital institution and the clinical and management levels of the healthcare system. UNICEF (2012) highlights that in South Africa; frontline staff such as nurses are primary providers of PMTCT in primary healthcare facilities where women are accessing MNCH services. However ART for HIV-positive pregnant women has yet to be initiated in many of these state hospitals.

“There is also a pressing need for full integration of the larger PMTCT and ART programs. This includes management and supervision, financing, laboratory systems, supply chain management, monitoring and evaluation...ART programs have typically had much greater funding than PMTCT programs, they have rarely focused on reaching pregnant women as a core objective” (UNICEF, 2012, p.6).

By excluding pregnant women, the main component in addressing the gaps in PMTCT programming is then ignored. Programs must examine both the numbers and proportions of pregnant women accessing ART, as well as the types and locations of facilities that are providing ART for pregnant women (UNICEF, 2012).

Why Consider the Perspective of the HIV-positive Pregnant Woman?

UNICEF (2012) stated that critical component for how well an intervention will work is how acceptable it is to its recipients, in this case the pregnant HIV-positive women. Often the efficacy of FDC is emphasized with less attention given to the acceptability of the programme by these women (UNICEF, 2012). Countries lack qualitative research capacity and have little understanding of women’s perceptions, attitudes and preferences with regards to Options B+ (Belle et al, 2014).

Qualitative studies can explore the broader scope of what women’s perceptions are and how their behaviour could possibly have a “spillover effect in reducing adherence in the larger national programming” (UNICEF, 2012, p.16).

Chapter III: Methods

Overview of Study Design

Context of Research Study

This research study is situated in Johannesburg, South Africa. The RMMCH is a state hospital located in the suburb of Coronationville, an area that the government delegated to coloured folk after the apartheid. A few squatter camps rest behind the hospital. RMMCH is formerly known as Coronation Hospital, has 110 general paediatric beds, 30 neonatal beds and a 6 bed intensive care unit (ESRU, 2013). The healthcare workers see more than 36, 000 outpatients annually and approximately 15 clinics refer to the antenatal clinic at the hospital creating a busy healthcare environment. RMMCH has more than 10, 000 births a year (ESRU, 2013).

Rationale

In January 2015, WHO guidelines were implemented for the Option B+ PMTCT programme at RMMCH. There is a lack of knowledge about what impact the guidelines will have on the healthcare workforce and this programme for patient's adherence to ART for life. The objective of the study is to describe the perceptions of both healthcare professionals in state hospitals in delivery of the programme and the patients on the programme and their adherence to ART for life. A qualitative study design is used to study a pilot health facility in Johannesburg, South Africa. RMMCH will serve as a state hospital that has already adopted Option B+ and is in the implementation stage of the new national guidelines, providing a platform to analyze the PMTCT programme.

Approach

In this study, a phenomenological approach is used to investigate lived experiences of HIV-positive pregnant women and healthcare professionals under the Option B+ PMTCT programme (Pope & Mays, 1995). Patients and healthcare professional's perceptions of HIV were investigated to learn more about their perspectives and stories previous to the implementation of Option B+. For example, patients were asked "*How did you feel when you first found out you were HIV-positive?*" This study will explore the specific phenomenon between healthcare workers (nurses, physicians and other management) and patients, providing in depth understanding of how the Option B+ programme is now impacting the work of healthcare professionals and the adherence of patients (Mann, 2003).

Qualitative studies are often criticized by research methodologists as not addressing issues of generalizability, but they are useful for understanding a situation in great depth (Stake, 1995). For instance, qualitative studies can inform strengths and weakness of policy implementation and the impact it has on individuals on different levels (Smit, 2003). The phenomenological approach to qualitative studies is very useful in capturing the perspective of an individual. Furthermore, RMMCH, a hospital environment will be used to examine the perceptions of healthcare professionals and patients in response to the emergence of the new national guidelines for the Option B+ PMTCT programme.

Protection of Human Subjects

Ethics approval for the study was granted by The Hamilton Integrated Research Ethics Board (HiREB) at McMaster University, Canada and the Human Research Ethics

Committee (HREC) at the University of Witswatersrand in May 2015. Authorization from RMMCH was granted to conduct the study in Coronationville (approval REB Number: 15-264-S/HREC Number: M150495).

There was no harm or risks associated with participating in the study. Participants were made aware that they had the right to withdraw from the study at any time and that the study results would be made available to them upon completion of the study.

To ensure participant confidentiality and anonymity, identification numbers were added to interview audio recordings, questionnaires and transcription records. Linkages of participants' personal information and the study identification numbers remained confidential. The study identification numbers list was kept on the principal investigator (PI) computer and locked in a password protected folder. The data from the patients and healthcare workers demographic questionnaire was kept anonymous and confidential and results have been aggregated, to ensure that participant responses cannot be linked to them. The participants were not identifiable through the study identification numbers.

To ensure confidentiality, the electronic versions of the transcripts and digital audio files, have been stored on a password-protected external hard drive and computer with access limited to the PI and research team. All data will be deleted from the computer and hard drive ten years after completion of the study. Hard copies of the questionnaires from all study participants will be kept in a locked cabinet in the Empilweni Services and Research Unit (ESRU) in the Paediatric Department at RMMCH during the project and will be destroyed ten years after the study is completed.

Sample

Recruitment of Study Participants

Potential HIV-positive patient participants and healthcare professionals were recruited through convenience sampling by the student researcher in the antenatal clinic, postnatal clinic, the antenatal ward, OBGYN and Department of Paediatrics and Child Health at RMMCH. Convenience sampling is a non-probability sampling technique where subjects are selected because of their convenient accessibility and proximity to the researcher (Pope & Mays, 1995).

Pregnant HIV-positive women would enter RMMCH and have to wait in the clinics and wards before seeing a nurse. In order to reach patient participants the PI had to utilize channels of communication through the nurses that could identify the HIV-positive patients and refer them to the PI. This was done in order for the PI to not be associated as a healthcare professional to reduce any bias from the patient in their responses (i.e. pressure to answer questions ‘correctly’ for a healthcare professional). A convenience sampling approach was used for recruitment of study patient participants. Convenience sampling is a form of non-probability sampling and made up of people who are easy to reach (Pope & Mays, 1995). Potential patient participants would first see a frontline nurse that would initially identify if the patient was HIV-positive and enrolled on the Option B+ PMTCT programme. This was necessary because the PI is unable to identify an HIV-positive patient in the waiting rooms and disclose her status. Frontline nurses would then ask if they would like to participate in this study being conducted by the student researcher. Those patients willing to participate were then taken to a separate private enclosed interview room to meet the student researcher.

Staff from selected units and departments, which included healthcare workers and executive management at the hospital site, were recommended by the Director of the Paediatric unit and contacted via email by the PI. The email consisted of an email link where if interested, potential participants could sign up for a time best suitable to participate in the study. Due to the RMMCH system, only one executive manager was reachable that directly worked with the PMTCT programme. The Director of the Paediatric Unit and ESRU was excluded from participating in the study because of the supervisory role with this study. Therefore, only one manager was accessible for the sample of executives from the departments and units involved in the Option B+ PMTCT programme.

In order to facilitate the selection of participants, healthcare workers and patients were provided with information letters and consent forms for recruitment into the study (see Appendix G). Those individuals providing informed consent were asked to fill out a questionnaire and participate in an interview with the student researcher. Potential participants that were illiterate were provided an oral consent form and a witness to sign that the student researcher has read and clarified any questions for the participant.

Therefore, in an observational study design and phenomenological approach, the objective is to obtain the greatest possible amount of information on a given problem or phenomenon (Yin, 2009). The selection of participants using convenience sampling is the most appropriate sampling strategy because the typical or average case is often not the richest in information (Yin, 2009). This is to confirm or irrefutably falsify the study's research question (Stake, 1995).

Study participants were selected so as to gain a selected representation of views from the identified groups of; pregnant HIV-positive women and healthcare professionals at RMMCH. Participants were not excluded based on race or language. The inclusion criteria for this study stated that participants must fulfill the age requirement of 15-49 (as this age group was determined for consent and may impact reproductive age of a woman), be pregnant, HIV-positive and either newly enrolled on Option B+ or had switched from Option A/B to Option B+. Healthcare workers had to have contact or involvement with patients on Option B+ or/and the initiation of the programme in RMMCH for at least the past six months (January 1, 2015) since Option B+ was implemented.

Sample Size

To determine the number of study participants needed was dependent on the study objectives and the qualitative research design. From a review of the literature it was determined the study would initially use 30 to 40 one-on-one semi-structured key informant interviews and questionnaires with both pregnant HIV-positive women and health care providers. However, this number was amended to 60 to 70 interviews and questionnaires to reach the appropriate number to achieve data saturation of emergent themes. The PI conducted interview with many English speaking pregnant HIV-positive women. In order to broaden the representativeness of the sample, participants that speak other languages were sought. Data saturation occurs when the researcher is no longer hearing or seeing new information emerging from the data (Pope & Mays, 1995). However, in this study, the objective was to obtain the greatest possible amount of

information about the subgroups of healthcare workers and patients at a given point of time (Mann, 2003).

Thus, the total number of interviews and questionnaires were increased to reach data saturation with the total number of participants interviewed being 67 cases. In total, 55 pregnant HIV positive women from the antenatal clinic, maternity and postnatal wards, 5 nurses in antenatal clinic and maternity ward, 3 Paediatricians, 2 Obstetricians and Gynaecologists, 1 Neonatologist/Intensive Care Unit (ICU), and 1 Executive Manager in Empilweni Services and Research Unit were interviewed and filled out demographic questionnaires.

Data Collection

The ability to use multiple techniques to collect data in a qualitative research strengthens and confirms the results (Stake, 1995). Based on the study objective, multiple sources of evidence were collected to address the objectives. The study data sources and data collection methods included:

1. Patients and healthcare workers profile and demographic data questionnaires administered to both clinical and management levels of frontline nurses, physicians and healthcare executives at RMMCH.
2. Semi-structured interviews with probes. Interviews were conducted with patients and healthcare workers at RMMCH (same study participants that completed demographic questionnaires).

Demographic Patient and Healthcare Workforce Questionnaires

A questionnaire was used to collect demographic data from the 67 participants which included HIV-positive pregnant women (n=55) from the antenatal clinic, maternity

and postnatal wards, nurses (n=5) in antenatal clinic and maternity ward, Paediatricians (n=3), Obstetricians and Gynaecologists (n=2), Neonatologist/Intensive Care Unit (ICU) (n=1), and an Executive Manager in Empilweni Services and Research Unit (n=1).

Two separate categorical questionnaires were developed; one for healthcare workers (see Appendix H) and another for patients (see Appendix I). The healthcare professional questionnaires asked information on their age, department, trust of their patients' medication adherence and challenges they themselves encounter with their patients and awareness of opportunity costs their patients may undergo, etc.

The patient questionnaires asked about the number of dependents, PMTCT education, method of transportation to the hospital and local health clinic. Patient questionnaires also asked about the duration on Option B+ programme, sources of information for Option B+, missed dosages of ARVs, trust of healthcare workers and obstacles that had any impact with medication adherence (i.e. family obligations, difficult working hours, lack of understanding the healthcare worker, lack of accessibility to the local health clinic or hospital, and lack of income). Patients had to fill out a categorical chart that allowed them to rate obstacles that can make it difficult to stick to their FDC regimen. The same chart was filled out by healthcare professionals to measure whether they understood obstacles that impact adherence for their patients. Questionnaires allowed for both healthcare workers and patients to rate certain aspects of their relationship such as trust and understanding of each other.

This quantitative dataset supplements the qualitative findings in providing a demographic profile and description of the healthcare workforce characteristics and patients at RMMCH. The use of the questionnaire added value to this qualitative study

because it allowed the participants to rate obstacles and place importance on certain factors that contributed to their adherence of Option B+. Furthermore, the questionnaire can ensure that different types of data were captured in order to develop an in-depth understanding of the Option B+ and issues that patients undergo with adherence to FDC and the changing work environment for healthcare professionals. All participants' demographic information was used in addition to the qualitative data entered using software QSR NVivo 10.0.

Semi-Structured Interviews

When following up with potential participants, the student researcher confirmed that participants have read, understood, and signed the consent form. The signed consent form was returned to the investigator in person before the questionnaire and interview. Participants were made aware that participation is completely voluntary and that they may withdraw at any time with no consequences. As well, participants were made aware that they may choose not to answer any questions for the questionnaire and interview.

During the interview process, the researcher ensured that participants were comfortable with continuing the interview. Participants were assured study results will not allow participants to be identified. Participants were not asked for personal information. With permission, the interview was audio recorded and transcribed. It was anticipated that the interview would last approximately one hour maximum. The interview guide was designed beforehand; however questions were tailored to the specific position of each participant. Interviews were continued until data saturation was reached, in which no new information was being provided by participants.

Interviews are an essential component of qualitative research because it can provide in-depth understanding of situations, and identify new relevant sources of evidences (Yin, 2009). Semi-structured interview guides were developed for patients and healthcare professionals that met the inclusion criteria for this study (see Appendix J & K). The interview guides focused on specific domains for discussion which allow the researcher to explore and facilitate a systematic data collection. Furthermore, the style and structure of the interviews by the PI used techniques to encourage discussion. These techniques included open-ended and informal questions when interviewing to make the participant feel comfortable. For example informal questions consisted of, “*How far along are you in your pregnancy?*” or “*What did you learn today from the nurses?*”

It is important to address the limitations of semi-structured interviews, because they are verbal reports that are largely dependent on the interviewee’s responses, and are subject to individual bias, recall bias, or inaccurate articulation (Pope & Mays, 1995). Therefore, in this qualitative study it was important to cross-check interview data from multiple data sources by using triangulation. Triangulation is defined as using more than one method to collect data on the same topic to assure the validity of research (Pope & Mays, 1995).

In this qualitative study, 67 individual interviews were conducted on site at the RMMCH facility. For each of the selected participant groups, pregnant HIV positive women from the antenatal clinic, maternity and postnatal wards (n=55), nurses in antenatal clinic and maternity ward (n=5), Paediatricians (n=3), Obstetricians and Gynaecologists (n=2), Neonatologist/Intensive Care Unit (ICU) (n=1), and Executive Manager in ESRU (n=1) were interviewed and surveyed.

The interviews were scheduled during clinic hours for patients and working hours for healthcare workers that were participants. A small meeting room in the antenatal clinic for the patient interviews. Healthcare worker interviews were conducted in the privacy of their own offices. It was important to have this study design flexible and adaptable to maintain responsiveness of the participants in unpredictable situations (Pope & Mays, 1995).

Informed consent forms were completed by all participants and a copy was given to each participant before the interview commenced. Throughout the interviews, probes were used to offer clarification and encourage elaboration from the participant on specific issues or topics that were domains of interest to the PI. The audio-recorded interviews ranged from 21 to 39 minutes and subsequently, transcribed verbatim to secure accurate participant responses. Typed notes were taken throughout the interviews for the purpose of cross validation with the audio recordings and final interview transcripts. Audio recording provided a more accurate representation of an interview than any other method and allowed for cross-checking if any notes were missed throughout the interview from the PI. A meeting among the committee members of the thesis research occurred after interviews had commenced and weekly follow-up with the LPI and supervisors to share initial perceptions of the content and process of the interviews.

Data Analysis

Demographic Patient and Healthcare Workforce Questionnaires

Responses from the demographic profile questionnaires of patients and healthcare workers were analyzed using QSR NVivo 10 software because of its ability to provide deeper analysis for rich qualitative data. Descriptive statistics, frequencies, measures of

dispersion and central tendency were compared to interview data. In order to link demographic and interview data, domains of interest were used. From these domains, themes emerged with participant descriptions. The quantitative data corroborated and clarified the participant's perceptions and demographic characteristics of the healthcare workforce of RMMCH.

Qualitative Semi-Structured Interviews

Data analysis for the qualitative interviews occurred alongside data collection. Prior to data analysis, all electronic transcripts were transcribed verbatim by the PI. There was no translation needed, all participants spoke English. For the qualitative semi-structured interviews with healthcare workers and patients, a thematic analysis using the Accessibility Framework was used to guide the identification of domains that emerged from all transcribed data and audio recordings with the help of QSR NVivo 10 software. Throughout data collection, analysis consisted of comparing the data to the literature and participant cases, reflection, and continuous refinement to hone on most prominent themes and relationships. The PI acknowledged and recognized biases and assumptions held by their influence on the emerging theoretical concepts in the data (Pope & Mays, 1995). For example, the PI may have a biased opinion about the availability of educational sessions held at hospital. Therefore, the theoretical concept of availability and educational services may influence data analysis and coding by the PI drawing that relationship. Therefore, the research conducted inductive and deductive analysis simultaneously. Inductive reasoning allows for the researcher to avoid separating stages of design, data collection and analysis but work forwards and backwards between data, conceptualization and period of collection (Pope & Mays, 1995).

The process of data reduction began with open coding; all interviews were first transcribed during the interview and audio recording, then re-listened to and re-read to identify possible meanings and concepts throughout the data collected. Open coding is the stage of analysis in which initial categories and subcategories are identified from the raw data collection. In addition, a journal with notes was maintained to track the progress of the study and included memos related to the analysis of the data, including concepts, categories, or possible corroboration that was occurring at specific points in time throughout the data collection. This was useful in facilitating data analysis and reporting by allowing the PI to keep track of the interviewees' body language and tone of voice when responding to specific questions. For example, if a patient stated they understood everything a healthcare professional tells them but when probed to explain what they learned by the PI, the patient may twist her body inwards, scratch her head and mumble demonstrating she was unsure and did not fully understand everything she was told. Therefore, journaling was able to capture social cues that an audio recording may not be able to pick up.

The transcribed data were analyzed using a two step method, first the audio recording and note taking was done simultaneously throughout the interview process, secondly the audio recording was replayed and transcribed. QSR NVivo 10.0 software, a qualitative data programme that helps organize the volume of data was used. The software helped draw relations and common themes throughout the literature that was also entered and analyzed using the Accessibility Framework for data collection. This strengthened the rigor of the study with open coding as subcategories and conceptual relationships were drawn and a coding scheme emerged.

The committee members informally compared perceptions of the data and contributed to the coding scheme. Transcriptions were coded separately and differences were brought up in scheduled meetings and discussion with committee members. A triangulation technique was utilized in order to cross verify data sources. To ensure the credibility of the findings, committee members as analysts reviewed the findings from transcribed interviews.

The second phase of analysis, axial coding was used. Axial coding is used in qualitative data analysis, as part of relating codes such as categories and concepts to each other by utilizing a combination of inductive and deductive thinking. The observations and any questions that were recorded in memos assisted in developing of an initial coding scheme. Consensus was then achieved on the third version of the coding scheme. These major categories were aggregated from the raw data collection and then NVivo 10.0 was used to reduce and identify themes across all sources of data. Themes that were identified were compared to determine relevance and value in describing the Option B+ PMTCT implementation at RMMCH. This included the perceptions of participants, both patients enrolled in the programme and healthcare professionals following policy, procedures and guidelines for the implementation of the programme. Interview transcripts were coded using the domains identified in the interview guide. For example, education was a domain that would then provide data about availability of educational ART services provided at RMMCH. This would be coded under the concept of availability according to the Accessibility Framework. The themes that emerged from the interviews were then clustered by characteristic similarity according to the four concepts (availability,

affordability, acceptability and adaptability) of the Accessibility Framework by NVivo 10.0 to inform the interpretation of the data.

Rigour

In qualitative studies, the investigator is the main tool for data collection and analysis. The investigator uses their own expertise and knowledge in analyzing the data for the case study. Therefore, the investigator must be able to use their own personal assumptions that may influence data interpretation to help guide them. However, it was crucial that these assumptions be acknowledged and disclosed, in order to enhance credibility and validate the findings of the study results. For example, an assumption that the investigator may have is that all patient participants may not disclose their HIV-positive status to their partner(s) due to fear of losing steady income being brought into the household. This could impact the findings for the concept of affordability because of the opportunity costs that a patient participant undergoes to retrieve her ARV supply from the hospital, overall impacting her adherence to Option B+. However, it is important to acknowledge that some participants disclose their status and develop a support system with their partner(s); this can impact the adherence and the woman's ability to stay on ART. To ensure bias is acknowledged, it is important that the investigators assumptions are articulated. Triangulation was used to enhance authenticity of the research process and findings, to ensure that different phenomenon of study participants were presented (Yin, 2009).

The validity of a study is dependent on the reproducibility of the research design and analysis (Pope & Mays, 1995). A record of the study was maintained through memos and journaling. The purpose of the memos was to maintain a process log and capture any

observations at specific points of time from the PI, especially when conducting the interviews (i.e. body language of participants when answering questions). Furthermore, memos allowed the PI to maintain a record of analytic decisions and any alterations made throughout data collection and analysis. For example, behaviour from participants was recorded to help open discussion and analyze certain themes that emerged and explore them further in depth. The written and electronic record from QSR NVivo 10.0 of the coding scheme and interpretative processes used in the data analysis included all files and any changes made to the database. Furthermore, the timelines for the study allowed the PI to complete tasks in a timely manner in order to allow time to cross check and ensure validity of the findings. A member check was completed with healthcare professionals to improve validity of the transcribed interviews. In order to ensure accuracy and understanding of the patient participant responses, the PI would ask patients to reiterate for further clarification.

Audio-recorded interviews were transcribed with the support of NVivo speech recognition software. The researcher listened to the interview recording, while transcription is occurring to ensure accuracy. Codes were assigned to interview transcripts and questionnaires and all identifiers were removed as soon as transcription is complete. Interview recordings were erased from the computer hard drive once data analysis was complete. In order to disseminate the findings from the research study, a presentation was given to all healthcare professionals from different departments at RMMCH that either participated or were interested in the topic of research. To reach the patient participants and the community attending RMMCH, an information booklet and fact sheet was provided (see Appendix L). This included information on Option B+, the

findings and recommendations that could inform and spread awareness to at risk and vulnerable pregnant women. The booklets and fact sheets were provided to all units of RMMCH.

In addition, regional and national practices of the current Option B+ outcomes were identified through a literature review along with data on current practices in Johannesburg, South Africa. This was collected through key informant interviews, site visits and document review. The package of service delivery offered at RMMCH was analyzed in detail, described and compared with key consideration for the South African context highlighted. A content analysis of relevant literature from the WHO, South African PMTCT guidelines for the Option B+ policy and procedures at RMMCH enabled the researcher to determine how information is understood and disseminated by key actors of health care professionals, participants and the government.

Chapter IV: Findings

In this chapter, the findings describe the impact of WHO's national consolidated guidelines for Option B+ PMTCT programme on both the work of healthcare professionals and for pregnant HIV-positive women's views and experiences with going on ART for life. The findings from the demographic questionnaires and qualitative semi-structured interviews are presented using the Accessibility Framework to address the study objectives by:

- 1) exploring the impact of the national consolidated guidelines for Option B+ PMTCT on the work of healthcare professionals at both clinical and management levels (including nurses, physicians, and management)
- 2) to understand pregnant HIV-positive women's views and experience with ART for life, as a way to better manage the Option B+ PMTCT programme within state hospitals

Demographic Profiles: Patient and Healthcare Workforce Data

The demographic characteristics and profiles of both the patients and healthcare workforce participants in the selected hospital site of RMMCH were provided.

Demographic data were collected from 67 participants which included HIV-positive pregnant women (n=55) from the antenatal clinic, maternity and postnatal wards, nurses (n=5) in antenatal clinic and maternity ward, Paediatricians (n=3), Obstetricians and Gynaecologists (n=2), Neonatologist/Intensive Care Unit (ICU) (n=1), and an Executive Manager in ESRU (n=1). The average age of the healthcare worker was 45.6 years old (see Table 1, Appendix M). It should be noted that these data were self-reported.

The average years of work experience reported by healthcare professionals in their current occupation was 13.5 years (see Table 2, Appendix M). The gender of the study sample of healthcare professionals was 75% female and 25% males (see Table 3, Appendix M). The majority of the healthcare professionals in the departments and units interviewed are employed full-time.

In summary, the findings from the healthcare professional workforce demographic data indicate that healthcare workers at RMMCH have acquired a great amount of experience in their own professional roles and departments.

The average age of a patient participant was 33 years old with three dependents and had undergone one stillbirth. For the total of 55 patient participants, 19 patients were married and 36 were not married. The oldest patient was 44 years old and the youngest was 19 years old. There were 34 patients out of the 55 patient participants were on Option B+ for 6 months and only 2 patients on Option B+ for less than a week.

In summary, the findings from the patient demographic data indicate that most women were placed on Option B+ for a duration of six months which is fairly recent to understand the long term benefits of the programme.

Framework to Organize Findings

The Accessibility Framework by McIntyre et al (2009) is used to analyze three dimensions of access, availability, affordability, and acceptability. In addition the concept of *adaptability* will be explored. The contextual understanding of one healthcare environment in which the Option B+ PMTCT programme operates within can address policy implementation and programming issues, this can inform how scalable and sustainable the program me is on a larger scale. The national guidelines have been

developed but adaptability may remain problematic in successful roll out of the programme outside of RMMCH.

The following findings provide the perceptions of a) patients b) frontline nurses c) healthcare physicians and d) executive managers for each of the four dimensions of access, *availability*, *affordability*, *acceptability*, and *adaptability*.

Findings: Themes in Qualitative Semi-Structured Interviews

The following is the description of the findings from the semi-structured, qualitative interviews with both pregnant HIV-positive women enrolled in Option B+ PMTCT and healthcare professionals at RMMCH. The findings demonstrate that the healthcare work environment has become difficult to manage for all healthcare professionals because the profile of HIV in South Africa is shifting with the release of the new national consolidated guidelines for the PMTCT and the management of the Option B+ programme for patients. RMMCH adopted the national consolidated guidelines, leading to a need for proliferation of protocols and practices regarding the initiation of the programme. An increased amount of data is needed in order to strengthen indicators for tracking to decrease LTFU because increased numbers of pregnant women are put onto ART at an accelerated fashion. Women are starting treatment on the same day as being diagnosed as HIV infected. There is inconsistency in delivery of counseling and support services needed for communication across clinical and management departments because guidelines are taking time to be translated across the healthcare system in a manner that allows for consistency in messaging. There is a lack of compassion and understanding by service providers due to frustration with their patients and overall understanding of the programme. The difficult healthcare environment has affected overall views and

experiences of pregnant HIV-positive women going on ART for life. Pregnant HIV-positive women are seeing the Option B+ strategy as for PMTCT only, not understanding the long term benefits for both the woman and her baby.

Perceptions of Option B+ PMTCT in RMMCH

The study findings suggest that the Option B+ strategy has good uptake and medication adherence in the initial phase. In the long-term use however, perceptions from both healthcare professionals and the patients themselves suggest adherence falls off. Reasons discussed were the lack of education, stigma and cultural issues that still exist and pose challenges in the initiation of the PMTCT programme in healthcare facilities such as RMMCH.

AVAILABILITY

Availability is concerned with whether appropriate health care providers or services are supplied in the right place and time to meet the needs of these HIV-positive pregnant women (McIntyre et al., 2009). Availability involves an interaction between the pregnant HIV-positive woman, the health care system, and the Option B+ PMTCT programme. This includes availability of psychosocial support and educational services for the patient. The healthcare professionals have an increasing demand for data to be made available in order to provide better services and quality of care to their patients. They are often perceived as unwilling to spend enough time with the patient due to the large demand of the patient population. The healthcare environment faces many organizational challenges such as ARV supply and the lack of human resources to deliver consistent information to the patient.

Patients Perceptions

Need for Services

The findings in this section demonstrate there is a need for educational and psychosocial support services to be offered for patients with the Option B+ PMTCT programme. These services can provide to HIV-positive pregnant women the opportunity to learn more about their treatment and inform them about ways to reduce the risks to their health.

Education: Beneficial or Harmful?

Pregnant HIV-positive women felt the need for more education to understand why they had to take FDC or had been switched to one pill a day. Participants wanted to learn more about the PMTCT Option B+ programme. The lack of PMTCT knowledge posed a barrier to retention for the patient in understanding benefits of medication adherence. Knowledge translation should occur from the healthcare provider to the patient, but often it is impeded by unequal power dynamics causing the patient to feel intimidated or nervous to be proactive and ask questions. Patients during counseling sessions may view healthcare professionals as authority figures. Many women reported it was difficult to understand what the nurses told them at times because it was either unclear or too noisy to hear. Some women expressed that it was hard to ask questions in front of their peers so they waited until they could get a chance to do so in private.

Patients have a lack of understanding the benefits or why they actually are told to take ART. Knowledge is power, the more educated the more aware the pregnant HIV-positive mother was. Education can be a useful component in increasing medication

adherence in patients at RMMCH. A 38 year old patient, married and has undergone three miscarriages states,

“I don’t feel like there is enough education here at RMMCH. I have gone to my local health clinic and they provided a three day workshop. I have done adherence events which were three hours each, teaching me about how to use ARVs.”

Whereas a 35 year old patient and eight months pregnant states,

“I have participated in education workshops here at RMMCH and find it useful. I learned about using condoms when having sex, eating healthy food and to not just sleep around. My local health clinic does not give me as much information. Though I feel comfortable asking questions at the clinic and it is not as far, I come here and spend a lot of money and receive more education.”

Education and information is not consistent across the local health clinics for Option B+ PMTCT. This can be harmful when only parts of the educational messages get across to patients. Patients are becoming overwhelmed with information they receive from various sources which include local health clinics, healthcare workers, media sources (i.e. TACs, campaigns, Google) and family/friends.

Need for Psychosocial Support Services & Privacy

Interviews with patients did reveal that very few of them are attending any form of psychosocial support services, though most women agreed that it would be a helpful component of care if made available.

Psychosocial support services are an essential component of the PMTCT programme at RMMCH. All HIV-negative women must be repeatedly counseled about

HIV prevention and at every visit. Healthcare workers must identify women at higher risk for poor adherence in order to provide enhanced support i.e. a pregnant HIV-positive woman taking ART for PMTCT rather than her own health, any signs of depression, substance abuse, lack of social support, gender based violence or food insecurity. Counselors should educate women about availability of child care grants and support options as well. Counselling includes consistent condom use, particularly important during pregnancy when risk of HIV acquisition is increased.

Many clients prefer one-to-one counseling or feel supported at times amongst a group session at the hospital, with the option to discuss in private any questions they may have with a nurse or healthcare worker. A 40 year old patient in her third pregnancy states,

“The counselor is friendly. I like that she recognizes people and this is the way you should interact with your patient. I feel comfortable to get and not nervous to ask the healthcare worker questions. I want to ask but in private and not in front of everyone.”

Meanwhile a patient that is thirty weeks pregnant states,

“I don’t really feel comfortable asking questions. The [healthcare] workers are nice. I am nervous and they will keep telling me things I already know. Sometimes you can’t keep asking, so you just listen to what they have to say... They keep my business private”

It is important to give the patient different options and ways that they can be proactive and interact with the healthcare worker comfortably. This can help build trust and an

open ended relationship increasing communication between the patient and healthcare worker.

Frontline Healthcare Workers Perceptions

The Increased Need for Data Information

The findings in this section demonstrate an emergence of a data-driven organizational culture that has changed the nature of health professional's work. The participants reported changing responsibilities and requirements related to data collection, monitoring and evaluation, and reporting for the indicators in order to strengthen the initiation of the new national consolidated guidelines. The findings in the following four sub-sections demonstrate that data requirements are changing within the organization.

Data Collection

Healthcare professionals that participated in the study reported on how data were collected specifically for HIV infections and the PMTCT programme to make decisions about patients clinically. At RMMCH, there is a heavy reliance on paper-based medical files. One source of synthesized data is antenatal cards that women use when visiting RMMCH. The antenatal card indicates medical history, HIV status, the specific ARVs the patient is prescribed, the local health clinic, and duration of pregnancy. A woman enters RMMCH with her antenatal card. After being screened by a nurse she is given a number written on a piece of paper that she must keep until she is called on. Women wait an average of 3-6 hours to see a physician in the antenatal clinic. This number, her antenatal card and her entire medical file is what she will carry with her for each medical appointment. An implication of this system has placed onus on the pregnant woman to keep her medical file safe.

Information Management and Data Assimilation

Managing information of HIV data collected from patients at RMMCH places a huge responsibility on executive management and clinical staff. In order to manage the data of many patients, a coordinated effort must take place across all departments and units. Additionally, patient files are non-electronic and manually recorded on paper and then kept with the patient themselves. One nurse states,

“This creates a risk if files are lost there is no backup file to track the patient which contributes to the LTFU.”

Issues Arising with the Available Information of Option B+ PMTCT

Many frontline workers believe that women are receiving information about Option B+ through their local health clinics and secondly at RMMCH. However, at times not enough education is provided at their local health clinics and patients depend on RMMCH to receive information. This has caused heavy reliance on frontline workers to deliver information that has the same messages about Option B+ PMTCT to a patient, as other departments and units across RMMCH. One nurse states issues faced with communicating updated information because of the constant changes to the new consolidated guidelines,

“Women are being educated. I think the problem is with all the changes we have to update our patients. So now I tell them it has changed. There needs to be more education with the healthcare workers, then that gets transferred to the patient effectively. This way the patient is updated and education can be emphasized. The

woman can't say they do not know. All sources they access need to align with the information they provide."

Another gap that was raised in interviews was the fact that some patients know about their HIV status for a long duration of time and are not on ARVs. They should already be on ART but because of the new guidelines, patients misunderstand and wait to return for a CD4 test again. Receiving many educational messages can become confusing for the patient. Patients have information thrown at them from their first encounter with frontline worker, from their local health clinic, when they are transferred between units at RMMCH and follow-up with a physician.

Screening Patients: Prevalence of HIV in Pregnant Women

Healthcare professionals reported an increase in the number of pregnant women with HIV, based on screening women who walk-in or are referred to RMMCH. According to healthcare professional participants the approximate year that an increase in the prevalence was perceived ranged from 2014 to 2015. Amongst the healthcare professionals interviewed, the increase in HIV infections in pregnant women is believed to be due to the new national consolidated guidelines with changes to screening patients for HIV. One nurse that has worked at RMMCH for 24 years noted,

"I don't know to be honest with you if it is Option B+ that is more effective. The fact that there is a better testing system for the mother and her baby may have to do with it. There was a time when we had two patients pass within the year and now we detect many positive patients and babies. It is hard to say whether it is the PMTCT programme itself or better testing methods."

Some healthcare professionals do not think there has been an increase in HIV infections in pregnant women and believe there has just been more attention paid to the presence of infections at RMMCH with the new national consolidated guidelines. It is unknown if there has been a true increase in HIV infections occurring with pregnant HIV-positive women or if this apparent increase results from vigilance in monitoring and screening HIV in patients, making the issue seem more evident.

Healthcare professionals that participated in the study reported that it is crucial to screen pregnant women on admission to RMMCH to determine what the next steps are for treating the patient in order to protect her and the baby. The charge nurse in the ANC stated healthcare workers conduct viral load and adherence monitoring for the patient,

“The RNs and nursing assistants report on duty by 7am. The delegation book must be signed and each worker must start to prepare for the moms that attend here as early as half past six. The nurses are responsible to collect the antenatal cards and assign numbers depending on a first come, first serve basis. Nurses proceed with observations, weighing, running urine and blood tests before the patient is seen by the doctor. If the woman is not tested for HIV, we try to make sure testing is done on a 3 month period. She will then have her medications issued. The patient gets to see the doctor, has their stats done and then is sent to the ward. If the pregnant woman is referred from another clinic she will undergo the same process.”

RMMCH’s antenatal clinic has adopted the HIV Testing Algorithm for Option B+ to screen efficiently for reactive and non-reactive pregnant women and encourage follow-up for HIV-positive pregnant women. Pregnant women that test negative, repeat the test

in three months to exclude any possibility of a window period (see Appendix N). The healthcare worker will explain to the patient their results and CD4/viral counts. The blood sample is sent to the lab for a final third test before the patient returns in 3-5 days for results of enzyme-linked immunosorbent assay (ELISA) follow-up. At the final stages of the HIV Algorithm from the ANC, ELISA is interpreted as positive or negative and counselling is provided in both states. If results are negative, the client is encouraged to repeat the test in 3 months to exclude the possibility of the window period where there may be a risk of infection occurring or a LTFU.

Many pregnant women become LTFU due to poor screening and inadequate assistance from psychosocial support services, even pregnant women who test negative. The patient's CD4 and viral counts are measured to determine their stage of HIV infection. Pre-ART management is executed, providing the pregnant HIV-positive woman her ARVs.

Perceptions of Organizational Challenges

The findings in this section demonstrate there are some organizational challenges, related to the implementation of Option B+ PMTCT for HIV, which have changed the nature of health professionals' daily work. These include resource limitations and the lack of human resources for healthcare service delivery.

Stock-Outs: Limited Medication Supply

Medication supply can be a challenge at times for keeping up with the demand for ARVs of patients. Some healthcare professionals were surprisingly unaware of RMMCHs struggle with medication supply. When asked *“How would you rate your medication*

supply here at your facilities on a scale from 1-10?” (10 being the highest) Responses differentiated between a frontline nurse versus a physician in the OBGYN unit,

“There was a time there was a shortage with drug supply a couple of months ago, this was due to not being supplied by companies. I would rate it about a 7, because we run short. There was a time for 4-5 months that we couldn’t give our patients medication. If we refer our patients to private doctors it is too expensive for them, many don’t use medical aid and pay cash. They rather stay at home without taking tablets.” –Nurse in ANC

“No I don’t think we have stock outs, I rate it a 9” – OBGYN

Frontline nurses had more direct contact with medication supply and were more aware of stock-outs than physicians. When interviewing nurses in the wards, it was brought to attention that FDC is not part of the ward stock. Patients in the wards are supposed to bring their ARVs and the frontline staff will register their ARV medication dosages when doing their rounds. One nurse states,

“Some women get admitted here without FDC and they don’t disclose their HIV status. They don’t bring medication and we are not allowed to order for them. If there is any in the ward it’s because a patient brings it in and there’s already an order waiting for her (making that double), we will keep it for the next patient.”

Healthcare Physicians Perceptions

The Development of Protocols and Procedures for the PMTCT National Guidelines

Healthcare professionals discussed the historical events that contributed to the development of the new consolidated national guidelines to make ART available for those who in need. There was a need for the voices of those that were HIV-positive and

those who were impacted by this disease to be included in order to strengthen policy implementation at RMMCH. The following section on treatment action campaigns highlights the massive amounts of information a patient can become bombarded with. This has caused miscommunication in understanding Option B+ PMTCT for patients.

Treatment Action Campaigns (TAC): Proliferation of Messages

TAC pushed for ARVs and the rights of HIV-positive people. One physician from the OBGYN unit stated,

“South Africa went through a history where the Department of Health considered HIV a disease of poverty and that ARV treatment was toxic. Pregnant HIV-positive women were condemned to no treatment, and mother to child transmission remained stagnant, courtesy of the Minister of Health at the time. TAC worked to ensure that at the very least there was some sort of prophylaxis to help slow the transmission between the mother to child. Those days they fought for a single dose of NVP and to this day we have come from that single dose of NVP to AZT to Option B to now, Option B+. A lot of credit must go to the people who fought and their sustained effort in getting the DoH to realize their obligation to provide pregnant HIV-positive women with ARVs. TAC were also instrumental in getting children under 5 years access to ART.”

Another nurse in alliance with TACs suggested,

“I certainly think it informs the patients about different options and many patients can distinguish between the different ARVs and other tablets, though I wouldn't say they know the names of the tablets. Media campaigns were used to encourage male circumcision. Profoundly this was one of the most convincing

methods with TAC and played a huge role to us being where we are today. This is the most progressive treatment guideline where it targets different groups of people, those who have TB, anyone with CD4 count less than 500 which qualify for lifelong ART and children under 5 years for ART and finally for pregnant HIV-positive women regardless of CD4 count.”

TAC have contributed massive amounts of information to the large population of South Africa. However, this has caused miscommunication at times with the messages being delivered to patients. It can become overwhelming for a HIV-positive pregnant woman to receive information from many different sources such as her local health clinic, media campaigns, internet, and hospital facility. These messages and information may not align or be consistent which is challenging for Option B+. Healthcare professionals recognize downfalls of TAC as well,

“There is a big place for TAC for PMTCT and HIV. However, the person that is supposed to implement the campaign at times may not fully understand the topic themselves. They don’t know how the ARVs work or how I as a healthcare professional encourage a patient to take it.”

Quality of Care

The RMMCH environment is very busy and there is a high demand for physicians to deliver good quality services. Healthcare professionals often transfer patients to different departments and units in order for the patient to receive better care and expertise for specific services they may need. Often, due to the busy environment, good quality services become sacrificed at times. The following three sub-sections will elaborate on

the areas that need attention from healthcare professionals in supplying good quality care to patients.

Connecting Departments in Transfers

Quality of care includes increasing the amount of time spent with the patient. Physicians will refer patients to counseling because they may not be able to spend enough time with them. One pediatrician explains,

“I refer because time is limited and I myself have no particular programme whereas counselors do. In the wards we explain to just take the ARVs until the baby is fine. Patients will try to hide their positive status from us. We risk LTFU.”

Respecting Patient’s Privacy

Patients should be provided with the best possible care from the staff at RMMCH. However at times and depending on the busy healthcare environment with limited space, it is challenging when it comes to respecting the patient’s privacy during HIV status disclosure. The lack of facilities can create an obstacle to counseling patients. Physicians will regularly have to take a woman to another room to talk to her separately because it is difficult in the wards. One physician states,

“We treat the patient as a whole, if there is a problem with HIV; we will take them to another room with the counselor so it’s private and away from other patients. We take reports, and I am not sure if it’s the medication that gives away the status- but though we close the curtains, another person can hear. Patients even discipline us doctors at times.”

Need for Support Groups

Physicians expressed how by the time the patient sees them, they understand that the patient has been tested by nurses and have had to go through the shock of finding out their diagnosis all in one day. By the time the physician talks with the patient, they find them to be passive because they are complete strangers. Some physicians take it personally while others understand it is a process. One physician states,

“Healthcare workers don’t understand at times, the patient has to be counseled repeatedly and in detail. It happens three times before the patient understands.”

Physicians express that there needs to be support groups for women to be able to open up and communicate what they are feeling. A physician expressed,

“We use to run a support group in the clinic on Fridays. Women liked being there and together. Now they just sit in the general public. The support groups are important.”

Executive Management Perceptions

Loss to Follow-Up (LTFU): A Barrier for Option B+ PMTCT

In the following section, several factors contributing to the LTFU will be described. The lack of indicators, managing medical files, regulating patient flow with challenges of low retention rates with foreigners and unsuccessful tracing have all impacted the healthcare professional environment of RMMCH.

Monitoring and Evaluation of the PMTCT National Guideline Indicators

The development of the new national consolidated guidelines for specifically PMTCT, has promoted the proliferation of numerous policies and protocols. This has led to developing indicators within RMMCH much like other healthcare facilities to help

monitor and evaluate the Option B+ PMTCT programme. Currently, the revision for strengthening these indicators is ongoing. Indicators are recorded monthly at the antenatal clinic at RMMCH and daily registers are used to record patients. Reports will be done monthly and annually for total births in the facility, maternal health, immunization, and HIV counseling and testing (HCT). The ongoing changes to indicators and recognizing gaps in monitoring and evaluating outcomes of the Option B+ PMTCT programme have become challenging for RMMCH. There are no established indicators, causing inconsistency in measuring the effectiveness of Option B+. This in turn, impacts the clinical training of healthcare professionals with their delivery of the PMTCT programme to patients at RMMCH. One executive manager states,

“I am finding a big gap and it is quite scary what education is being told to our patients at times, they are falling off the grid and incorrect information is an example of the issues with the education component of PMTCT programme. The first person that speaks to a patient or the first interaction that patient has with information is what they will believe. It is hard to come in and now say something different to them. Incorrect information can act as a barrier.”

Healthcare professionals and administration staff are finding it challenging to monitor the ongoing progress of Option B+ PMTCT for reports at RMMCH. One administrator in the Empilweni HIV clinic emphasizes issues with indicators that are arising,

“The WHO created these guidelines with unrealistic indicators that do not address certain gaps. For instance, say you have one hundred pregnant women being tested for HIV, out of those hundred women, say there are 10 positive babies delivered. There isn't any indicator that has been developed to tell us that

those 10 babies belonged to 10 positive women from those 100 that were tested.

There is a huge loss to follow-up with these women. Therefore the outcome of what is measured is not telling us the entire truth.”

Regulating Patient Flow: Management

RMMCH supplies HIV-positive pregnant women with their necessary ARVs for the Option B+ programme. South Africa provides free ARV treatment in government hospitals like RMMCH. This has attracted an increase in the number of non South African patients attending the hospital facilities. An executive manager stated,

“We need more drug companies on board. We don’t supply to everybody and that is simply a reason of this. If people paid a bit for their treatment, they would appreciate it more and not abuse the system. There are a lot of foreigners that come in for delivery and free treatment and this is totally wrong, they fly in and out, it is causing a major problem.”

The patients attending the antenatal clinic at RMMCH consist of many walk-ins in comparison with referred patient population served by units such as OBGYN, postnatal wards and the Empilweni Clinic attend to. A pediatrician states,

“I work in ICU and the ward for two weeks at a time. I see about 10% of patients are referrals, the rest are walk-ins...”

Whereas a nurse in charge in the antenatal unit commented,

“We have about 15 clinics that refer patients to us on a daily basis. We receive up to 30 referrals. Its emphasized to mothers to book at their local health clinics and walk ins are mothers that are very sick and cannot attend their local health clinics, so we get about 46 moms. The subsequent visits are mothers that have

been here before and given dates for follow-up. We can count up to 100 subsequent mothers sometimes.”

Therefore, the department or unit a healthcare professional works in will determine whether the patient is a walk-in versus a referral. It is crucial that if a patient is being referred to the unit internally, that follow-up is completed in order to track the pregnant HIV-positive woman from her initial stage of pregnancy up to delivery.

Lack of Human Resources for Healthcare Service Delivery

The healthcare environment in the ANC has undergone a lot of changes overtime. Previously, there was an HIV focus group for women held at the clinic weekly which allowed women to come together and discuss issues they were encountering with their status. This group allowed members to build a network and support system outside of their homes. A manager that has spent the past 8 years working at RMMCH states,

“Women thoroughly enjoyed coming in and expressed how they looked forward to the focus group. It was a way for them to keep positive and understand they weren’t alone with their HIV diagnosis. We unfortunately removed the focus group; women would have to come twice a week. Changes were made where Fridays became the postnatal clinic at the ANC instead.”

This is a prime example of how changes made to the ANC have impacted the educational component of the Option B+ PMTCT programme for HIV-positive women in a detrimental way. There is a large demand for knowledge translation to occur effectively between healthcare professional and patient. Without follow-up educational sessions and focus groups at RMMCH for Option B+ PMTCT then heavy reliance is placed upon communicating messages at the first point of contact with a patient.

Time is Money

Making time for patients is very crucial. Often healthcare workers are under pressure due to the high demand of patients at RMMCH. Managing time is a challenge for healthcare workers and it has unfortunately caused them to deal with patients inappropriately. An executive manager stated,

“We are not aware much of the complaints from the community we serve here at time. Once patients get here, the treatment is not exactly friendly from the nursing staff. It is a struggle to access our hospital sometimes for these women and I know clinicians are poor at identifying patients due to the high demand of patients that we see here. Our catchment area is not geographically large and I was not aware patients bought addresses. Pretty sure that someone who comes in may have a difficult time getting here but will keep silent about it.”

AFFORDABILITY

Affordability is concerned with the individual's ability to pay in order to access healthcare services (McIntyre et al, 2009). Often HIV-positive pregnant women have to undergo opportunity costs in order to use healthcare. This can be the cost of travelling to and from the healthcare facility, waiting for service and additional costs associated with using care. For example, attending a clinic may involve both income losses associated with time of work and out of pocket costs for transport. This cost will vary with the frequency and duration of the treatment. These opportunity costs are individualized and dependent on the context in which the costs are experienced. The impact of ill-health can place a burden on a household's affordability to access the healthcare system. Therefore

affordability of healthcare services, such as the Option B+ PMTCT programme can be measured by opportunity costs.

Patients Perceptions

Lack of Income: Barrier to Receive Health Care

FDC treatment is provided for free to pregnant HIV-positive women on Option B+. However, women incur opportunity costs associated with adherence to the programme such as lost income from missed time at work. In addition, women may struggle to maintain a healthy lifestyle (e.g. diet) due to their income level.

Opportunity Costs

Many patient participants expressed how balancing their daily duties of being a mother and wife can pose challenges in adhering to their ARVs and attending their local healthcare facilities or RMMCH. For instance, some patients were working but had to take time off work to make appointments at the hospital or return for follow up. Women reported that they sometimes have a hard time with their managers, even though they provide a doctor's note to their employer.

Patients expressed concern over their lack of income which makes it difficult for them to travel to RMMCH. One pregnant HIV-positive woman states,

“It is hard to get the taxi to go get the medication at times, I have to miss work and tell my manager I have to get medication. I get paid sometimes if I miss work, depending on if I provide a letter from the doctor. The little bit of money I make is only for groceries...it is very hard because I have my children's school fees, transport and other commitments...their father is not active.”

Many study participants reported that taking the FDC at night did not interfere and many did not work difficult hours and were home to make dinner and then take her medication before bed. Though ARV treatment costs were covered by the South African government, almost all of the study participants still reported that if they had to pay for their medication, whether or not they were working, they could not simply afford to do so and were already struggling to cover school fees for other children dependents, groceries for the family, transportation costs of mini bus taxis and the everyday expenses that came from their own pockets.

Pregnant HIV-positive women were more concerned about their need for income generation. Many women walked in eating junk food (i.e. fatty chips like Niks-Naks) at early hours of the morning in the antenatal clinic. It is crucial that nutrition be emphasized in educational workshops for patients to understand that it is part of treatment along with adherence to ART. One patient stated,

“I am responsible for my actions. I sit and listen to the education and counseling sessions. I was a counselor myself for HIV pregnant women. I find it useful and okay the way they do it here. [PI: Is there anything you would change here to make it more effective?] R: The one-on-one sessions done for healthy eating should include exercise. I use to do it at my local health clinic.”

Patients are interested in learning about ways they can maintain and afford a healthy diet with the little income they have.

Retrieving Medication Supply

Many pregnant HIV-positive women when interviewed about if there were any challenges in retrieving ARVs for treatment would respond that it was “easy” to get

medication but then explain that they wait on average two and a half hours. Many of these women wake up early (before work if they are employed), rush their children to school, and then wait in line to get their treatment. One 35 year old woman and thirty one weeks pregnant responded,

“I get my medication at Helen Joseph and Mayfair clinic. It is easier to get meds from Helen Joseph hospital. I make an appointment to get it. I have to wait long to get medication, maybe three hours or more so. I have to be early to get through the line-up fast. I am not paying for my medication or use medical aid. I am working but it depends on price. I don’t think I could afford the medication but if I had no choice then I would have to pay and be willing to do so...On your side here at RMMCH, it is not as long and I don’t have to pay for medication.”

Pregnant HIV-positive women will access treatment from their local health clinic or hospital facilities like RMMCH. Many of these women are not working or cannot afford medical aid or treatment, even if they are employed.

Frontline Healthcare Worker Perceptions

Buying Addresses

RMMCH has many patients that do not live in the catchment areas that the hospital serves. Often a patient will enter the interview room carrying her antenatal card. This card provides the name of her local health clinic in which she may be referred from in order for the healthcare professional to understand if she is from the catchment areas the hospital. Frequently, the address that she provides is different from the one written on the card, while in some cases the card is photocopied or is a fake. Often women finish at the antenatal clinic and are unable to afford transport home. A nurse commented,

“We provide money out of our own pockets to patients so they are not left stranded at the hospital... It is the governments’ duty to supply patients with medication. Our patients do not have medical aid and most are not working. They lie about their addresses and if they do not live in surrounding areas, they have to go the closest hospital where they stay. These pregnant HIV-positive women end up buying addresses for proof of residence and will pay community members in the squatter camps behind RMMCH.”

Unsuccessful tracing and LTFU was mostly due to incorrect addresses that are given to healthcare workers, likely from clients giving false addresses due to fear of stigma and discrimination associated with using their local facilities. Patients may not attend their local health clinic and be staying with a partner in the squatter camps nearby the hospital. If RMMCH is their closest healthcare facility and the patient does not want to pay for private services then buying an address appears attractive to the patient.

Healthcare Physicians Perceptions

Understanding Opportunity Costs that Our Patients Face with Option B+ PMTCT

Healthcare physicians were asked about the challenges their patients face with the adoption of the Option B+ PMTCT programme at RMMCH and how ART for life has impacted patients’ ability to adhere to medication. Topics such as affordability for transportation, and opportunity costs that the patient may incur from time missed at work were discussed. One pediatrician states,

“The patients are reluctant to comply; they forget medication and then blame the stigma. We have problems with patients because they don’t want to be discharged from the wards and they lie about their addresses and say they won’t be able to

come back because it is too expensive. There are social problems and they don't want to go home, nobody visits them and their next of kin has no valid number that is provided to us."

There are issues with patients who buy addresses and have to travel to RMMCH, which is very far and they arrive late. Physicians believe that patients will not complain because they want to be able to access services for free up to when they deliver the baby.

Some physicians come to RMMCH to simply fulfill their duties and are not aware of the challenges and opportunity costs that a patient may incur just to see the healthcare professional. One physician states,

"None of the patients really complain if you don't specifically ask them. Once I know one is stable on the regimen, I don't function for after hours for their problems."

Executive Manager Perceptions

ART is Affordable

Executives perceived there was a major issue with affordability for these HIV-positive pregnant women when it came to ART. Managers felt that women have no choice but to have to take time off work and wait in the antenatal clinic for six hour periods. One executive manager states,

"Getting to the facility is needed, a woman's employer is not very sympathetic and if it isn't a sick day then they cannot afford to pay them. It has to come from their annual leave. This is one of the financial barriers these women are facing."

ACCEPTABILITY

Acceptability is concerned with the fit between provider and patient perceptions towards and expectations of each other (McIntyre et al., 2009). This includes perceptions towards characteristics of both the healthcare professional and HIV-positive pregnant woman on Option B+. This includes characteristics of gender and language which impacts the relationship of delivery and recipient of care. Respect and the ability to listen and discuss treatment conducted by the healthcare provider are very important, especially at the first point of contact with the patient (McIntyre et al., 2009). The ability to create a comfortable environment no matter what resources there are, to minimize burden and to avoid stigmatization will impact adherence. Perceptions and beliefs of the healthcare worker can influence the patients' ability to follow the Option B+ PMTCT programme. Perceptions of the patient can in turn influence the healthcare provider's willingness to involve them in the decision making process.

Patients Perceptions

The Ubiquitous Nature of HIV Transmission

Pregnant HIV-positive women participants perceived that HIV transmission is occurring within their community and though Option B+ aims to reduce HIV transmission between mother and child, much onus is placed on the patient to return home to their community with medication and adhere after leaving the hospital facility. They re-enter an environment submerged in South African culture, often filled with stigma and cultural shaming. One HIV-positive pregnant woman participant states:

“Different cultures are present in South Africa. However, it is the way you see what HIV is from your perspective. There is this ‘not going to die alone’ black

mentality. It makes you think HIV is a death penalty. I learned that I did not have the knowledge as well as my community members and this created an instant fear that I was dying.”

This ‘mentality’ has become normalized and not often questioned. All pregnant HIV-positive women that participated in the study were asked, ‘*How did you feel when first learning about your positive status?*’ Many of the study participants responded that they were sad and shocked at first, but then felt comfortable with their status because many people around them have HIV as well. Some study participants responses were:

“Yoh! I felt I was about to die and the world was ending. I was angry and confused and even blaming myself. I wouldn’t say I was depressed and I always find someone to talk to -like my mother. I trust her the most. I didn’t go through denial, I accepted it and moved forward and why, is because I suspected my partner and it was that kind of situation. I wouldn’t blame him and I didn’t know if I had it. I just want to see my life go on and I don’t know if I am angry still, I just want to move on. I panicked at the moment and felt like killing myself, and I want to beat this. I am not sure if I want a partner.” -35 year old woman and 39 weeks pregnant with second child.

“I was shocked because I did not want to have a positive status. I have seen people from the outside, they are sick with HIV and it is not nice. Now I feel much better, under control and understand it is not the end of the world. I must accept and move forward with my life.” -35 year old woman, 32 weeks pregnant and had two miscarriages in 2005.

Whereas a 41 year old woman and 37 weeks pregnant with her first baby states,

“Shocked, I do have a cousin that is positive and I learned from her how to accept and had support from family. She was very kind and explained to me the side effects of the ARVs, and I was aware. I was scared to take it but not anymore.”

Many pregnant HIV-positive women expressed that if they had a support system or knew of someone that had HIV/AIDS; it helped the acceptance of their status and even sticking to taking their ARVs. Some examples of responses from patients were:

“The person who was first ill was my husband and thought I would leave him and he kept taking his meds and I have not left him since 2004 till today. I got checked out in 2013 and then went on meds. I got tested in 2006 and was not allowed to take medication due to my CD4 count. I was not shocked or depressed, it was in the news and my mother is also on meds, I am use to it and my mother was taking it since 2002. Not shocked because it is normal and like any disease, not like the first time when we heard about it, it is preventable.”

Some women expressed that they have a support system at home with their partner and children,

“My husband knows I am taking the pill and we have a good support system. I am honest with him. The family reminds me and encourages me to take my medication.”

Disclosure of HIV status from Healthcare Professional

Many patient participants felt there was insufficient time to absorb the shock of finding out their status of being HIV-positive and having to start lifelong treatment immediately. Some patients felt overwhelmed, whereas others could cope immediately

and thought their HIV-positive status was the social norm. One HIV-positive pregnant woman participant states,

“I was shocked when I first found out about my status. I didn’t think I was going to be HIV-positive and I never thought about it and I didn’t know where it came from. I found it difficult when the healthcare worker said I have to take this medication every day... this one big pill, I was frustrated.”

Pregnant HIV-positive women are not given adequate time to absorb the shock of their HIV status which is challenging for uptake of the programme. They undergo testing, disclosure of HIV status and are initiated onto treatment for Option B+ all in a day. These women are bombarded with a large amount of information and need time and guidance to adjust for going onto lifetime treatment.

Maintaining Open Communication: How Much Information is Actually Understood?

Many women that participated in the study stated they trust their healthcare professional. Patients were most likely to rank their trust in the healthcare worker as 5 (I trust them mostly) or 6 (I trust them always) on a scale from 1-6. However, patients were unsure of everything the healthcare worker told them about the programme.

The Fixed Dose Combination (FDC): More Manageable?

The study findings suggested that participants found swallowing the fixed dose combination (FDC) difficult in the first two weeks of starting ART or switching to Option B+. Patient participants found it easier to manage one pill a day after two weeks. There was an average of 0 to 3 missed dosages for women that were on FDC over a period of 6 months. Pregnant HIV-positive pregnant women found that taking the FDC reduced stigma at home and in the community because it was easier to hide one pill bottle

in their purse than have many multiple bottles of ARVs. Women found it was easier to manage one pill and take it at night before going to bed.

However, all patient participants experienced side effects such as dizziness, tiredness, nausea, and vomiting but on average felt better on the one pill a day after the first two weeks after starting the FDC. When patients were asked if anything changed in their ability to take the medication, many responded that the pill has become part of their daily routine. For example, one woman, 35 years old, not married and 39 weeks pregnant with her second child responded,

“The pill may be really big and hard to swallow at first. I never miss any dosages –maybe with time sometimes because I drink it at night and usually take it at 9pm and sometimes I am a few minutes late. I think I would go crazy if I missed it because I have made it part of my life.”

Perceived to be Effective?

Many patient participants perceived the FDC for Option B+ PMTCT to be effective, adhering to treatment over duration of six months. A 38 year old participant, twenty seven weeks along in her pregnancy with her third child started ARVs on January 27th, 2015. She states,

“When I started at the clinic, my CD4 count was 500 and then it went up to 707. I find this one pill a day to be effective because of the results it has given me. The healthcare worker has told me that everything is normal.”

These pregnant HIV-positive women feel better and though they experience side effects that may cause confusion with symptoms of being pregnant HIV-positive (i.e. vomiting);

the most common answer is that they think it is working. When asked why they think it is, some women respond with,

“I don’t know, I feel better, I think it is working.”

Uncontrollable Variables: Knowledge Gaps

The following four sub-sections discuss factors that contributed to difficulty in adherence amongst pregnant HIV-positive women. There are many uncontrollable variables that contribute to whether a pregnant HIV-positive woman can effectively participate and adhere to the Option B+ PMTCT programme and FDC regimen. Examples of uncontrollable variables are noncompliance to Option B+ or inconsistency of the new national consolidated guidelines within the hospital facility. According to study participants, other variables can contribute to the perception of the Option B+ PMTCT programme and overall uptake of the new FDC drug regimen. These variables include, access to ART and PMTCT education, which in turn impacts, safe sex practices, breastfeeding, family planning, use of traditional medicine, and overall maintaining open communication between the healthcare professional and patient.

Unsafe Sex Practices

43 of the pregnant HIV-positive women interviewed thought that having unprotected sexual intercourse with a partner that was also HIV-positive was fine as long as they were both on ARVs. These pregnant HIV-positive women did not understand and were not aware that re-infection can occur. Patients thought that taking ART could mean engaging in unprotected sex. Many women did not understand why their viral load was increasing whilst on treatment.

When these women were asked if they are sexually active many would say they were not and then when proceeding with the interview, they would state that they engaged in sex last week. There was uncertainty in responses when asked if a method of prevention is used and how often. One 29 year old woman, not married and 36 weeks pregnant with her second child states,

“I am sexually active; the last time I had sex was two months ago. I use a condom every time and I don’t want to make any mistake. I am now pregnant with this child...I don’t know what happened, maybe the condom broke... I was having problems with my boyfriend. We would always use a condom, but for this pregnancy during the intercourse it was taken off. I felt like he knew something and took it off, always coming up with excuses during sex...like how he has a rash...”

Serodiscordant Couples

When conducting key informant interviews with HIV-positive pregnant women, there was an obvious tension at times in the room when the question of, *“Is your partner aware of your status?”* was posed. Many women would respond stating that they have multiple partners but are not exclusive. For example, if the interviewer asked the patient, *“Do you have a partner?”* The patient may respond with *“Yes, I have a boyfriend.”* Then the interviewer would ask, *“Are you married?”* The patient may also respond with, *“Yes, I am married.”* This revealed that many women were involved in different sexual relations with men, married or not. Answers varied when it patient participants were asked about disclosure of their status with their husband, boyfriend or multiple partners. Women disclosed at times that their spouse was HIV-negative and did not know she had

engaged in sexual intercourse many times without use of a condom or other types of protection. A 40 year old woman, not married separated from her partner and is 32 weeks pregnant stated,

“I am not sexually active, fortunately. The last time I was sexually active, I was still together with my partner, who knows I am pregnant. A condom was used regularly, except the first time when we met and then I fell pregnant. I cannot say I regret it; I am an adult and responsible for my actions... My partner knows I am taking the ARVs and he is angry at me actually. He says it is going to take time because he is HIV-negative and asked for some time to go and heal.”

Breastfeeding: Miscommunication of Messages

A serious concern with misunderstanding the programme by patient participants was discovered. Many pregnant women thought after delivery, it was not a risk to stop their ART during breastfeeding. Women would sit in the waiting room of the antenatal clinic and hear education sessions, but most importantly do not actually understand the messages communicated to them entirely. This aligned to data collected that woman's body language, confused facial expressions, twisting of the body, and scratching of the head demonstrated uncertainty.

When participants at times were asked, *“Did you attend any of the education sessions in the waiting room ran by the nurses?”* Many participants would respond, *“Yes.”* It is one thing to attend the information sessions that are provided in a lecture style format from the nurses in the waiting room- but to actually listen, understand and actually apply what is being taught to the patient was a challenge. When patients were asked, *“What did you learn from the education given in ANC?”* Many participants state,

“Breastfeeding when the baby is born is good...Is it true I can do that? [Only on ARVs]...oh...” or “I learned that I can breastfeed regardless of my status.”

Healthcare professionals are communicating messages to the patients; sometimes the patient will only understand part of the message which can be more harmful in the end. If the woman decides to breastfeed, they need to be carefully pre-counseled about adherence to ART and exclusive breastfeeding. Post breastfeeding and 18 month HIV tests should be done as well. If the woman has a viral load of <1000 copies/ml then the baby should preferably not be breastfed and infant formula can be substituted. One healthcare professional stated,

“RMMCH promotes that all infants, regardless of maternal HIV status, should be exclusively breastfed unless medically indicated; the mother or infant are physically incapable; non-ART medications are not suitable for breastfeeding; mother is on second or third line therapy and her viral load is >1000 copies/ml. Repeated feeding counseling should reinforce messaging and 6 months exclusive breastfeeding is executed, meaning no water, pap or other solids, can give medication, introduce complementary foods only from 6 months and continue to breastfeed if; 12 months the mother is HIV positive, 24 months she is negative with repeat testing, or 24 months if the infant is confirmed HIV positive.”

Family Planning & Child Spacing

There is a large dependence on partner(s) for support from a large number of pregnant HIV-positive women interviewed. When questioned, *“What does your partner think about you taking ARVs?”* A 26 year old woman revealed,

“I had sex about three days ago. Sometimes I use a condom and now that I am drinking medication around my partner I am more careful and make sure to use a condom...My partner does not know what my treatment is for and he sees me drinking it. They say I must not tell the partner and they may not like that I have HIV. This baby was not planned and I do not want to lie to you. I will tell him after at the clinic and disclose the status after the birth of the baby.”

Many of these women are unable to disclose HIV-status with partner and feel the need to hide their ARV medication. This is largely due to the fear of losing their partner(s) and not having support to provide for their dependents and newborn child.

RMMCH focuses largely on mother and child with its delivery of Option B+ PMTCT. It has caused an issue with excluding the important male figure in family planning methods. Therefore, if a woman receives her HIV-status and information is provided to her about disclosing to her partner(s) (whether it be her boyfriend or husband), there is a barrier for the family unit to progress further because psychosocial support and adherence counseling services along with family planning will not be provided to the male component.

Pregnant HIV-positive women participants on average had three dependants and one still birth. One woman states,

“I am 37 years old and not married but I have a partner. My first child died in 2007 and it was a still birth. I did not get to keep him at birth. I have been pregnant a few times, all died and one even buried at the age of five. I am 5 months pregnant with my next baby; this will hopefully be my first living child.”

An issue that presented itself was that women are likely to stop treatment in between pregnancies. Child spacing needs to be addressed in educational sessions with one-on-one counseling to these pregnant HIV-positive women for their own health. It is crucial in order to reduce the risk of transmission between mother and child, especially if she is not practicing safe sex and not using protection in between births.

Do HIV-Positive Pregnant Women Think/Feel They Have a Choice?

All 55 pregnant HIV- positive women that were interviewed responded that the main reason why they choose to take the one pill a day for life is to protect the health of the baby. Many women feel that treatment can be stopped after giving birth which is the largest barrier for effective initiation of Option B+ PMTCT. At times, the use of the word “Option B+” would confuse pregnant HIV-positive women thinking it wasn’t necessarily “a must” to stick to regimen for life. Some of the responses of women were,

“I feel like I have no option. I do this for the sake of the baby. I don’t want to lie but I am bad with tablets. I care about the baby and don’t want to play with its life and mine. I am responsible for another life and it is better this way” -32 year old woman, married with three dependents.

“I do have a choice. I don’t think anyone can force me and they told me that it is not healing and it can treat the virus to be manageable” -31 year old woman, not married and six months pregnant.

“I feel like it’s a must to take this pill and I have to take it because if I had a choice I would not take it and then when I ask about my status I would not be happy. I take the meds to survive and protect my baby-my number one priority”- 29 year old, two miscarriages and 34 weeks pregnant with second baby.

“I would say it’s a must, and I wouldn’t say it’s a choice because if you choose not to take it, it means you will die. Instead of a pill I wish there was something else. I choose to take the pill because with the pill I feel like I will live a very long time. I feel like I have been given a choice in life and it is whether up to me to use it or not” -40 year old, married with two dependents.

Frontline Healthcare Worker Perceptions

Barriers to Frontline Nurses Implementation of Option B+ PMTCT Programme

The following several sub-sections will describe barriers that frontline nurse’s experience with implementation of Option B+ PMTCT programme with patients. These barriers create an impact on the patients experience at the hospital and understanding of the healthcare worker. This contributes to the overall acceptance by the patient of the programme.

First Point of Care

Frontline nurses are the first healthcare worker that a pregnant HIV-positive woman comes into contact with at RMMCH. Nurses each attend to an average of 21 patients a day. Many of the pregnant HIV-positive women nurses see a day have been on Option B+ for a maximum of six months. These nurses usually work with patients for many reasons, some of which include; vital sign tests; blood tests; medication distribution; non-stress tests; monitoring heart beat; patient comprehensive reporting; make beds; urine tests; temperatures, etc.

Nurses give women the opportunity to ask questions and tell them that they should feel free to come and ask any questions they may have and can do so in private. One nurse in ANC states what she does to provide the best possible care to her patients,

“I teach them and tell them the importance of why they are attending the clinic and education, making sure they know why they take the medication. If she wants to speak to you privately, you listen to her and give her the best advice you can. It’s hard you aren’t with her 24-7, once she goes home it depends on her.”

Gender Dynamics: Maintain Comfort Level

Many pregnant HIV-positive women felt comfortable interacting with female healthcare workers such as nurses, the antenatal counselor, or an educator that would provide information in a lecture format to patients and hand out baby supplies in the waiting room. Pamphlets were distributed to patients and it was beneficial in cases where patients forget all the overwhelming amounts of information they are receiving.

The way a frontline worker deals with the patient can have a huge impact on whether that patient builds a level of comfort and trust. One nurse states,

“The women feel comfortable with us. The friendlier we are the more they confide in us. Sometimes I get grouped with different nurses and we are not all the same, we are human beings. We may get along and work together well, or some of us have a rough day and are more moody.”

Difficulty handling side effects with taking treatment and being unable to communicate this first to a nurse can be challenging in passing this message on to a healthcare physician (who may be male). This is a barrier to ART adherence and Option B+ PMTCT. Gender impacts the relationship between the healthcare worker and the ability of the patient to interact, build trust and feel comfortable in the health clinic and hospital environment. In addition, the Empilweni Clinic provides patients tours on their first visit to make them feel comfortable and supply of sandwiches from faith based initiatives.

Educational Background & Training

Interviews with frontline nurses discussed where they had first learned about the Option B+ PMTCT programme. One nurse states,

“The Project Manager for PMTCT provided training sessions with us in a three day course this past November (2014) about the new guidelines. It covered training on everything relating to HIV, adolescents and adults, treatment protocols, stats and was done from a clinician perspective. We covered educating the patient around the programme too. The new changes and developments were shared with us and pamphlets were distributed. We receive certificates...If you do it in private it is two weeks and you pay to attend conferences.”

In the Empilweni HIV clinic, in service training is done to teach nurses topics of relevance to the clinics so there is an understanding if they speak to patients. There has to be acceptance from the frontline healthcare workers in understanding the new guidelines. Then nurses can communicate what they are trained to do to the patient for knowledge translation to occur in an appropriate manner.

Delivery of Educational Sessions in ANC

Nurses rotate in delivering patient education for mothers on breastfeeding, HIV, smoking and alcoholism, c-sections, etc. A nurse stated,

“Effectiveness depends on the patient and individual, some are intelligent enough to understand and some draw a blank and do not understand what you are talking about. Some women will listen and other will sleep. I wake them up to keep them engaged. Most are listening and just keep quiet. The information us nurses give is important, even if it is a lot of people and noisy in the waiting room.”

Language: Barrier for Knowledge Translation

Language does pose a barrier at times for effective knowledge translation. RMMCH has a high foreigner population that accesses its healthcare services. One nurse states,

“We get everyone from over the mountains and seas. We check for another patient that may speak the same language and ask for them to translate. I really don’t think exact translation occurs, because you can assess that something else is being said. South Africa has nine official languages.”

An issue that was raised was that most times a husband will interpret for his wife what the nurse is saying; often there is disclosure of her HIV status. This becomes very problematic with the respect to individual privacy of the woman.

Traditional Medicine: Screening

A nurse in charge discusses her perspective with mothers who are ashamed to disclose they are practicing traditional medicine and not taking FDC for the Option B+ PMTCT programme. She states,

“We come across such mothers that engage in alternative medicine practices. Reaction can occur with the levels of potency and the ARVs. The mother usually tends to get sick somehow...I would then draw bloods and sometimes this shows nothing and then the woman will tell the truth to me. If nurses are suspicious, the doctor will pull bloods again. The CD4 count is either low or the viral load is higher. The mother will have to tell the truth because it shows she is not taking her meds...Her kidney, liver may be damaged. We counsel her to tell her benefits of the FDC and that the medication is free and for the sake of the baby.”

Behaviour: A Barrier

Nurses expressed their concern about promiscuous behaviour and how it has contributed to the spread of HIV stating,

“It is the main problem for TACs because people still partake in this behaviour. It seems like it is normalized and accepted in society. Education is ongoing and there is new advancement to make sure the patient is informed. Sometimes we take for granted they do know something and then in the interim they don’t. Especially the black women and such, the condom according to the culture and customs where the men refuse to wear it. Making sure education is enforced- we give it in more of a lecture style, the interactive part is only the one on one if they come to ask us questions after.”

Nurses seemed to convey a perspective of judgment and stigmatization rather than being compassionate for the patient and understanding to help empower the pregnant HIV-positive woman.

Their Patients Medication Adherence: Improving?

Many nurses think that Option B+ is effective because the FDC is easier to manage as one pill instead of taking three ARVs. Patients are doing better on one pill that have children dependents because it is one ARV dosage in the evening, so they are able to send their children to school and go off to work. They find more women are sticking to FDC, though some are reluctant because they are scared of the side effects and the stigma that still exists about HIV/AIDS. One nurse expressed,

“Most women stick to the regimen, some are in denial. Adherence is increasing, unless they are telling us lies. When I speak with a patient, what they tell us we

have to believe what they say about their adherence. We do the viral load test, but it depends on their CD4 count...The non-pregnant women attend the HIV clinic on a regular basis, the pregnant lady we see her with her baby and once she delivers we have very little to do with them.”

Most nurses rated their trust level of their patients 3 out of 5 meaning they trust their patients sometimes but not always. They feel that patients are not missing dosages as frequently with the FDC, rating a total of zero to three for the number of missed dosages of their patients.

Emotional Risk Factors

The less amount of time working at RMMCH, the more emotional attachment there was for the healthcare professional when informing the patient about their HIV status, CD4 count and viral load test results. Some nurses responses were,

“We speak to the patient regarding her CD4 count and viral load; tell them about medication and healthy lifestyles, condom usage and breastfeeding options so she can make an informed decision after finding out her diagnosis. We speak about FDC, the side effects and what they may experience. How do I feel? It is a situation, you feel sad but on the other hand you know they are getting help. It is ambivalent, feeling sad that she has this diagnosis but happy she is getting help for it.”

“Counselors, nurses like myself and the doctors will tell her that she goes on the medication for life. I feel terrible to tell a patient, some sit here and cry and cry, and you have to sit and listen and give her a chance to talk.”

“I am not sad or depressed. The mother is counseled before we even do the test and it is something confidential we take her to the room with the counselor and it can be a RN and trained in counseling and trained in HIV or mothers as well. If she is positive mum, then we show her the slide that there are two lines on the slide means that you are positive and you keep quiet for a while and wait for the reaction. Obviously the mum is shocked, angry, surprised. We counsel for 10-15 minutes to the mother and listen to what she has to say. It takes a lot from a person, it is a shock to her and you try to be neutral and balance her in her shoes and understand how she must be feeling and start educating her prevent re-infection by using condoms and if she is ready to tell the partner...opt for abortion if she has three kids at home. You offer her your number, if she can't sleep at night she needs to talk to someone then she can call you.”

Do the frontline nurses think/feel that patients have a choice with Option B+ PMTCT?

Most frontline nurses believe that these pregnant HIV-positive women do not have a choice and that it is a must for them to take FDC everyday for life, some responses were,

“For pregnant HIV-positive ladies, breastfeeding mother and the newly pregnant, it is a must that they take this medication or else she is going to get sick.”

“They don't really have a choice; it's a must because if they don't take it then the risk of transmission is great to the baby, partners and themselves as well. Their quality of life does not remain the same, HIV is not the end of the world, there is so much more they can achieve.”

Healthcare Physician Perceptions

ART Initiation

Healthcare workers at RMMCH are trained to always educate these mothers about their next steps. Healthcare physicians provide clear written documentation for patients to take to the next facility including details about their HIV status, treatment initiation date, ART regimen, latest monitoring results, adherence history, and the management plan for the mother and baby. If the woman is HIV negative, the date of the last HIV test should be recorded along with her contact details that are kept up to date.

At RMMCH, HIV-positive women are initiated on FDC the same day unless for three reasons; concern about abnormal renal function; active psychiatric illness; or newly diagnosed TB or high suspicion of active TB. All women with contraindication to FDC initiation must receive AZT 300mg bd at their first visit. No woman should leave her first ANC visit without any ARV cover for PMTCT and without a follow-up visit in one week for her blood test results. One physician in the neonatal ICU states,

“It is difficult to tell the patient she is positive, you send her with medication on her way. Most of the patients are just told to take it rather than being educated about the benefits because they have this low socio-economic status.”

The patients’ acceptance of ART for life depends on her ability to understand the long term benefits of the Option B+ PMTCT programme.

Viral Load Monitoring

Adherence is usually measured by word of mouth and RMMCH is now utilizing tests for viral loads in order to monitor whether the patient is telling the truth about

sticking to regimen. These viral load tests can really inform the healthcare worker as to whether the patient is accepting ART for life and adhering to her medication or not.

Pregnant women on Option B+ for less than 3 months and are to conceive the baby must have their viral load repeated on the day of delivery. The healthcare professional needs to confirm if the woman is virally suppressed. Women who are virally suppressed, if their viral load is less than 1000 copies/ml, a repeat test will be done every six months and reviewed within two weeks after blood is drawn. The National Health Laboratory Service will process her viral load if the blood request form is completed indicating if the patient is also part of the PMTCT programme.

The healthcare worker must advise women with a viral load >1000 copies/ml to take ART. If the viral load is undetectable, the healthcare worker will monitor adherence closely and repeat viral load in one month or sooner if there are concerns about patient's adherence. The physician should educate her about the link between her viral load and the risk of MTCT and safety of ART in pregnancy.

Inconsistency in Thorough Counseling and Follow-Up

Physicians recognize that one of the biggest challenges is the opportunity for proper counseling that could influence pregnant HIV-positive women to make informed choices about treatment for life. Pre-therapy counseling is missing by definition of Option B+ PMTCT. The difference between Option B and Option B+ is that under Option B, the woman had the opportunity to digest the diagnosis of HIV and to decide whether she wants to take the ARVs for life, until she gave birth, or until the time she stops breastfeeding but with Option B+ though that choice is gone. This is overwhelming for an increased proportion of women not knowing their HIV positive and on the same

day prescribed antiretroviral therapy for life. There is clearly an opportunity for more counseling with the Option B+ PMTCT programme.

HIV-positive pregnant women have difficulties in understanding immediate ART initiation. Similar views on same-day testing and initiation on ART and viewed same-day testing and initiation on ART as “too rapid” for clients to be able to process. One healthcare worker in the OBGYN department stated,

“A woman, a mother comes into the hospital and may enter our antenatal clinic thinking she is just fine and healthy. Then a nurse asks her, to run a test, after of course waiting approximately from 6am to mid-day. She is tired, exhausted and carries on to pre-test thoroughly. Her test results come out as HIV-positive after cross-checking, the counselor now sees her for post-test counseling...Keep in mind now that she has not even seen the doctor yet. She waits to hear that she has an HIV-positive status. Now she may be very upset, not know how to register what is going on, and barely has any time at this particular moment to process before she is given an FDC pill and told that this will help her...whether or not she fully understands the benefits, who knows...”

This has caused inadequate space for counseling, and long waiting periods to see a healthcare professional. The patient is rushed for testing and treatment which deters the patient from returning. At RMMCH, women still have to visit multiple departments in a single day with long waiting times. This can overall impact the patients experience and acceptance of Option B+ PMTCT and her ability to return for follow-up appointments.

Traditional Medicine

Research suggested that some of the pregnant HIV-positive women attending RMMCH use both ART and traditional medicine practices but feel like it is frowned upon from the healthcare worker. Opinions varied amongst healthcare professionals of how to involve patients in decision making around ARVs and traditional medicine. One physician states,

“Women have little knowledge about what they are taking. Patients will come here and I believe taking ART and supporting cultural beliefs can co-exist, provided that they don’t interact with each other. Now there are herbs that patients are taking that have a negative effect with the ART or by themselves. It may help foster better adherence, if we as healthcare professionals seek to understand the patients’ cultural background. I think it would help a lot if we can really understand the patient holistically, provided we know it is happening within a safe place.”

Healthcare professionals felt paternalistic at times and face conflict with balancing their personal beliefs and the message that they are trained to deliver in order to advise the patient. This can cause confusion for the patient. Furthermore, physicians found it very difficult to offer advice to the patient because they were unaware of what traditional medicine the patient was engaging with, the potency and effects of mixing this with ARVs would have. A pediatrician states,

“Patients want to pursue traditional medicine with ARVs sometimes, and I am sure that patients feel reluctant to disclose this to me. I would hope they don’t feel like they have to hide that. Things may adversely interact but with what they are doing it may not always be harmful. We need to create an environment where they

can discuss their practices openly. It's about counseling...not that their options are bad necessarily but to be realistic in how we discuss it because we don't always know what they are taking. If we are aware, then we can possibly advise."

It is crucial for a healthcare worker to maintain an open communication with their patient. The first point of contact for a patient with their healthcare environment can instantly determine whether or not the woman feels comfortable to discuss sensitive topics and their behaviour towards the physician.

Their Patients Medication Adherence: Improving?

Many physicians believe that it is too early to determine whether Option B+ PMTCT is effective because it is going to take time and research to learn if people are defaulting at an increased rate. One physician from OBGYN unit states,

"When FDC was introduced, counseling and support services were reduced. It shouldn't delay treatment but there has been LTFU. This may be caused by the swap over of the new guidelines...Patients may stop FDC once in a while, but to drop out completely- that is a different story."

Physicians have noticed a major issue with pregnant HIV-positive women with adherence declining after giving birth. A physician explains why this may be,

"Women are motivated to take these medicines because there is a purpose to it during pregnancy, to prevent transmission for their unborn baby. Once the baby is out, that purpose becomes lost and there may be no incentive to maintain adherence."

Emotional Risk Factors

Physicians often have to take on more than their main role of delivering healthcare services of good quality to their patients. Often, young teenage mothers that are scared and stressed abandon their baby and the physician is left to deal with the aftermath. One physician states,

“Teenage moms freak out and they have to go to school, they end up abandoning the baby. They come and deliver and leave the baby behind. We end up having to call the police and try to locate the teenage mom, often we can’t.”

When physicians have to disclose the patients HIV status, most express that they felt neutral in comparison to frontline nurses, who had more of an emotional attachment with disclosure. One pediatrician states,

“I feel I have disclosed to patients so many times, I don’t feel bad for them anymore. When I was new to this about 15 years ago, then...Thank god we know we can do something about it. It is not a death sentence.”

Do physicians think/feel that patients have a choice with Option B+ PMTCT?

Physicians’ responses suggested that there is no other choice and that HIV-positive pregnant HIV-positive women are offered the best possible care with the new guidelines,

“Did they ever have a choice? I don’t think they have a choice even when they had three ARVs...they have to because they don’t have a better option. We have guidelines and it is designed to give the patients the best benefit.”

“I think most patients get the impression that they don’t have the choice with Option B+ ...If they have reservations, we want them to voice it because from a long term health point of view, they aren’t offered alternatives.”

Executive Manager Perceptions

EMTCT Training

Clinical training was provided to all frontline nurses by the Project Manager for PMTCT in the ESRU. EMTCT training stated that there was a no turn away policy for all women who attend RMMCH for pregnancy confirmation or a first visit to ANC, must be seen on that day. There should be no booking made to come back for another date in order to retain follow up. All women are to be counseled and tested for HIV at their first visit to RMMCH and be re-tested regularly.

HIV positive women must be counseled and initiated on ART on the same day. All HIV- negative women should be re-tested 3 months during pregnancy, at labour/delivery no matter when she was last tested, at 6 week follow-up visit and 3 months during breastfeeding. RMMCH re-tests HIV-negative women because they may seroconvert at any point during pregnancy or breastfeeding, and during seroconversion the viral load is incredibly high. The higher the viral load, the higher the risk of MTCT. Early MTCT relies on identifying maternal seroconversions, initiating newly infected mothers on ART and providing infants with appropriate prophylaxis.

Knowledge is Power

The executive management level expressed that women need to understand the benefits in order to continue treatment. It is difficult to know whether patients are actually taking the medication because they are being told to do so or they actually

understand the benefits clearly. This relies on knowledge translation from the healthcare professionals consisting of both frontline nurses and counselors and healthcare physicians. One executive manager states,

“The system is designed for doctors to be paternalistic to their patients when it comes to involving the patient in the treatment decision making process. This means no patient involvement, choice or patient authority- to enforce one direction. Partially because the pregnant HIV-positive women we see at the ANC, at no fault of their own do not have education and little knowledge about what they are on. It is unfortunately the system that perpetuates the lack of patient involvement while they sit there waiting.”

Initiatives that RMMCH Can Take

Executives suggested that there needs to be more promotion done at RMMCH, *“I think what we can do is possibly an intervention with a media drive or there needs to be patient awareness campaigned around the importance for continuation of ART, and the benefits around breastfeeding, etc. I suspect that not enough focus is placed on ART and to what extent adherence may be a problem long after ART has been stopped.”*

Do executives think/feel that patients have a choice with Option B+ PMTCT?

Management acknowledged that there may be issues in rolling out the PMTCT programme at RMMCH. However there are still choices that have to be made by the patient in order for successful adoption of Option B+ PMTCT in the hospital. A manager stated,

“I do think women have a choice, their first choice is whether to take ART, the second whether to undergo an HIV voluntary test, and third is to maintain adherence...It is a problematic programme, it is not an option but a prescription. This is it for life and there are women that refuse it and the bulk who take it. As long as they know you are not judging them and at the end of the day the decision is theirs. Knowledge is power and at the end of the day as long as we provide information, it is up to them whether or not they utilize certain practices or not.”

ADAPTABILITY

Adaptability is a concept crucial in understanding what barriers impact both the short and long term scalability and sustainability of the Option B+ PMTCT programme. The contextual understanding of one healthcare environment in which PMTCT programme operates can address policy implementation and programming issues, this can inform how adaptable Option B+ PMTCT programme is on a larger scale. Adaptability considers the patient’s perspective of their overall experience with the Option B+ PMTCT programme and whether or not that experience extends outside of RMMCH. Option B+ PMTCT is in its early implementation stage and there may not be enough long term data to analyze whether the Option B+ PMTCT programme is adaptable to healthcare facilities outside of RMMCH, i.e. local health clinics or other state hospitals in Johannesburg. The national guidelines have been developed but adaptability may remain problematic in successful roll out of the Option B+ programme outside of RMMCH.

Can the Option B+ PMTCT programme be implemented in strained health systems and still provide universal access to patients? A similar system model for the programme that includes the perception of the patient and healthcare professional could

provide consistent information across facilities, services they receive and experience with qualified healthcare professionals.

However, it is too early to tell whether or not the Option B+ PMTCT programme can be adaptable to healthcare facilities that extend outside of RMMCH. This study recognizes that it has only conducted research that is within RMMCH and has not extended its research to other healthcare facilities.

Patient Perceptions

Patients did not comment on the sustainability or scalability of the Option B+ PMTCT programme at RMMCH. Patients when asked if they thought the programme was effective over a longer term would only comment on a surface level about the medication itself. A 27 year old, not married and 26 weeks pregnant commented,

“I don’t know if this programme is effective for a long time. I just hope it works and I take the medication like I am told.”

Frontline Healthcare Workers Perceptions

Frontline nurses suggested that scalability of the programme outside of RMMCH may require more research in adapting the programme to other healthcare facilities. This would mean system planning and ensuring that the programme is sustainable. A nurse commented,

“It is going to take time and way more research to understand whether the programme can scale-up outside of RMMCH. All we know from research is that pregnant mothers are defaulting...”

Healthcare Physicians Perceptions

When healthcare physicians were asked about whether the Option B+ PMTCT programme would be effective, many could not comment because of the lack of long term data about sustainability and scalability of the programme. One healthcare professional in OBGYN unit stated,

“It is very difficult to evaluate the long term sustainability of the Option B+ programme. I cannot comment even on the effectiveness of Option B+ in the short term. I have to look at long term data that further reduces PMTCT and it is currently not available for Option B+. This programme was only introduced in January this year at RMMCH and I don’t think there is sufficient data yet for South Africa.”

Executive Manager Perceptions

The perception of an executive that manages the Option B+ PMTCT programme at RMMCH aligns with healthcare professionals that there is not sufficient data to analyze whether the programme will be scalable outside of RMMCH. RMMCH is still undergoing programme implementation issues and would need to strengthen its system planning model before roll out of the programme occurs. An executive manager stated,

“I am the project manager for PMTCT and my main function is to make sure the programme is running well and implemented properly at the facilities... We have only introduced Option B+ for five to six months now. To be honest, I can’t really say if it is really working because there has not been any evidence.”

Chapter V: Discussion

Principal Findings

How Option B+ PMTCT Programme Has Impacted RMMCH

The analysis of the study revealed that the national consolidated guidelines and the implementation of the Option B+ PMTCT programme has been challenging for both patients and healthcare professionals. The following four sections will describe the principal findings guided by the Accessibility Framework of how the national consolidated 2013 guidelines for Option B+ HIV PMTCT have impacted the healthcare work environment for (a) patients; (b) frontline nurses; (c) healthcare physicians; and (d) managers.

Patients: Pregnant HIV-Positive Women

The findings suggest that patient acceptability of medication adherence and the changes in their ART regimen is influenced by the information they receive. The quality of care made available to patients can affect their overall experience which contributes to decision-making for a patient. In addition, patient's willingness to incur opportunity costs and return to RMMCH is largely dependent on their experience. Patients require education and continuous support to understand the benefits of Option B+ PMTCT and ART for life. All 55 patient participants responded that they chose to take the FDC to protect the health of the baby and felt that treatment could be stopped after giving birth, unaware of the benefits for the woman to continue treatment.

Frontline Nurses

The findings suggest for nurses that the Option B+ PMTCT programme has created emotional risk factors for frontline staff. Until frontline nurses are accepting

of how their work has changed then the patient experience may be undermined. The initiation and maintenance of the programme have increased responsibilities for healthcare professionals in patient care. The responsibilities include making services available for the patients which include; good quality care, delivery of educational sessions, communication and consistent messaging for patients, monitoring ART adherence, and the provision of thorough counseling.

Healthcare Physicians

The findings suggest for healthcare physicians that the healthcare work environment has become more ineffective with managing the large demand of patients. The physician's role has changed from providing available support for the patient to spending less time managing patient adherence and conveying the importance of benefits of ART for life. Physicians are unaware of the opportunity costs pregnant HIV-positive women undergo to attend RMMCH. However increased access to ART does not resolve internal issues with healthcare workers. There are issues with ART initiation, viral load monitoring, thorough counseling and support groups, communication between department transfers, privacy, and overall quality of care for patients.

Executive Managers

The findings suggest that the hospital organization has initiated positive administration practices to help manage transmission of HIV in PMTCT. However, Option B+ PMTCT has challenges in education and awareness of ART and its integration into the already existent stigma and cultural beliefs in the South African community. The executive staff has utilized strategies that include PMTCT HIV strategies. Educational lectures and training across departments need to assist healthcare professionals in better

understanding the implementation of the programme at RMMCH. There is still need to strengthen indicators in order to better manage the implementation of the programme.

Major Themes

Three major themes that emerged from the data guided by the Accessibility Framework that demonstrate the impact of the Option B+ PMTCT programme on healthcare professional's daily work and patients adherence. The findings demonstrate that work has changed and become difficult to manage for all healthcare professionals because of:

1) Affordability: The Need to Strengthen Indicators to Decrease Patient LTFU

Patients are becoming LTFU because they cannot afford to incur opportunity costs and return to RMMCH. There is a need to strengthen indicators for the programme in order to decrease LTFU because increased numbers of pregnant women are put onto ART at an accelerated fashion, starting treatment the same day as being diagnosed HIV infected.

2) Availability: Inconsistency in Delivery of Support Services & Communication

There is inconsistency in service delivery of counseling and support services made available to patients at RMMCH. There is a dire need for communication across clinical departments because guidelines taking time to be translated across the healthcare system in a manner that allows for consistency in messaging.

3) Acceptability: Lack of Compassion & Understanding by Service Providers

There is a lack of compassion and understanding by service providers due to the emotional risks that healthcare workers are undergoing because their work has changed.

The implementation of the new guidelines has created frustration for both clinical and management levels at RMMCH.

The difficult healthcare environment at RMMCH has affected overall views and experiences of pregnant HIV-positive women going on ART for life. All 55 patient participants responded that they chose to take the fixed-dose combination (FDC) for life to protect the health of the baby and felt treatment can be stopped after giving birth and not stick to regimen for life.

Analyses of the three abovementioned themes reveal an approach towards *interdisciplinary collaboration* for better implementation of the Option B+ PMTCT programme at RMMCH.

Findings in Relation to Other Studies in the Field

The Need to Strengthen Indicators to Decrease Patient LTFU

The findings suggest that healthcare professionals at RMMCH need to address strengthening Option B+ PMTCT programme indicators, in order to decrease patient LTFU. RMMCH is undergoing changes in the different clinical departments in switching over to the new guidelines. The hospital is still undergoing major changes with trial and error of indicators, reporting feedback to the Steering Committee for PMTCT. The committee reports to the National DoH to discuss any concerns with the indicators and for suggestions on what RMMCH is executing to decrease LTFU.

Review of literature sources demonstrated that RMMCH is undergoing many of the challenges that Malawi faced in its rapid implementation approach of the Option B+ PMTCT programme. This includes patient LTFU that surfaced when Option B+ was implemented three years ago. Keehn & Karfakis (2014) conducted a study of pregnant

women in Malawi that were enrolled on Option B+ and found that women who were started on ART for Option B+ PMTCT the day they were diagnosed were more likely to never return to the clinic. Women much alike in South Africa are becoming lost in the system because the new guidelines are constantly changing but by strengthening indicators it can potentially track patients for follow-up.

RMMCH has an increasing number of foreign mothers that use the facilities up until they give birth and buy addresses which have contributed to the inability to trace a patient. An evaluation of a defaulter tracing programme in KwaZulu-Natal observed the heavier burden of maintaining up-to-date tracking information with paper-based systems (Vella, 2008). The main challenge with tracing was the lack of telephone numbers in records and unclear addresses. Studies suggest that tracing should be done the first week once a patient misses an appointment because it is the most critical period, since after treatment is initiated it is crucial that the woman remain on ART (Vella, 2008).

Inconsistency in Delivery of Support Services & Communication

The findings suggest the Option B+ PMTCT programme requires more consistency in the delivery of counselling and support services to patients. The role of healthcare professionals is changing in communicating and educating the patient about the Option B+. The programme has placed onus on the patient for adherence, being sent home with ARVs the same day as diagnosis. Most women do not understand the actual benefits of FDC and stop treatment after delivery of the baby. Only 23% of HIV-positive pregnant women receiving ARVs received them for their own health (UNICEF, 2012).

Strategic positioning across clinical departments and managerial levels increased integration and communication with health systems and local health clinics (Kamuyango

et al., 2014). Healthcare professionals can help to reduce waiting time and provide higher quality counseling, educational workshops and support, as compared to the rushed services that patient's experience. "The success of Option B+ will be determined by women's ability to remain on lifelong ART; therefore, characterizing challenges and designing interventions to support women will help ensure that the investment of resources in Option B+ translates to long-term improvements in maternal and infant health" (Kamuyango et al., 2014, p.336).

Lack of Compassion & Understanding by Service Providers

The findings suggest the first point of contact of care for a patient is with a frontline nurse at the hospital. Frontline workers reported they were more agitated and sometimes moody when dealing with patients and communicating messages to them about Option B+ and the FDC regimen. The constant repetition and inability to get through to pregnant women triggered a lack of compassion and understanding for patients. Often, healthcare professionals do not address issues that the patient feels are as relevant to maintaining their care, and insufficient attention is given to psychosocial issues like poverty and transport to and from the healthcare facility (Levy, 2009). Patients' behaviour will highly depend on their first interaction with a healthcare professional. The importance of HIV care for the mother's own health must be embraced by health care workers and public health programs (Clouse et al., 2014).

Implications for Policy and Practice

Policy

The recommendation for policy is to include the perceptions of both patients and healthcare professionals because this can help address issues before policy

implementation is executed. Often, stakeholders and policymakers come together to create a policy to do what they see may be best from a top down approach. However, by using a community based approach, implementation plans can take place as a discussion by including the patient and healthcare workers at the table and spark open dialogue between the key actors and those impacted by the implementation. Community based approaches can empower individuals, such as these HIV-positive pregnant women to acknowledge expectations about themselves, their behaviour and potential. The involvement of the patient living with the illness in the community can provide insight as to how Option B+ could be integrated and adapted to meet the unique needs and values of the surrounding community at healthcare facilities undergoing high resource constraints.

Practice

It is recommended for practice that healthcare professionals in highly constrained resource settings, such as RMMCH use an approach for interdisciplinary collaboration when managing the Option B+ PMTCT programme.

Approach for Interdisciplinary Collaboration for Option B+ PMTCT Programme

Management

The following approach towards interdisciplinary collaboration consists of recommendations for better implementation of the Option B+ PMTCT programme at both the clinical and management levels.

Strengthening Indicators for Follow-Up

Interdisciplinary Department Meetings & Training

Collaboration across the departments and units of RMMCH can provide perspective and insight as to what indicators need to be strengthened for the Option B+

PMTCT programme. This can be executed through interdisciplinary department meetings and training may encourage dialogue between staff internally and report any issues and concerns they may be experiencing with the programme to upper management. RMMCH has existent clinical training sessions done specifically with frontline nurses. By including the physicians and counsellors that work within the departments, this can overall strengthen the communication between healthcare professionals. Remember all healthcare professionals can provide feedback as to how their work environment is managing these indicators, which may be entirely different depending on which department they work in.

Electronic Database: Fast Tracking Patients

The increasing number of foreign mothers that use the facilities up until they give birth has contributed to the LTFU. Patients buy addresses in order to access healthcare services if they are not in the catchment areas contributing to the inability to track a patient. One mechanism to address this could be to switch to an electronic database instead of having patients walk around with a paperback file to their appointments. This way a unique ID number could be used to track the patient and pull up their medical history. Foreign mothers would be recorded in the database and have to return for follow-up in order to utilize the services provided at RMMCH.

The electronic database could also be used for department transfers internally within the hospital. This could reduce patient waiting times. In clinic fast track ARV distribution has been used in South Africa in clinic care so that stable clients are only seen by a clinician every six months to pick up their ARVs at the clinic every two months. Healthcare workers only check vital signs and distribute drugs, with this model

the clinic is able to support approximately 1200 patients a month and reduce waiting times. This had increased collection of ARVs over a 9 month from 2.2% to 13% (Maharaj et al., 2014). Furthermore electronic files could be linked to local health clinics in the catchment area as well to allow tracking of patients being referred to and from RMMCH.

Consistency in Delivery of Support Services & Communication

Consistent Messages

There is a need to address knowledge gaps of patients in understanding the benefits of sticking to the FDC regimen for life, breastfeeding while on ARVs and the fact that re-infection can occur when having unprotected sex with a partner who is also HIV-positive. The pressure to take ART immediately with little or no support around decision making can impact the adherence and retention rates of the programme.

A recommendation is for collaboration with all healthcare professionals to occur in order to address the knowledge gaps with patients and work on step-by-step procedures on how to address these issues. RMMCH is a busy work environment with a high demand of patients, in order to have collaborative sessions that are feasible, existent training sessions can manage time with a rotation schedule for workers to come together and give their input. There is a dire need for consistency in the messages being delivered on Option B+ PMTCT programming to patients because they are extracting certain parts of messages that can become detrimental to their own health and health of their baby.

Interactive Education & Support Groups

The study findings suggest that many pregnant women were interested in learning more about the ARVs they were on, especially FDC and why they had to take it. Limited

information is provided from the education that nurses give in the antenatal clinic. It is recommended that instead of delivering education and information in a lecture style format, it should be conducted as interactive sessions to stimulate the patients and keep them engaged. Interactive sessions allow pregnant HIV-positive women to build mentorship and a network where they can form healthy relationships which can improve their adherence to ART (Keehn & Karfakis, 2014).

Women's perceptions of their partners' approval of their HIV status have been identified as a strong predictor of willingness for women to return to the antenatal clinic (Ghanotakis et al., 2012). RMMCH provides women with counselling but often males are not allowed into the facility which acts as a barrier to uptake. A recommendation is to provide additional support groups where the male partners can attend to increase open communication by including the male in child spacing and family planning methods.

Compassion & Understanding by Service Providers

Support Workshops for Healthcare Professionals

A challenge for healthcare professionals was the ability express sympathy for the patient. In highly constrained resource settings, a recommendation is to have support workshops for healthcare workers engaged in this work to manage and cope better. It is important to maintain the health of RMMCH's staff. Support workshops can allow healthcare workers to come together and build closer relations to each other, understanding that they are all undergoing changes in their work.

Maintaining Open Communication

Open communication and discussion around sensitive topics can be beneficial in understanding the patient's perspective. Often, physicians will transfer patients to

counsellors because they feel there is no consistent programming on their side. The patient receives mixed messages and it is difficult to build trust with the healthcare professional due to inconsistency with service delivery at times.

Maintaining open communication and working on compassion and patience will make workers more aware that their attitude and behaviour towards patients can impact the quality of care the patient receives. It is recommended that training workshops be held for frontline nurses and physicians.

Research Implications

The implications for future research include the need to address changes within the healthcare system at both clinical and management levels.

It is crucial to incorporate *the perspective of patients* in policy implementation; uptake and adherence are key indicators in informing whether the Option B+ PMTCT programme is being adapted into state hospitals effectively.

Adaptability is a concept crucial in understanding what barriers impact both the short and long term scalability and sustainability of the Option B+ PMTCT programme. The contextual understanding of one healthcare environment in which PMTCT programme operates can address policy implementation and programming issues, this can inform how adaptable Option B+ PMTCT programme is on a larger scale. Adaptability considers the patient's perspective of their overall experience with the Option B+ PMTCT programme and whether or not that experience extends outside of RMMCH. Option B+ PMTCT is in its early implementation stage and there is not enough sufficient long term data to analyze whether the Option B+ PMTCT programme is adaptable to healthcare facilities outside of RMMCH, i.e. local health clinics or other state hospitals in

Johannesburg. The national guidelines have been developed but adaptability may remain problematic in successful roll out of the Option B+ programme outside of RMMCH.

This study recognizes that it has only conducted research that is within RMMCH and has not extended its research to other healthcare facilities.

Therefore there needs to be extensive research on how to strengthen indicators for long term sustainability and scalability of the programme. A longitudinal study of 5 years can be done to provide more sufficient data on the Option B+ programme that could compare the indicators of the programme, analyzing system planning and its adaptability within state hospitals and local healthcare clinics across Johannesburg, South Africa. There is major uncertainty amongst healthcare professionals if the programme will be effective according to the national consolidated guidelines in the future.

Strengths and Limitations

Policy often excludes the voices of those that are most impacted by its implementation. The strength of this study was its ability to provide a platform for pregnant HIV-positive women to share their lived experiences with ART for life. The study was able to explore the perceptions of healthcare professionals from both clinical and management levels and how their work has been impacted by the national consolidated guidelines as a way to inform Option B+ PMTCT programming. Qualitative research develops concepts that can provide better understanding and speak to the concerns of those who provide health care and the interaction with their recipients (Pope & Mays, 1995).

In qualitative studies, the researcher is the main instrument of data collection and analysis (Pope & Mays, 1995). The use of body language and physical appearance of the

researcher, interpreter (of data), and student may have affected the results through moderator bias. Therefore acknowledgement and disclosure of the principal investigator's perspective enhances the credibility of the study (Giacomini & Cook, 2008; Ploeg, 1999). The use of triangulation strengthened the validation of the data in the study. In addition, because of the study's diverse and large sample, the study findings may be transferrable to other settings that are implementing this programme.

This study focused on one hospital system in Johannesburg, South Africa, which limits the ability to make assumption about the findings beyond the context in which this study was conducted. Additionally, a convenience sample of healthcare professionals was selected for qualitative interviews based on recommendations from the Head of the Paediatric and Child Health department and Director of the ESRU. In order to mitigate the limitation of biased selection of the healthcare professionals, a purposeful random sampling method could be used to increase credibility of the study. Furthermore, convenience sampling was used where patients were sent to the interview room after asked by sisters if they wanted to participate in the study. A limitation would be not using a convenience sample to ensure that patients were not subjected to selection bias based on their ability to speak English, which can decrease the validity of the research and gain a maximum representation of views.

Chapter VI: Conclusion

The study findings demonstrate that the national consolidated guideline has affected the work of healthcare professionals in managing the implementation of the Option B+ PMTCT programme. There are major challenges in keeping current with the changes of the national guidelines. These changes affect the policies and procedures at RMMCH both at the clinical and management levels.

Pregnant HIV-positive women's views and experiences of the Option B+ PMTCT programme are very informative in understanding the patients' perception about going on ART for life.

In order for the Option B+ PMTCT programme to function and be successful in other settings for HIV-positive pregnant women, certain components need to be addressed. By providing these pregnant women with better counseling and support services for this programme, women may better understand ART for life.

The Option B+ PMTCT programme implemented at RMMCH needs to improve their internal communication and collaboration amongst healthcare professionals to strengthen indicators for the programme and understand their roles in delivering consistent messages and services to mothers. Communication is essential in helping patients build trust in service delivery, decreasing the LTFU and can overall alter the patient perception on long term adherence. Most importantly, an HIV-positive pregnant woman can understand the long term benefits of FDC for both the woman and the baby.

It is crucial in understanding barriers to the short and long term sustainability of the Option B+ programme. Understanding the environment in which a PMTCT programme operates can address policy implementation and programme issues and hence

inform how adaptable Option B+ PMTCT programming is on a larger scale. The national guidelines have been developed but *adaptability* may remain problematic to successful roll out of the Option B+ programme outside of RMMCH.

Implications for this research include the need to address changes within the healthcare system at both clinical and management levels. It is crucial to incorporate the perspective of patients in policy implementation; uptake and adherence are key indicators in informing if the Option B+ PMTCT programme is adopted into state hospitals effectively. In addition, extensive research needs to be done on how to strengthen indicators for long term sustainability of the programme in conducting a longitudinal study comparing system planning between healthcare facilities and state hospitals. Future evaluations need to address if interdisciplinary collaboration within hospitals can improve the management and understanding of Option B+.

REFERENCES

- Besada, D., Van Cutsem, G., Goemaere, E., Ford, N., Bygrave, H., & Lynch, S. (2012). The case for Option B and Optional B+: Ensuring that South Africa's commitment to eliminating mother-to-child transmission of HIV becomes a reality. *Southern African Journal Of HIV Medicine*, 13(4), 178. doi:10.4102/hivmed.v13i4.112
- Belle, J. A., Ferriera, S. B., & Jordaan, A. (2014). Attitude of Lesotho health care workers towards HIV/AIDS and impact of HIV/AIDS on the population structure. *African Health Sciences*, 13(4), 1117-1125.
- Cleary, S., Birch, S., Chimbindi, N., Silal, S., & McIntyre, D. (2013). Investigating the affordability of key health services in South Africa. *Social Science & Medicine*, 80, 37-46.
- Clouse K et al. "What They Wanted Was to Give Birth; Nothing Else": Barriers to Retention in Option B+ HIV Care Among Postpartum Women in South Africa. *Journal of Acquired Immune Deficiency Syndromes* 67: e12-e18, 2014
- Coutsodis A, Goga A, Desmond C, Barron P, Black V, Coovadia H. Is Option B+ the best choice? *Lancet* 2013;381(9863):269-271. [http://dx.doi.org/10.1016/S0140-6736(12)61807-8]
- Department of Health, Republic of South Africa (2014). *National consolidated guidelines for the prevention of mother-to-child transmission of HIV (PMTCT) and the management of HIV in children, adolescents and adults*. Pretoria: Department of Health.
- Empilweni Services and Research Unit. (2015, July 14). *About Us*. Retrieved August 14, 2015, from ESRU: <http://www.esru.co.za/Home/AboutUs.aspx>
- Fasawe, O., Avila, C., Shaffer, N., Schouten, E., & Chimbwandira, F. (2013). Cost-Effectiveness Analysis of Option B+ for HIV Prevention and Treatment of Mothers and Children in Malawi. *PLOS One*. 2013 8:3 p.1-10
- Fried, J., Sunderji, A., Birch, S., & Eyles, J. (2013). The reason that I did not go—determinants of the use of antenatal care services in South Africa, two decades after the end of apartheid. *Canadian Journal of African Studies/La Revue canadienne des etudes africaines*, 47(1), 27-50.

- Ghanotakis, E., Peacock, D., & Wilcher, R. (2012). The importance of addressing gender inequality in efforts to end vertical transmission of HIV. *Journal of the International AIDS Society*, 15. Retrieved from: <http://www.jiasociety.org/index.php/jias/article/view/17385>.
- Giacomini, M. & Cook, D.J. (2008). Chapter. 11.5: Qualitative research. In, Guyatt GH, Rennie, D., Meade, MO, & Cook, DJ (editors). *User' Guides to the Medical Literature. A Manual for Evidence-Based Clinical Practice (2nd Edition)*. (pp 341- 360). US: McGraw Hill.
- Gopalappa, C., Stover, J., Shaffer, N., & Mahy, M. (2014). The costs and benefits of Option B+ for the prevention of mother-to-child transmission of HIV. *AIDS*, 28, S5-S14.
- Kamuyango, A. A., Hirschhorn, L. R., Wang, W., Jansen, P., & Hoffman, R. M. (2014). One-year outcomes of women started on antiretroviral therapy during pregnancy before and after the implementation of Option B+ in Malawi: A retrospective chart review. *World journal of AIDS*, 4(3), 332.
- Kieffer, M. P., Mattingly, M., Giphart, A., van de Ven, R., Chouraya, C., Walakira, M., ... & Simonds, R. J. (2014). Lessons learned from early implementation of option B+: the Elizabeth Glaser Pediatric AIDS Foundation experience in 11 African countries. *Journal of acquired immune deficiency syndromes (1999)*, 67(Suppl 4), S188.
- Larsson, E., et al. (2012). Opt-out HIV testing during antenatal care: experiences of pregnant women in rural Uganda. *Health Policy Plan*, 27(1), 69-75. doi: 10.1093/heapol/czr009.
- Maharaj, T., et al. Strategies to address clinic waiting time and retention in care; lessons from a large ART center in South Africa. 17th International Conference on AIDS and STIs in Africa, abstract no. ADS058.
- Mann, C.J. (2003). Observational research methods. Research design II: cohort, cross sectional, and case-control studies. *Emerg Medical Journal*, 20:54-60.

- McIntyre, D. I., Thiede, M., & Birch, S. (2009). Access as a policy-relevant concept in low-and middle income countries. *Health Economics, Policy and Law*, 4(02), 179-193.
- O'Brien, L., Shaffer, N., Sangrujee, N., & Abimbola, T. O. (2014). The incremental cost of switching from Option B to Option B+ for the prevention of mother-to-child transmission of HIV. *Bulletin of the World Health Organization*, 92(3), 162-170.
- Ploeg, J. (1999). Identifying the best research design to fit the question. Part 2: qualitative designs. *Evidence Based Nursing*, 2, 36-37.
<http://ebn.bmj.com/content/2/2/36.full>
- Pope, C., & Mays, N. (1995). Qualitative research: Reaching the Parts Other Methods Cannot Reach: An Introduction to Qualitative Methods in Health and Health Services Research. *BMJ*, 311, 4245.
<http://libaccess.mcmaster.ca/login?url=http://bmj.bmjournals.com/cgi/content/full/311/6996/42>
- Siberry G, Williams P, Mendez H, et al. (2012). Pediatric HIV/AIDS Cohort study (PHACS). Safety of tenofovir use during pregnancy: Early growth outcomes in HIV-exposed uninfected infants. *AIDS* 2012;26(9):1151-1159.
[<http://dx.doi.org/10.1097/QAD.0b013e328352d135>]
- Silal, S. P., Penn-Kekana, L., Harris, B., Birch, S., & McIntyre, D. (2012). Exploring inequalities in access to and use of maternal health services in South Africa. *BMC health services research*, 12(1), 120.
- Smit, B. (2003). Can Qualitative Research Inform Policy Implementation? Evidence and Arguments from a Developing Country Context. *Forum Qualitative Sozialforschung / Forum: Qualitative Social Research*, 4(3). Retrieved from <http://www.qualitative-research.net/index.php/fqs/article/view/678/1466>
- Stake, R. E. (1995). *The art of case study research*. Thousand Oaks, CA: Sage.
- UN. (2006) *Millennium Development Goals Report 2006*. Brussels: United Nations.
- UNICEF. (2012). A Business case for Options B and B+ to eliminate mother to child transmission of HIV by 2015. A Discussion Document for the Global Steering Group Presented by the Business Leadership Council and UNICEF. *Collaboration with the Clinton Health Access Initiative*. New York: UNICEF.

- UNICEF. (2012). Options B and B+: Key Considerations for Countries to Implement an Equity-Focused Approach. *Geneva, Switzerland: UNICEF.*
- Vella, V. (2008). Evaluation of the antiretroviral therapy in KwaZulu-Natal, South Africa. Published by KZN Department of Health. Retrieved from: <http://www.kznhealth.gov.za/italian/arv.pdf>.
- Webb, R., & Cullel, M. M. (2013). *Understanding the perspectives and/or experiences of women living with HIV regarding Option B+ in Uganda and Malawi*. Malawi: ICW.
- World Health Organization (WHO). (2014). Implementation of Option B+ for prevention of mother-to-child transmission of HIV: the Malawi experience.
- World Health Organization (WHO). (2015, September 5). *Consolidated ARV Guidelines, June 2013*. Retrieved August 11, 2015, from World Health Organization: <http://www.who.int/hiv/pub/guidelines/arv2013/intro/intro/en/>
- Yin, R. K. (2009). Case study research: Design and method, (4th ed). Thousand Oaks, CA: Sage.

APPENDICES

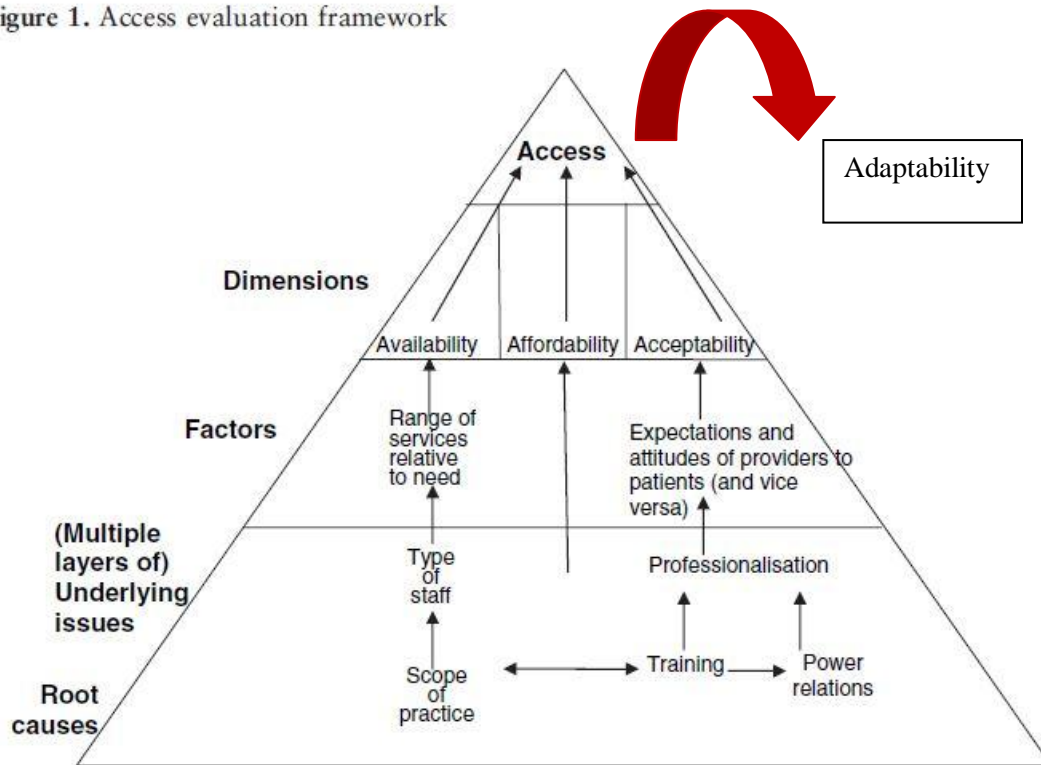
Appendix A. Option B+ for PMTCT

Table 1: Three Options for PMTCT ¹			
	Treatment (for CD4 count < 350 cells/mm ³)	Prophylaxis (for CD4 count > 350 cells/mm ³)	Infant receives
Option A	Triple ARVs starting as soon as diagnosed, continued for life	<i>Antepartum:</i> AZT starting as early as 14 weeks gestation <i>Intrapartum:</i> at onset of labour, single-dose NVP and first dose of AZT/3TC <i>Postpartum:</i> daily AZT/3TC through 7 days postpartum	Daily NVP from birth until 1 week after cessation of all breastfeeding; or, if not breastfeeding or if mother is on treatment, through age 4–8 weeks
Option B	Triple ARVs starting as soon as diagnosed, continued for life	Triple ARVs starting as early as 14 weeks gestation and continued intrapartum and through childbirth if not breastfeeding or until 1 week after cessation of all breastfeeding	Daily NVP or AZT from birth through age 4–8 weeks regardless of infant feeding method
Option B+	Triple ARVs starting as soon as diagnosed, continued for life	Triple ARVs starting as soon as diagnosed, continued for life	Daily NVP or AZT from birth through age 4–8 weeks regardless of infant feeding method

Source: UNICEF(2012). Options B and B+: Key Considerations for Countries to Implement an Equity- Focused Approach. *Geneva, Switzerland: UNICEF.*

Appendix B. McIntyre Framework for Accessibility

Figure 1. Access evaluation framework



Note: Due to space constraints only one example is given for each of availability and acceptability. Clearly many factors can influence each dimension.

Source: McIntyre, D. I., Thiede, M., & Birch, S. (2009). Access as a policy-relevant concept in low-and middle income countries. *Health Economics, Policy and Law*, 4(02), 179-193.

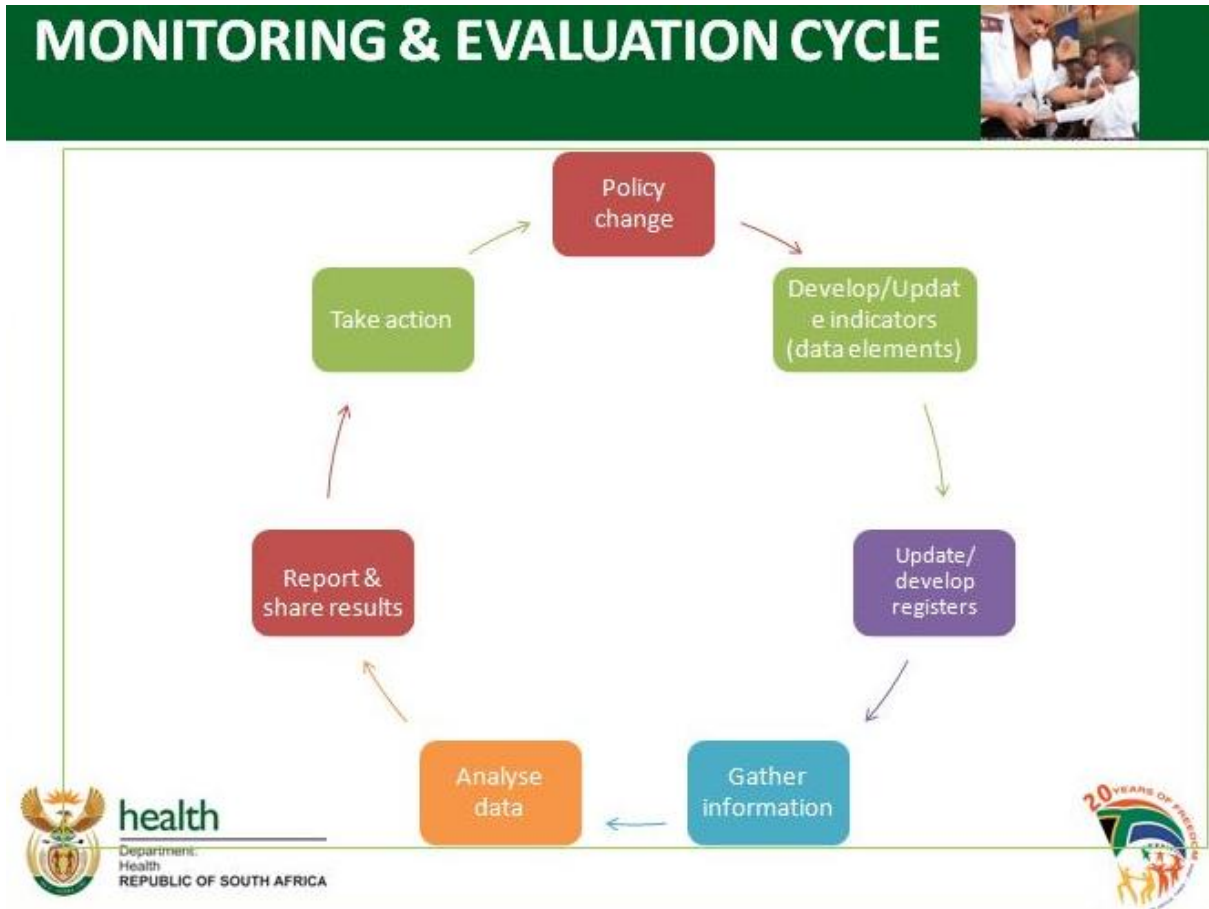
Note: The adaptability concept has been added to Figure 1. Access evaluation framework.

Appendix C. WHO's Clinical Staging for Children, Adolescents and Adults

CLINICAL STAGE	CLINICAL CONDITIONS OR SYMPTOMS (Adolescents and Adults)	CLINICAL CONDITIONS OR SYMPTOMS (Children)	CLINICAL STAGE	CLINICAL CONDITIONS OR SYMPTOMS (Adolescents and Adults)	CLINICAL CONDITIONS OR SYMPTOMS (Children)
Primary HIV infection	<ul style="list-style-type: none"> Asymptomatic Acute retroviral syndrome 			<ul style="list-style-type: none"> (haemoglobin < 8 g/dL) Neutropenia (neutrophils < 500 cells/μL) Chronic thrombocytopenia (platelets < 50,000 cells/μL) 	<ul style="list-style-type: none"> Unexplained anaemia (< 8 g/dL), neutropenia (< 0.5 \times 10⁹ per litre) And/or chronic thrombocytopenia (< 50 \times 10⁹ per litre)
Clinical stage 1	<ul style="list-style-type: none"> Asymptomatic Persistent generalized lymphadenopathy 	<ul style="list-style-type: none"> Asymptomatic Persistent generalized lymphadenopathy 			
Clinical stage 2	<ul style="list-style-type: none"> Moderate unexplained weight loss (< 10% of presumed or measured body weight) Recurrent respiratory infections (sinusitis, tonsillitis, otitis media, and pharyngitis) Herpes zoster Angular cheilitis Recurrent oral ulceration Papular pruritic eruptions Seborrheic dermatitis Fungal nail infections 	<ul style="list-style-type: none"> Unexplained persistent weight loss Hepatosplenomegaly Papular pruritic eruptions Extensive wart virus infection Extensive molluscum contagiosum Fungal nail infections Recurrent oral ulcerations Unexplained persistent parotid enlargement Lineal gingival erythema Herpes zoster Recurrent or chronic upper respiratory tract infections (otitis media, otorrhoea, sinusitis or tonsillitis) 	Clinical stage 4	<ul style="list-style-type: none"> HIV wasting syndrome, as defined by the CDC (see Table 1, above) Pneumocystis pneumonia Recurrent severe bacterial pneumonia Chronic herpes simplex infection (orolabial, genital, or anorectal site for > 1 month or viscerol herpes at any site) Oesophageal candidiasis (or candidiasis of trachea, bronchi, or lungs) Extra pulmonary tuberculosis Kaposi sarcoma Cytomegalovirus infection (retinitis or infection of other organs) Central nervous system toxoplasmosis HIV encephalopathy Cryptococcosis, extra pulmonary (including meningitis) Disseminated non-Tuberculosis mycobacteria infection Progressive multifocal leukoencephalopathy Candida of the trachea, bronchi, or lungs Chronic cryptosporidiosis (with diarrhoea) Chronic isosporiasis Disseminated mycosis (e.g., histoplasmosis, coccidioidomycosis, penicilliosis) Recurrent non-typhoidal Salmonella bacteraemia Lymphoma (cerebral or B-cell non-Hodgkin) Invasive cervical carcinoma Atypical disseminated leishmaniasis Symptomatic HIV-associated nephropathy Symptomatic HIV-associated cardiomyopathy Reactivation of American 	<ul style="list-style-type: none"> Unexplained severe wasting, stunting or severe malnutrition not responding to standard therapy Pneumocystis pneumonia Recurrent severe bacterial infections (such as empyema, pyomyositis, bone or joint infection or meningitis but excluding pneumonia) Chronic herpes simplex infection (orolabial or cutaneous of more than one month's duration or visceral at any site) Extra pulmonary tuberculosis Kaposi sarcoma Oesophageal candidiasis (or candidiasis of trachea, bronchi or lungs) Central nervous system toxoplasmosis (after one month of life) HIV encephalopathy Cytomegalovirus infection: retinitis or cytomegalovirus infection affecting another organ, with onset at age older than one month Extra pulmonary cryptococcosis (including meningitis) Disseminated endemic mycosis (extra pulmonary histoplasmosis, coccidioidomycosis) Chronic cryptosporidiosis Chronic isosporiasis Disseminated non-tuberculous mycobacterial infection Cerebral or B-cell non-Hodgkin lymphoma Progressive multifocal leukoencephalopathy Symptomatic HIV-associated nephropathy or HIV-associated cardiomyopathy HIV-associated rectovaginal fistula
Clinical stage 3	<ul style="list-style-type: none"> Unexplained severe weight loss (> 10% of presumed or measured body weight) Unexplained chronic diarrhoea for > 1 month Unexplained persistent fever for > 1 month (> 37.6°C, intermittent or constant) Persistent oral candidiasis (thrush) Oral hairy leukoplakia Pulmonary tuberculosis (current) Severe presumed bacterial infections (e.g. pneumonia, empyema, pyomyositis, bone or joint infection, meningitis, bacteraemia) Acute necrotizing ulcerative stomatitis, gingivitis, or periodontitis Unexplained anaemia 	<ul style="list-style-type: none"> Unexplained moderate malnutrition not adequately responding to standard therapy Unexplained persistent diarrhoea (14 days or more) Unexplained persistent fever (above 37.5°C intermittent or constant for longer than one month) Persistent oral candidiasis (after first 8-8 weeks of life) Oral hairy leukoplakia Acute necrotizing ulcerative gingivitis or periodontitis Lymph node tuberculosis Pulmonary tuberculosis Severe recurrent bacterial pneumonia Symptomatic lymphoid interstitial pneumonitis Chronic HIV-associated lung disease including bronchiectasis 			

Source: Department of Health, Republic of South Africa (2014). *National consolidated guidelines for the prevention of mother-to-child transmission of HIV (PMTCT) and the management of HIV in children, adolescents and adults*. Pretoria: Department of Health.

Appendix E. Monitoring and Evaluation Cycle



Source: Department of Health, Republic of South Africa. (2014, November 4). Training on the Revised ART Guidelines for Children, Adolescent and Adults Including Pregnant and Breastfeeding Mothers [Powerpoint]. *Monitoring and Evaluation*. Lecture conducted from Protea Hotel Capital, Department of Health, Pretoria, South Africa.

Appendix F. RMMCH's Paediatric Information District System (PIDS) Indicators

Monthly Indicators for Antenatal Care (ANC)

GAUTENG DEPARTMENT OF HEALTH

Antenatal Monthly Data Input Form

Facility: Month : Year :

Sub- district:

Completed by: (Print name) (Sign) Tel no.: ..

Verified by: (Print name) (Sign) Tel no.: ..

Version 1: November 2014

No	Data Element	Value
Visits		
1	Antenatal 1st visit before 20 weeks	
2	Antenatal 1st visit 20 weeks or later	
3	Antenatal 1st visit total	
4	Antenatal client on HAART at 1st visit	
5	Antenatal client known HIV positive but NOT on ART at 1st visit	
STI		
6	STI treated - new episode (ANC)	
TB/HIV Collaboration		
7	HIV positive status known at first ANC visit	
8	HIV positive new antenatal client screened for TB	
9	HIV positive ANC client with confirmed TB	
10	HIV positive new ANC client started on IPT	
11	HIV positive ANC client started on CPT	
TB		
12	Antenatal client screened for TB	
13	Antenatal client with confirmed TB	
HIV/AIDS		
14	Antenatal client pre-test counselled for HIV	
15	Antenatal client HIV 1st test	
16	Antenatal client HIV 1st test positive	

17	Antenatal client HIV re-test	
18	Antenatal client HIV re-test positive	
ART		
19	Antenatal client eligible for ART initiation	
20	Antenatal client CD4 1st test	
Comments:		
Monthly report to be submitted by the 7th of the following month.		

Source: RMMCH & Gauteng National DoH PIDS System Indicators (p.126-127).

Appendix G. Participant Information and Consent Form



LETTER OF INFORMATION/CONSENT: (AUDIO RECORDING)

A Study of/about: Option B+ PMTCT Programme at Rahima Moosa Mother to Child Hospital, Johannesburg, South Africa.

Student Investigator:

Melanie Bisnauth
Department of Global Health
McMaster University
Hamilton, Ontario, Canada
(905) 525-9140 ext. XXXXX
E-mail: bisnauma@mcmaster.ca

Purpose of the Study:

To evaluate the new Option B+ policy for HIV-positive women in pregnant mother to child transmission (PMTCT) programmes at Rahima Moosa Mother and Child Hospital. To discover information about how women feel towards the policy that will be beneficial for healthcare professionals to better understand what factors may act as barriers to taking medication and contribute to how they feel about being asked to do so.

What am I trying to discover?

Women's attitudes towards the Option B+ policy in the pregnant mother to child transmission programme, to better understand how they feel about being asked to take the drugs. To discover what barriers exist for pregnant women in the programme.

Research Question

For HIV-positive South African pregnant women, aged 15-49 attending Rahima Moosa Mother and Child Hospital, is Option B+ effective in the increase of medication adherence? How do these pregnant women think about going on ARVs for life? What factors may act as barriers to them taking the drugs as required?

You are invited to take part in this study because it involves healthcare workers or females like yourself that are pregnant, HIV-positive and in the Option B+ programme. I want to give you a chance to express your feelings about the programme. I am hoping to learn more about ways Rahima Moosa Mother and Child Hospital can help women follow treatment better and what they can change to do so. I am doing this research for a thesis for part of my programme in Global Health.

What will happen during the study?

If you decide that you want to be part of this study, first you will be asked to fill out this consent form. Second, I will ask you to fill out a survey. Third, I will ask you to participate in an interview in a separate room in Rahima Moosa Hospital. With your permission, this interview will be **audio recorded** and handwritten notes will be taken. This all should take about 1 hour. While doing

these things, if you do not know what to say or do next, you can say 'I do not know'. Please feel free to ask any questions throughout the study. If you do not understand some of the words or concepts, I will take time to explain them to you as we go along. I am going to talk about things like your feelings about the programme, and access to treatment at Rahima Moosa Hospital. I will be asking you questions about your personal income, if you have children, if you have a partner. I will also ask you for some demographic/background information like your age and education. You do not have to answer any question or take part in the interview/survey if you don't wish to do so, and that is also fine. You do not have to give us any reason for not responding to any question, or for refusing to take part in the interview.

Are there any risks to doing this study?

It is not likely that there will be any harms, discomforts, inconveniences or risks associated with this study. You do not need to answer questions that you do not want to answer or that make you feel uncomfortable. I describe below the steps I am taking to protect your privacy.

Are there any benefits to doing this study?

The research will not benefit you directly. I hope to learn more about how healthcare workers or women like yourself feel about the Option B+ programme. I hope that what is learned as a result of this study will help Rahima Moosa Mother and Child Hospital to better understand what factors may act as barriers to taking medication and contribute to how women feel about being asked to do so.

Who will know what I said or did in the study?

You are participating in this study confidentially. I will not use your name or any information that would allow you to be identified. No one will know whether you were in the study. Every effort will be made to protect your confidentiality and privacy. The information/data you provide will be kept in a locked desk where only I will have access to it. Information kept on a computer will be protected by a password. Once the study has been completed, an archive of the data, without identifying information, will be maintained for 10 years.

What if I change my mind about being in the study?

Your participation in this study is voluntary. It is your choice to be part of the study or not. If you decide to be part of the study, you can withdraw from the study for whatever reason, even after signing the consent form or up until approximately **July 31st, 2015** when I expect to be submitting my thesis. If you decide to withdraw, there will be no consequences to you. In cases of withdrawal, any data you have provided in the interview process will be destroyed unless you indicate otherwise. If you do not want to answer some of the questions you do not have to, but you can still be in the study.

You will still receive all the services that you usually do and it will not have any bearing on your job. If the interview takes place, the person cannot 'stop participation' but request that the information by them not be used in the research study. *Once* you have submitted your responses for this anonymous survey: your answers will be put into a database and will not be identifiable to you. This means that once you have submitted your survey, your responses cannot be withdrawn from the study because I will not be able to identify which responses are yours.

How do I find out what was learned in this study?

I expect to have this study completed by approximately **August 18th, 2015**. If you would like a brief summary of the results, please let me know how you would like it sent to you.

Questions about the Study:

If you have questions or need more information about the study itself, please contact me at:

Melanie Bisnauth Rahima Moosa Mother and Child Hospital Department of Paediatrics and Child Health <i>Phone # will be provided</i>

This study has been reviewed by the McMaster University Research Ethics Board and received ethics clearance. If you have concerns or questions about your rights as a participant or about the way the study was conducted, please contact:

McMaster Research Ethics Secretariat
Telephone: (905) 525-9140 ext.23142
C/o Research Office for Administrative Development and Support
E-mail: ethicsoffice@mcmaster.ca

CONSENT

- I have read the information presented in the information letter about a study being conducted by **Melanie Bisnauth** of McMaster University.
- I have had the opportunity to ask questions about my involvement in this study and to receive additional details I requested.
- I understand that if I agree to participate in this study, I may withdraw from the study at any time or up until approximately **July 31, 2015**.
- I have been given a signed copy of this form.
- I agree to participate in the study.

1. I agree that the interview can be audio recorded.

...Yes.

...No.

2. ...Yes, I would like to receive a summary of the study's results.

(If the organization agrees to disseminate results to participants, the summary will be provided at Rahima Moosa Hospital, Department of Paediatrics and Children Health)

... No, I do not want to receive a summary of the study's results.

Signature: _____ Date: _____

Name of Participant (Printed) _____

***two copies of the form will be provided 1) researchers file 2) participant to keep

Evaluation of the new Option B+ PMTCT programme for HIV infected women at hospital facilities: Case Study at the Rahima Moosa Mother and Child Hospital, Johannesburg, South Africa.

Researcher: Melanie Bisnauth

Oral Consent Script

Introduction:

Hello. I'm Melanie Bisnauth. I am conducting interviews and surveys about the new Option B+ policy for the pregnant mother to child transmission programme at Rahima Moosa Hospital. I'm conducting this as part of research for my thesis at McMaster University's Masters of Science in Global Health programme in Hamilton, Ontario, Canada.

What am I trying to discover?

Women's attitudes towards the Option B+ policy in the pregnant mother to child transmission programme, to better understand how they feel about being asked to take the drugs. To discover what barriers exist for pregnant women in the programme.

What will happen during the study?

If you decide that you want to be part of this study, first you will be asked to fill out this consent form. Second, I will ask you to fill out a survey. Third, I will ask you to participate in an interview in a separate room in Rahima Moosa Hospital. With your permission, this interview will be audio recorded and handwritten notes will be taken. This all should take about 1 hour. While doing these things, if you do not know what to say or do next, you can say 'I do not know'. Please feel free to ask any questions throughout the study. If you do not understand some of the words or concepts, I will take time to explain them to you as we go along. I am going to talk about things like your feelings about the programme, and access to treatment at Rahima Moosa Hospital. I will be asking you questions about your personal income, if you have children, if you have a partner. I will also ask you for some demographic/background information like your age and education. You do not have to answer any question or take part in the interview/survey if you don't wish to do so, and that is also fine. You do not have to give us any reason for not responding to any question, or for refusing to take part in the interview.

Are there any risks to doing this study?

It is not likely that there will be any harms, discomforts, inconveniences or risks associated with this study. You do not need to answer questions that you do not want to answer or that make you feel uncomfortable. I describe below the steps I am taking to protect your privacy.

Are there any benefits to doing this study?

The research will not benefit you directly. I hope to learn more about how healthcare workers or women like yourself feel about the Option B+ programme. I hope that what is learned as a result of this study will help Rahima Moosa Mother and Child Hospital to better understand what factors may act as barriers to taking medication and contribute to how women feel about being asked to do so.

I will keep the information you tell me during the interview confidential. Any data from this research which will be shared or published will be the combined data of all participants. That means it will be reported for the whole group not for individual persons.

Who will know what I said or did in the study?

You are participating in this study confidentially. I will not use your name or any information that would allow you to be identified. No one will know whether you were in the study. Every effort will be made to protect your confidentiality and privacy. The information/data you provide will be kept in a locked desk where only I will have access to it. Information kept on a computer will be protected by a password. Once the study has been completed, an archive of the data, without identifying information, will be maintained for 10 years.

Voluntary participation:

- Your participation in this study is voluntary.
- You can decide to stop at any time, even part-way through the interview for whatever reason, or up until approximately **July 31st, 2015**.
- If you decide to stop participating, there will be no consequences to you.
- If you decide to stop we will ask you how you would like us to handle the data collected up to that point.
- This can include; data can be destroyed or using the data collected up to that point.
- If you do not want to answer some of the questions you do not have to, but you can still be in the study.
- If you have any questions about this study or would like more information you can call or email Melanie Bisnauth at **(number will be provided for office)**

You will still receive all the services that you usually do and it will not have any bearing on your job. If the interview takes place, the person cannot 'stop participation' but request that the information by them not be used in the research study. *Once* you have submitted your responses for this anonymous survey: your answers will be put into a database and will not be identifiable to you. This means that once you have submitted your survey, your responses cannot be withdrawn from the study because I will not be able to identify which responses are yours.

This study has been reviewed by the Hamilton Integrated Research Ethics Board (HIREB). The HIREB is responsible for ensuring that participants are informed of the risks associated with the research, and that participants are free to decide if participation is right for them. If you have any questions about your rights as a research participant, please call the Office of the Chair, HIREB at (905) 521-2100 x 42013.

Please let me know if you would like a summary and what would be the best way to get this to you.

Consent questions:

- Do you have any questions or would like any additional details?
[Answer questions.]
- Do you agree to participate in this study knowing that you can withdraw at any point with no consequences to you?
[If yes, begin the survey and interview.]
[If no, thank the participant for his/her time.]

Read aloud:

- I have read the information presented in the information letter about a study being conducted by **Melanie Bisnauth** of McMaster University.
- I have had the opportunity to ask questions about my involvement in this study and to receive additional details I requested.
- I understand that if I agree to participate in this study, I may withdraw from the study at any time or up until approximately **July 31, 2015**.
- I have been given a copy of this form.
- I agree to participate in the study.

1. I agree that the interview can be audio recorded.

... Yes.

... No.

2. ...Yes, I would like to receive a summary of the study's results.

(If the organization agrees to disseminate results to participants, the summary will be provided at Rahima Moosa Hospital, Department of Paediatrics and Children Health)

... No, I do not want to receive a summary of the study's results.

Signature: _____ Date: _____

Name of Participant (Printed) _____

***two copies of the form will be provided 1) researchers file 2) participant to keep

Appendix H. Demographic Questionnaire for Patients

Questionnaire for Rahima Moosa Mother and Child Hospital Patients

Evaluation of the new Option B+ PMTCT programme for HIV infected women at hospital facilities: Case Study at the Rahima Moosa Mother and Child Hospital, Johannesburg, South Africa.

Melanie Bisnauth (Masters of Science in Global Health)
(Department of Global Health – McMaster University)

A. Questionnaire

Please be informed that the following information provided by your participation will be confidential. We conform to all aspects under the Code of Ethics. *“Unless the respondent waives confidentiality for specified uses, we shall hold as privileged and confidential all information that might identify a respondent with his or her responses. We shall also not disclose or use the names of respondents for non-research purposes unless the respondent grants us permission to do so.”*

If in agreement, please sign below. We thank you for participating in the survey.

Signature

Demographic Data

UNIQUE CODE #

1. What is your age?

<input type="radio"/> 0-15
<input type="radio"/> 16-21
<input type="radio"/> 22-37
<input type="radio"/> 38-43
<input type="radio"/> 44-49
<input type="radio"/> 49+

2. What is your status?

<input type="radio"/> Single
<input type="radio"/> Married
<input type="radio"/> Common-Law
<input type="radio"/> Divorced
<input type="radio"/> Widowed
<input type="radio"/> None of the above

3. Do you have any children or dependents?

<input type="radio"/> Yes
<input type="radio"/> No

4. How old are they?

<input type="radio"/> 0-6 years	<input type="radio"/> 14-21 years
<input type="radio"/> 7-13 years	<input type="radio"/> 21 and over

5. What is your method of transportation to Rahima Moosa Hospital?

<input type="radio"/> Walk
<input type="radio"/> Taxi Bus
<input type="radio"/> Drive Automobile
<input type="radio"/> None of the above

Program Effectiveness

6. How long have you been on the Option B+ programme?

<input type="radio"/> Less than 1 week
<input type="radio"/> Less than 1 month
<input type="radio"/> 1-2 months
<input type="radio"/> 3-4 months
<input type="radio"/> 5-6 months

7. Where did you learn about the Option B+ programme?

<input type="radio"/> Treatment Action Campaign or Ad	
<input type="radio"/> Healthcare Worker at Rahima Moosa	
<input type="radio"/> Healthcare Worker outside Rahima Moosa	
<input type="radio"/> Family and friends	<input type="radio"/> Other _____

8. Do you think Option B+ programme is easier to follow?

<input type="radio"/> Yes
<input type="radio"/> No
<input type="radio"/> I don't know

9. Have you missed any dosages of treatment/medication?

<input type="radio"/> Yes

<input type="radio"/> No

If yes, how many dosages have you missed?

<input type="radio"/> 0-3 doses	<input type="radio"/> 8-10 doses
<input type="radio"/> 4-7 doses	<input type="radio"/> 10 and over

Decision Making Factors

10. On a scale from 0-5 (5 is the highest), How much do you trust your healthcare worker at Rahima Moosa Hospital?

0 I don't trust them at all	1 I barely trust them	2 I trust them a bit	3 I trust them sometimes	4 I trust them mostly	5 I trust them always
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

11. Where does the income come from in your household? Check all that apply.

1. Spouse contribution	<input type="radio"/>
2. Immediate family contribution	<input type="radio"/>
3. Government assistance	<input type="radio"/>
4. Financial subsidies	<input type="radio"/>
5. Housing subsidies	<input type="radio"/>
6. None of the above	<input type="radio"/>

12. On a 5 point scale, rate the obstacles that impact you taking your treatment:

Obstacle	Not a Conflict 1	Slight Conflict 2	Important Conflict 3	Rather Conflicting 4	Very Conflicting 5
Family Obligations (children, spouse, elderly people)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Difficult working hours	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Lack of understanding healthcare worker	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Lack of accessibility to hospital or clinic	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Lack of money	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Lack of transportation	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

13. Have you had sexual intercourse within the past week?

<input type="radio"/> Yes
<input type="radio"/> No

14. If yes, was protection used (i.e. condom)?

<input type="radio"/> Yes
<input type="radio"/> No
<input type="radio"/> I don't know

15. Do you find the education from the programme useful?

<input type="radio"/> Yes
<input type="radio"/> No
<input type="radio"/> I don't know

Thank you for taking the time to fill out our survey. Your input is greatly appreciated.

Appendix I. Demographic Questionnaires for Healthcare Professionals

Questionnaire for Rahima Moosa Mother and Child Hospital Healthcare Workers

Evaluation of the new Option B+ PMTCT programme for HIV infected women at hospital facilities: Case Study at the Rahima Moosa Mother and Child Hospital, Johannesburg, South Africa.

Melanie Bisnauth (Masters of Science in Global Health)
(Department of Global Health – McMaster University)

B. Questionnaire

Please be informed that the following information provided by your participation will be confidential. We conform to all aspects under the Code of Ethics. *“Unless the respondent waives confidentiality for specified uses, we shall hold as privileged and confidential all information that might identify a respondent with his or her responses. We shall also not disclose or use the names of respondents for non-research purposes unless the respondent grants us permission to do so.”*

If in agreement, please sign below. We thank you for participating in the survey.

Signature

Demographic Data

UNIQUE CODE #

1. What is your age?

<input type="radio"/> 16-21
<input type="radio"/> 22-37
<input type="radio"/> 38-43
<input type="radio"/> 44-49
<input type="radio"/> 49+

2. How long have you worked at Rahima Moosa Hospital?

<input type="radio"/> Less than 1 year
<input type="radio"/> 2-5 years
<input type="radio"/> 6-10 years
<input type="radio"/> 10 years or more

Please indicate your department/unit you work in:

3. On average, how many patients do you see a day?

<input type="radio"/> 0-5	<input type="radio"/> 11-20
<input type="radio"/> 6-10	<input type="radio"/> 21 and over

4. What is your method of transportation to Rahima Moosa Hospital?

<input type="radio"/> Walk
<input type="radio"/> Taxi Bus
<input type="radio"/> Drive Automobile
<input type="radio"/> None of the above

Program Effectiveness

5. How long have most of your patients been on the Option B+ programme?

<input type="radio"/> Less than 1 week
<input type="radio"/> Less than 1 month
<input type="radio"/> 1-2 months
<input type="radio"/> 3-4 months
<input type="radio"/> 5-6 months

6. Where do you think most of your patients get their information about Option B+ from?

<input type="radio"/> Treatment Action Campaign or Ad	
<input type="radio"/> Healthcare Worker at Rahima Moosa	
<input type="radio"/> Healthcare Worker outside Rahima Moosa	
<input type="radio"/> Family and friends	<input type="radio"/> Other _____

7. Do you think Option B+ programme is easier to follow?

<input type="radio"/> Yes
<input type="radio"/> No
<input type="radio"/> I don't know

8. Have your patients missed any dosages of treatment/medication?

<input type="radio"/> Yes
<input type="radio"/> No

If yes, on average how many dosages have they missed?

<input type="radio"/> 0-3 doses	<input type="radio"/> 8-10 doses
<input type="radio"/> 4-7 doses	<input type="radio"/> 10 and over

9. On a scale from 0-5 (5 is the highest), How much do you trust your patients at Rahima Moosa Hospital?

0	1	2	3	4	5
I don't trust them at all	I barely trust them	I trust them a bit	I trust them sometimes	I trust them mostly	I trust them always
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

10. How would you rate your services supplied to patients at your facilities? (0 the lowest and 10 being the highest) Circle a number that corresponds.

0 1 2 3 4 5 6 7 8 9 10

11. On a 5 point scale, rate the obstacles that impact your patients taking their treatment:

Obstacle	Not a Conflict 1	Slight Conflict 2	Important Conflict 3	Rather Conflicting 4	Very Conflicting 5
Family Obligations (children, spouse, elderly people)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Difficult working hours	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Lack of understanding healthcare worker	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Lack of accessibility to hospital or clinic	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Lack of money	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Lack of transportation	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

12. Do you find the education from your PMTCT programme useful?

<input type="radio"/> Yes
<input type="radio"/> No
<input type="radio"/> I don't know

Thank you for taking the time to fill out our survey. Your input is greatly appreciated.

Appendix J. Patients Interview Guide (with Domains/Prompts)

Interview Questions- Patients

Evaluation of the new Option B+ PMTCT programme for HIV infected women at hospital facilities: Case Study at the Rahima Moosa Mother and Child Hospital, Johannesburg, South Africa.

Melanie Bisnauth, (Master of Science student)

(Department of Global Health – McMaster University)

Information about these interview questions: This gives you an idea what I would like to learn about the Option B+ policy integration into the existent pregnant mother to child transmission programme at Rahima Moosa Hospital. Interviews will be one-to-one and will be open-ended (not just “yes or no” answers). Because of this, the exact wording may change a little. Sometimes I will use other short questions to make sure I understand what you told me or if I need more information when we are talking such as: “*So, you are saying that ...?*”), to get more information (“*Please tell me more?*”), or to learn what you think or feel about something (“*Why do you think that is ...?*”).

Domain of Interest	Questions & Probes
Family Obligations Stage of Pregnancy	1) Information about you: Your age now? Are you married? Do you have children and how old are they? Do you have a partner/spouse? How far along are you in your pregnancy?
Challenge: Distance Travelled Waiting Times	2) How far do you live from Rahima Moosa Hospital? What area? How long does it take you to get here? What method of transportation do you use?
First Interaction with Option B+ ARV History	3) Please tell me how long you have been on the Option B+ programme? Were you on ARVs before?
Resources for Education & Sources of Information	4) Where did you learn about the Option B+ programme?
Determine to what extent medication adherence is enhanced by this new policy	5) Do you think it is effective? [] Yes [] No

<p>for a greater number of HIV infected women:</p> <p>Understanding Benefits of FDC</p> <p>Changes in Adherence Level</p>	<p>Please tell me more about why you think that?</p>
<p>Program Effectiveness</p> <p>Affordability</p> <p>Accessibility</p> <p>Availability</p>	<p>6) How do you find accessing treatment? Easy, difficult? Method of payment? If you had to would it be hard to pay, why?</p>
<p>Easier to Manage FDC</p>	<p>7) Is there anything that has changed with your ability to take medication/treatment? [] Yes [] No</p> <p>Please tell me more about why you think that? Do you miss any dosages?</p>
<p>Obstacles for Patients (cross-checked with categorical chart for questionnaire)</p>	<p>8) Is it easier or difficult to follow? Why? What are some challenges you are facing in taking your medication? (i.e. accessibility, transportation, time, missed work)</p>
<p>Relationship with Healthcare Professional</p> <p>Stigma of HIV</p> <p>Social & Cultural Barriers</p>	<p>9) How did you feel when first learning about your positive status? How did you feel when the healthcare worker told you that you would have to take this medication/treatment for life? [] Depressed, sad [] Not sad or depressed.</p> <p>If no, please tell me more.</p>
<p>Decision Making Factors</p> <p>Knowledge Gaps</p>	<p>10) Are you sexually active? Have you had sexual intercourse within the last</p>

<p>Sexual Activity and Understanding Re-Infection Serodiscordant Couples</p> <p>Barriers in Communication Educational Barriers</p>	<p>month, week? Was any method of prevention used? What do you think about the education from PMTCT programs? Do you use it? What does your partner think about you taking the pill? (Do they know?)</p>
<p>Privacy Comfort Level with Healthcare Professional</p> <p>Alternative Practices</p>	<p>11) If you have questions, do you feel you get enough help from a healthcare worker at Rahima Moosa Hospital?</p> <p>i.e.Traditional Medicine Use</p>
<p>Finding Adherence Declines- Adhering for Herself AND the Baby</p>	<p>12) Do you feel you have a choice with this programme?</p>

END

Appendix K. Healthcare Professionals Interview Guide (with Domains/Prompts)

Interview Questions- Healthcare Workers

Evaluation of the new Option B+ PMTCT programme for HIV infected women at hospital facilities: Case Study at the Rahima Moosa Mother and Child Hospital, Johannesburg, South Africa.

**Melanie Bisnauth, (Master of Science student)
(Department of Global Health – McMaster University)**

Information about these interview questions: This gives you an idea what I would like to learn about the Option B+ policy integration into the existent pregnant mother to child transmission programme at Rahima Moosa Hospital. Interviews will be one-to-one and will be open-ended (not just “yes or no” answers). Because of this, the exact wording may change a little. Sometimes I will use other short questions to make sure I understand what you told me or if I need more information when we are talking such as: “*So, you are saying that ...?*), to get more information (“*Please tell me more?*”), or to learn what you think or feel about something (“*Why do you think that is...?*”).

Domain of Interest	Questions & Probes
Experience in Department and Work Collaborated with Different Departments or Units	1) Information about you: Your age now? How long have you worked at Rahima Moosa Hospital? In which department(s)?
Consistency in Work Relationships with Patients Patient Turn-Over	2) Please tell me about your daily routine? (if there is one) What tasks does this include? How many referrals vs. walk-ins do you see? What are some of the reasons for patients to come in to see you?
First Interaction with Option B+ Resources for Education & Sources of Information	3) Where did you learn about the Option B+ programme? Where do you think most of your patients get their information about PMTCT programs? Option B+?
Influence of Healthcare Professional on Patient	4) Do you think that Option B+ is effective? <input type="checkbox"/> Yes <input type="checkbox"/> No

Adaptability of Programme Personal Perception vs. Professional Training	Why? Do you think the programme is sustainable/scalable?
Determine to what extent medication adherence is enhanced by this new policy for a greater number of HIV infected women: Changes in Adherence Level Guidelines Impacting Adherence Trust in Patients Adherence Finding Adherence Declines- Miscommunication: Adhering for Herself AND the Baby	5) How are you finding your patients medication adherence? Is it increasing or decreasing in general? Are they missing dosages more frequently? Please tell me more about why you think that? What are some of the reasons you think adherence declines after these pregnant women give birth?
Stock-Outs and Limited Resources Understanding or Awareness of Stock-Outs on Different Healthcare Professional Levels Adopting New Guidelines in Work Environment	6) How would you rate your medication supply here at your facilities on a scale of 1-10 (10 being the highest) 1 2 3 4 5 6 7 8 9 10 Why this rating? Do you think medication supply for ARVs for the Option B+ programme is a burden to the hospital's budget? Why or why not? Do many patients utilize medical aid?
Identifying Barriers for their Patients in Implementation of Option B+ PMTCT programme	7) What are some challenges that you are finding that your patients face with this new programme option/policy? How is it impacting their ability to comply with medication (i.e. accessibility, transportation, time, missed

	<p>work)</p> <p>Are there any other challenges, maybe patients voice complaints on getting to the facility etc?</p>
<p>Ability to Sympathize with Patient</p> <p>Habitual Patterns #years of experience influence how they deal with their patients?</p>	<p>8) What do you do when you find out a patient is HIV-positive? How did you feel when you tell your patient that she would have to take this medication/treatment for life?</p> <p><input type="checkbox"/> Depressed, sad <input type="checkbox"/> Not sad or depressed.</p> <p>If no, please tell me more.</p>
<p>Compassion of Healthcare Professional</p>	<p>How do you feel when you have to tell her she is going on it for life?</p>
<p>Media Influence</p> <p>Healthcare Professional Up-to-Date with Option B+</p>	<p>9) Do you think that treatment action campaigns (TACs) are working? What are some issues that you have found with the education component of the Option B+ PMTCT programme?</p>
<p>Assessment of the Current Policies and Processes in RMMCH</p> <p>Barriers in Communication</p> <p>Educational Barriers Executed in an Appropriate Manner</p>	<p>10) If your patient has questions, do you think they feel comfortable enough to come to you for follow up or more information? If so, how do you ensure they feel comfortable? Does language pose a barrier at times, how do you overcome this?</p> <p>Are you finding any issues with the educational component of Option B+ PMTCT programme?</p>

Privacy Respect for the Patient Personal Opinions on Alternative Practices and Ability to Manage Role as Healthcare Professional	11) What initiatives do you take to make sure you are providing your patient with the best possible care? (stigma, respect individual privacy...) What do you do if your patient prefers alternative medicine practices (i.e. traditional medicine) instead of ARVs? How do you involve the patient in decision making around alternative treatment options?
Healthcare Professional Opinion Understanding of Patients Perspective	12) Do you think/feel that your patients have a choice with this programme? Why or why not?

END

Appendix L. Patient's Information Booklet and Fact Sheet

This research was
conducted in partnership
with



Inspiring Innovation and Discovery

Rahima Moosa Mother
& Child Hospital

Oudtshoorn St.
Johannesburg, SA 2093
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<http://www.esru.co.za/>

Evaluation of the
new 2015
Guidelines for
Pregnant Mother-
to-Child
Transmission
program for HIV
infected women
at hospital facilities

Case Study at the
Rahima Moosa Mother &
Child Hospital.

INFORMATION BOOKLET

LET'S HELP EACH OTHER LIVE



WHAT IS NEW 2015 GUIDELINES?

The new 2015 guidelines PMTCT program aims to reduce HIV transmission amongst pregnant women to child and keep mothers alive and healthy. This program also known as the Option B+ strategy involves the use of ARVs throughout pregnancy and for life, thereafter for all women.



HOW DOES THIS POLICY IMPACT RAHIMA MOOSA HOSPITAL?

Rahima Moosa Mother and Child Hospital (RMMCH) is a healthcare facility in Johannesburg, South Africa that is currently working towards implementing these guidelines and adapting policies and procedures to help mothers and children at the hospital and increase adherence in taking antiretroviral medication.



SPECIAL THANKS TO THE PARTICIPANTS



A special thank you to the study participants for taking the time out of their busy days and participating in this research study. Your voices are a huge contribution in understanding how to serve you better here at Rahima Moosa Mother and Child Hospital. Your opinions matter.

QUESTIONS?

To receive more information about the study or about Option B+ PMTCT program at Rahima Moosa Mother & Child Hospital.

Contact:

ANTENATAL CLINIC
&

EMPILWENI SERVICES AND RESEARCH
UNIT (ESRU)
BLOCK B
FIRST FLOOR

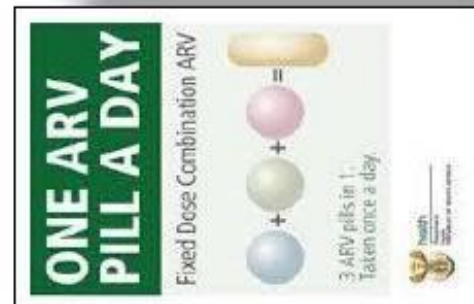
MELANIE BISNAUTH
LESLIE ROSE
ASHRAF COOVADIA

ABOUT THE STUDY

In May 2015, 55 pregnant HIV-positive women from the antenatal clinic (ANC), maternity and postnatal wards and 12 healthcare professionals at the hospital were interviewed, in order to investigate:

RESEARCH QUESTIONS

- What do pregnant women think about going on ARVs for life?
- What factors may act as barriers to pregnant women taking the new drug regimen in South Africa?



Currently in its implementation phase, Rahima Moosa Mother & Child Hospital served as a case study.

There is little evidence when it comes to evaluating whether this policy is adaptable due to differences in resources and access to care for pregnant women in Johannesburg.

WORLD HEALTH ORGANIZATIONS' (WHO) POLICY

In 2013, new consolidated guidelines for treating and preventing HIV from WHO included recommendations for the prevention of mother-to-child transmission (PMTCT).



WHY ASK PREGNANT WOMEN LIKE YOURSELF?

Pregnant women's attitudes towards the policy will be beneficial for healthcare workers to understand what factors may act as barriers to adherence and better inform how to integrate the new guidelines at Rahima Moosa Mother & Child Hospital.



WHAT DO PREGNANT WOMEN THINK ABOUT GOING ON ARVS FOR LIFE?

The study findings suggested:

- It is difficult at first to take the one pill a day
- Insufficient time to absorb the shock of finding out she is HIV-positive and has to start lifelong treatment immediately
- To swallow one big pill that cannot be broken up was difficult in the first two weeks of starting antiretroviral treatment or switching to Option B+
- Easier to manage one pill a day, not as many missed dosages
- Reduces stigma by taking one pill
- Feel better on the one pill a day after first have weak

SO WHY DO PREGNANT WOMEN CHOOSE OPTION B+?

"I take the ARVs to protect my baby and to live a healthier life..."

-Study Participant
Mother of two children,
26 years old

The number one reason when pregnant women were asked why they choose to take the one pill a day for life is to protect the health of the baby.

WHAT ARE THE BIGGEST CHALLENGES PREGNANT WOMEN FACE TAKING THE NEW DRUG REGIMEN?

The study findings suggested:

- It is difficult at first to take the one pill a day because of experiencing side effects (i.e. nausea, dizziness, vomiting, tiredness)
- Balancing daily duties of being a mother, wife, etc
- Many women work but have to take time off to make appointments at the hospital and have a hard time with managers
- Lack of income which makes it difficult to travel to the hospital
- Feel the need for more education to understand why they take it

DO IT FOR YOU AND THE BABY

Many pregnant women feel that the one pill a day should only be taken up until birth of the baby and then **STOP** treatment after giving birth. This is a **RISK** for both the mother and child.



Patient Guideline

WHAT CAN YOU DO TO HELP YOURSELF?

Here are a few topics that were talked about with pregnant women, like you.



EDUCATION

- Participate in sessions that sisters give in the antenatal clinic
- Feel free to ask questions in private after sessions, we are happy to help



BREASTFEEDING

- Ask about breastfeeding your baby and learn what is good about it
- Make sure you are always on ARV treatment when breastfeeding



FAMILY PLANNING

- Ask your healthcare professional about family planning methods
- Child spacing is important for both mother & child's health



RESPONSIBILITY

- Ask if you are not sure what the healthcare worker tells you
- Follow-up is IMPORTANT, come to appointments, testing, and get your medication supply



SAFE SEX

- Safe sex practices are lower risk of HIV transmission
- Find out more about condom use and safe practices from a healthcare worker



OPEN COMMUNICATION

- To help serve you better, tell the healthcare worker about your worries and questions
- Pregnant women feel comfortable to speak to the healthcare workers, you should too



TRADITIONAL MEDICINE

- If you are using traditional practices, please inform your healthcare worker to reduce risk to your health and the baby

Appendix M. Workforce Demographic Data of Study Sample

Table 1.0

Healthcare Professionals: Age in Years

Healthcare Professional	Age of Participant (# of years)	Mean-Age in Profession (# of years)
Nurse (n=5)	64 60 49 48 35	51.2
Pediatrician (n=3)	41 41 39	40.3
OBGYN (n=2)	50 37	43.5
Neonatologist (n=1)	35	35
Executive Manager (n=1)	49	49
TOTAL (n=12)	548	45.6

Table 2.0

Healthcare Professionals: Number of Years at their Current Occupation

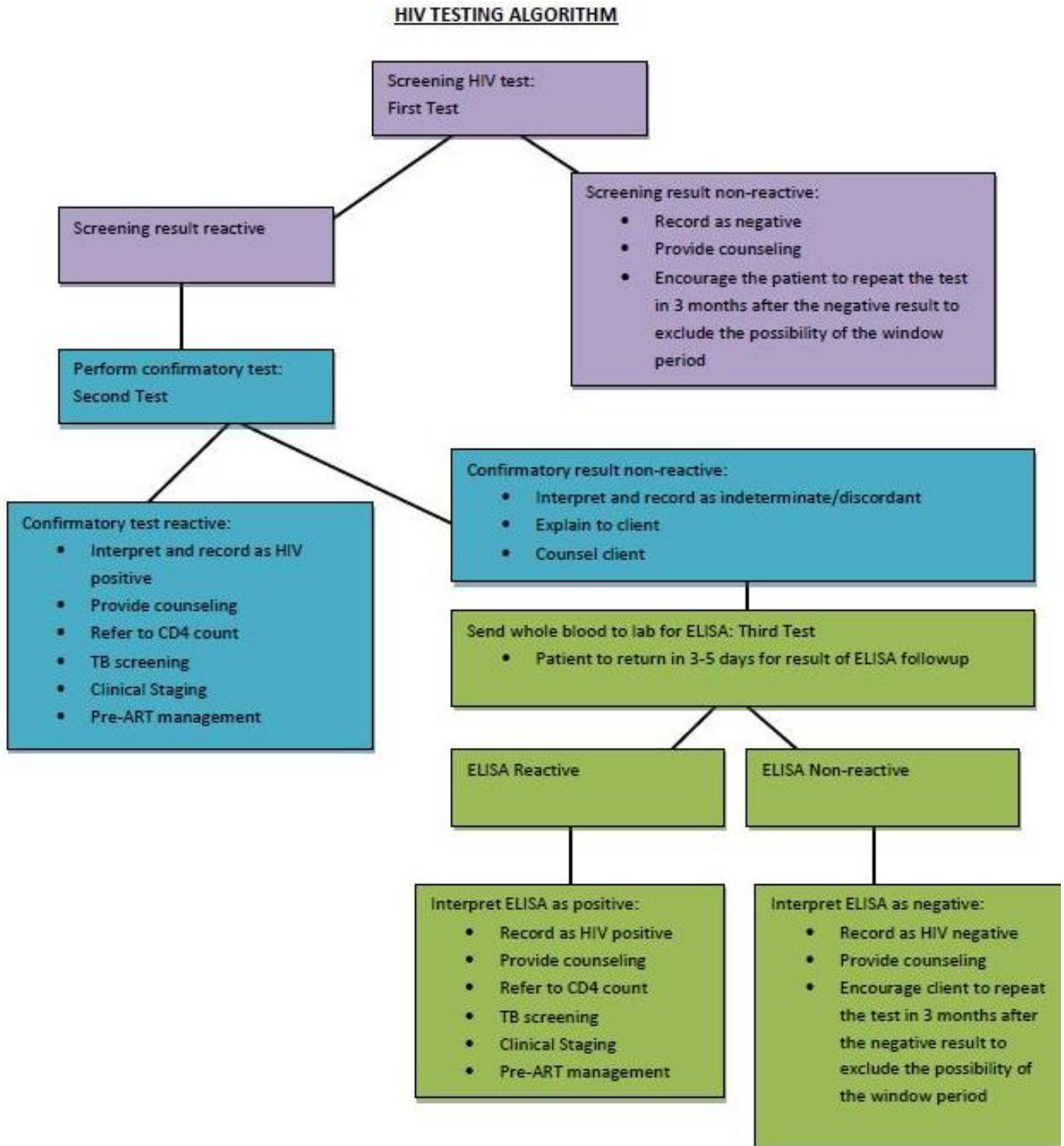
Healthcare Professional	Occupation Experience (# of years)	Mean-Experience in Profession (# of years)
Nurse (n=5)	30 31 3 24 17	21
Pediatrician (n=3)	11 9 10	10
OBGYN (n=2)	6 6	6
Neonatologist (n=1)	7	7
Executive Manager (n=1)	8	8
TOTAL (n=12)	162	13.5

Table 3.0

Healthcare Professionals: Gender

Healthcare Professional	Female n (%)	Male n (%)	Total
Nurse	5 (100.0)	0 (0.00)	5 (100.0)
Pediatrician	1 (33.3)	2 (66.6)	3 (100.0)
OBGYN	1 (50.0)	1 (50.0)	2 (100.0)
Neonatologist	1 (100.0)	0 (0.00)	1 (100.0)
Executive Manager	1 (100.0)	0 (0.00)	1 (100.0)
Total	9 (75.00)	3 (25.00)	12 (100.0)

Appendix N. Antenatal Clinic: HIV Testing Algorithm



GLOSSARY OF TERMS

Definition of Key Terms

Term	Working definition in this thesis research
Infant	Child younger than one year of age
Child	10 years of age and younger
Adolescent	Aged 10 to 15 years of age
Adult	19 to 49 years of age
ART	Antiretroviral therapy refers to the use of combination of three or more ARV drugs or the one pill regimen of FDC to achieve viral suppression and is usually given for life
ARV	Antiretroviral drugs refer to the medicines themselves and not their use
Birth HIV PCR testing	HIV PCR testing at birth for all HIV exposed neonates
CICT	Client initiated counseling and testing; testing process initiated by an individual who wants to learn his/her HIV status
Community Health Workers	Health workers who received standardized training outside a medical curriculum
Continuum of care	Concept of an integrated system of care that guides and tracks patients over time, through a comprehensive array of health services spanning from screening for HIV, to diagnosis and management of HIV, to initiation onto ART, retention in care and psychosocial support and counseling services
Couple	Two people in an ongoing sexual relationship
Eligible for ART	Refers to patients living with HIV for whom ART is indicated
Healthcare provider	Anyone who renders healthcare; includes doctors, physicians, sisters/nurses, counselors
HIV-exposed infant	Infant born to a woman who is HIV-positive or who becomes HIV-positive anytime during pregnancy, labour, delivery or breastfeeding. The infant is at risk of acquiring HIV infection from the mother. The infant/child may test HIV-positive on antibody testing, reflecting the mother's

HIV symptomatic infant	antibodies. Any HIV-exposed infant displaying failure to thrive, haematological abnormality such as anaemia or thrombocytopenia, congenital pneumonia, pneumonia, hepatosplenomegaly, extensive oral candidiasis, significant lymphadenopathy and any opportunistic infections
Key populations	Both vulnerable and most-at-risk populations
PICT	HIV testing and counseling recommended by healthcare provider in a clinical setting
Sero-discordance	Sexual partners where one partner is living with HIV and the other is HIV-negative
Treatment failure/Virological failure	Treatment failure in adults such as pregnant women and children, including infants, is defined by a persistently detectable viral load exceeding 1000 copies/ml (that is, 2 consecutive viral load measurements within a 2-month interval, with adherence support between measurements) after at least six months of using ARV drugs
Viral suppression	Refers to the aim of ART to maintain viral load below detectable levels of available assays (<50 copies/mL)