

# THE UNIVERSITY OF ZAMBIA SCHOOL OF MEDICINE DEPARTMENT OF PUBLIC HEALTH MASTERS OF PUBLIC HEALTH - POPULATION STUDIES DISSERTATION

# Effectiveness of Option B+ towards elimination of mother to child transmission of HIV: A Retrospective Cohort Study of Selected Facilities in Lusaka, Zambia

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#### ABSTRACT

Most countries in sub-Saharan Africa are encouraged to adopt WHO recommended Option  $B^+$ , but there is a general fear that the evidence for its effectiveness has not been demonstrated in different settings. Option  $B^+$  is an intervention that ensures administering of life-long HIV treatment to HIV infected pregnant women regardless of their CD4 count. Zambia for example, still has a generalized HIV epidemic and thus programs that focus on reducing mother to child transmission of HIV ought to have clear evidence of the effectiveness of new interventions so as to correctly focus interventions.

The main objective of the study was to compare the number of HIV infant infections between options A, B and B+ cohorts at six (6) weeks in selected facilities of Lusaka district in Zambia.

Using a retrospective cohort research design, clinical records of HIV+ positive women and their infants drawn from 6 public health facilities of Lusaka were analyzed. A two-step analysis was used. The first step involved a bi-variate analysis in order to generate the average percentages of children who tested positive at 6 weeks with the help of the mother's background characteristic. In addition the relationship between attrition and PMTCT options (Options A, B and B+) was analyzed. The second approach, logistic and multinomial regression were used to measure the effect of independent variables on the dependent variable of positivity of children at 6 weeks.

The study findings showed that both options A and B+ recorded 6% infant infections whereas option B at 13%, recorded the most infections. In assessing attrition levels, Option A recorded the least deaths at 21% compared to 39% in option B and 37% in option B+. Option B+ recorded 39.6% transfer outs compared to 24.7% in option B and 30.9% in option A.

Antiretroviral treatment (ART) and other effective interventions for the prevention of mother-tochild transmission (PMTCT) can reduce this risk to below 5% (WHO, 2014). Therefore, option B+ results from the study at 6% infant infections show that the initiative has potential of reducing the HIV burden in Zambia and thereby contributing favorably to the HIV free generation dream. Support activities that ensure less attrition are critical in ensuring successful implementation of prevention interventions so as to reduce transmission of HIV in the target population.

# DECLARATION

I hereby declare that this research report has not been submitted for a Degree in this or any other
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# DEDICATION

I dedicate this research to my loving wife, Monde Sasa Hanunka and to our lovely Children Lumba and Tumelo Hanunka. Their perseverance, love and prayers have made me accomplish this work.

# APPROVAL

This dissertation is approved in partial fulfillment of requirements for the award of a Masters of Public Health by the University of Zambia.

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# **ABBREVIATIONS**

AIDS	Acquired Immune Deficiency Syndrome
ANC	Antenatal Care
ART	Antiretroviral Therapy
ARV	Antiretroviral
CDC	Centers for Disease Control and Prevention
DBS	Dried Blood Spot
DHS	Demographic and Health Surveys
EID	Early Infant Diagnosis
EMTCT	Elimination of mother-to-child transmission (of HIV)
HEI	HIV-exposed infant
HIV	Human immunodeficiency virus
IATT	Interagency Task Team
M&E	Monitoring and Evaluation
PEPFAR	United States President's Emergency Plan for AIDS Relief
РМТСТ	Prevention of mother-to-child transmission of HIV
UNAIDS	Joint United Nations Program on HIV/AIDS
UNICEF	United Nations Children's Fund
WHO	World Health Organization
MTCT	Mother to Child Transmission

# **OPERATIONAL DEFINITIONS**

# **Option A**

Under option A, long life anti-retro therapy (ART) provided when CD4 count is  $\leq$ 350 or WHO stage 3 or 4. In cases where CD4 >350, and WHO stages 1 and 2, antenatal and intrapartum prophylaxis (AZT, NVP, TDF/FTC) provided and this would be extended to infants using NVP syrup for breast feeding infants.

# **Option B**

Under option B, all HIV-infected pregnant women to be initiated on ART regardless of CD4 count. Those with CD4  $\leq$ 350, or WHO stage 3 or 4, would be initiated on life-long ART and those with CD4 >350 and WHO stages 1 and 2 to stop ART after delivery if not breast feeding, or after cessation of breast feeding.

# **Option B+**

Option B+ implies administering of life-long ART for all HIV infected pregnant women regardless of CD4 count

#### **CHAPTER ONE**

#### **1.0 INTRODUCTION**

The AIDS epidemic is one of the most destructive epidemics that the world has ever witnessed (WHO, 2009). Globally, it is estimated that 35.3 million adults and 3.2 million children under the age of 15 years were diagnosed and living with HIV in 2012 (WHO, 2009). The major contributor to these numbers is Sub-Saharan Africa and Zambia belongs to this region. With the HIV prevalence rising among adolescents and youth, there is a corresponding increase in the number of children under 5 years of age infected with HIV (WHO, 2013). Mother-to-child transmission (MTCT) of HIV accounts for over 90% of these cases. The risk of HIV transmission from mother to child, without preventive interventions, ranges from 15% to 40% (WHO, 2013).

One of the solutions to bringing about "zero new infections" of HIV is ensuring that children born from HIV infected mothers are born free of the virus. Therefore, it is important to research on the infant HIV infections in a prevention of mother to child transmission (PMTCT) setting so as to evaluate the contribution of initiatives such as options B+ that aim at saving lives. Option B+ is an intervention that ensures administering of life-long HIV treatment to HIV infected pregnant women regardless of their CD4 count.

In order to give meaningful credibility to option B+, there is need to conduct more studies in different epidemiological settings such as that of a generalized epidemic in Zambia. This is because, interventions may be perceived to be effective because of other confounding factors such as prudent management, infrastructure and a well-coordinated supply chain system of commodities and reagents. In other circumstances, some countries with very poor systems may not realize the desired outcomes of Option B+ due to difficulties with implementation.

Despite evidence that the rate of increase in new HIV infections in Zambia is declining, HIV continues to pose a serious threat to the health of many Zambians. The transmission of HIV from a HIV infected mother to her child during pregnancy, delivery or breastfeeding is one of the key drivers of the AIDS epidemic in Zambia (ZAMBIA, 2012). Some of the successes recorded in Zambia thus far are:

• The proportion of pregnant women receiving prophylaxis to prevent HIV transmission to infants increased from 61.9% in 2008 to 84.5% in 2011 (ZAMBIA, 2012)

• The risk of children acquiring HIV infection from their mothers in Zambia has reduced from 30% - 45% before the era of antiretroviral treatment (ARV) to 22% in 2010 and 9% in 2011 at age 6 weeks. However, infants can still acquire HIV infection during the rest of the breastfeeding period, which implies that the actual risk is higher than, for example, the 9% reduction in 2011 (ZAMBIA, 2012).

In exploring the performance of the option B+ initiative in comparison with the previous interventions, there is a great opportunity to review and strengthen current and future programs. Clear understanding of both infant and maternal outcomes is helpful to ensure the realization of an AIDS free generation. In PMTCT, the major goal is to ensure that children born from HIV+ mothers are free of infections. Success of PMTCT programs is measured by exploring the rate of infant survival owing to being born without infection.

#### **1.1 Problem statement**

Most countries in sub-Saharan Africa have been advised to adopt WHO recommended Option B+, but there is a general fear that the evidence for its effectiveness has not been demonstrated in different settings. The main argument is that on the basis of implementation evidence and the high fertility rates in Zambia, long duration of breastfeeding, and limited capacity in laboratory services, Option B+ may be the best possible initiative. Further, the other initiatives (Option A and Option B) require functional and efficient laboratory services for CD4 count testing, and these are not universally available in Zambia and in fact most other countries in Africa (Chi et al., 2012). The predicament that exists at present is for countries to shift to this new initiative without much implementation evidence or continue with the choice of an impractical policy and accept low coverage of services. It is important to note that Zambia commenced with the roll out of Option B+ in late 2013 even with very little internal evidence. This study added value to the body of knowledge on PMTCT in general even as the world considers "zero HIV new infections".

#### **1.2 Rationale**

A study on real results obtained from the highly publicized option B+ initiative in comparison with the previous method of delivery in a prevention of mother to child transmission (PMTCT) setting was of supreme value in understanding lessons learnt. This study therefore contributed positively in obtaining Zambia specific comparisons on the old and new initiatives in PMTCT. The results from the study made it possible to judge whether the switch to option B+ brought better outcomes in reducing mother to child transmission of HIV/AIDS.

# **1.3 Research questions**

- 1. Does Options A, B, and B+ have similar protective benefits with respect to prevention of HIV transmission from mother to child?
- 2. Is option B+ the best choice?
- 3. Is attrition a contributing factor to the effectiveness of option A, B and B+?

# **1.4 Hypothesis**

The Null hypothesis stated that HIV positive pregnant women enrolled under the option B+ era were more likely to give birth to infants infected with HIV. The alternative hypothesis stated that HIV positive pregnant women enrolled in the option B+ era would have a much improved chance of delivering HIV-free infants.

# 1.5 Main Objective

The main objective of the study was to compare the number of HIV infant infections between options A, B and B+ cohorts at six (6) weeks in selected facilities of Lusaka District in Zambia.

# **1.5.1 Specific Objectives**

The following were the specific study objectives:

- To compare the number of infant infections between options A, B and B+ cohorts at six
   (6) weeks
- 2. To compare attrition at 3 months among HIV+ pregnant women in options A, B and B+.

#### **CHAPTER TWO**

#### 2.0 LITERATURE REVIEW

There is a lot of developing research and theories on the prevention of HIV and the numerous methods that can be employed to being about epidemic control. According to Jessica (2013), the Zambian Minister of Health, Dr. Joseph Kasonde, on January 14, 2013, authorized the immediate operationalization of Option B+ to provide free life-long ART to all HIV infected pregnant women, regardless of their CD4 count. The news feature further said one in every eight pregnant women in Zambia is HIV positive and an estimated 26 infants are infected with HIV every day. The expectation was that the simplifying of PMTCT regimens for HIV positive pregnant women would result in reducing the number of new pediatric HIV infections, improving maternal health and survival rates, and reducing HIV transmission to uninfected partners.

#### 2.1 Effectiveness of Option B+

As part of Option B+, all infants born to HIV infected mothers would receive ARV prophylaxis for a period of six weeks regardless of breastfeeding practice (Schouten et al. 2013). For quality purposes and tracking, free life-long tests such as CD4 count, chemistry, syphilis, viral load and early infant diagnosis will be performed to monitor patients. Further, the provision of lifelong ART to pregnant women living with HIV would have to be implemented at a high cost at the onset, but estimated savings of \$38 million will be generated by 2025 from the 18,000 pediatric HIV infections that will be averted (Paranjape and Franz, 2015).

About 57% of pregnant women living with HIV in low and middle income countries received effective antiretroviral drugs for prevention of mother to child transmission (PMTCT), a substantial increase from 48% in 2010. The report also highlighted the implementation challenges among them the high proportions of women and children in need of antiretroviral therapy (ART). The report further indicated that global access to ART among HIV positive pregnant women in need was basically yielding lower results of 30% compared to the previous years.(Kurth et al. 2011)

Malawi envisioned that Option B+ would be easier to implement due to its simple "one size fits all" approach which would enable women to access ART at high levels even in settings with

poor access to CD4 testing (Njunga and Blystad, 2010). The early experience with Option B+ in Malawi has borne this out with a more than five-fold increase in the numbers of pregnant women being enrolled on ART in only the first quarter of full nationwide implementation.(Coutsoudis et al. 2013)

With regards implementation of option A, there exists numerous challenges such as the requirement of drug changes across the continuum of care (antenatal, delivery and postpartum care). It also cardinal to take into consideration the long period of AZT monotherapy in option A, which has potential to being about thymidine analogue (TAM) mutations.(Besada et al. 2012). There is further argument on how options A complicates clinical management and possess delays in treatment initiation especially in settings where access to CD4 count measurement is not readily available. In the case of South Africa, and other sub Saharan Countries, effective service provision is hampered by congested health facilities and a general lack of human resources. The discourse in favor of options B and B+ continues in that it reduces the burden on healthcare workers because it provides the opportunity for the same first-line regimen for all adults including pregnant women (Besada et al. 2012).

It is important that people working in the field of HIV contribute to the current discourse on whether the introduction of long-life antiretroviral therapy (ART) for all HIV pregnant women regardless of the CD4 count (Option B+) should be adopted as the best practice in realizing an AIDS free generation (Ahmed et al. 2013).

Despite availability of arguments that sound credible, there lacks sufficient evidence to aid the prudent decision making process on both the pros and cons of option B+. This implies that with little evidence of benefits and potential risks of the B+ approach, distinguishing individual health concerns for mother and their children may be over looked.

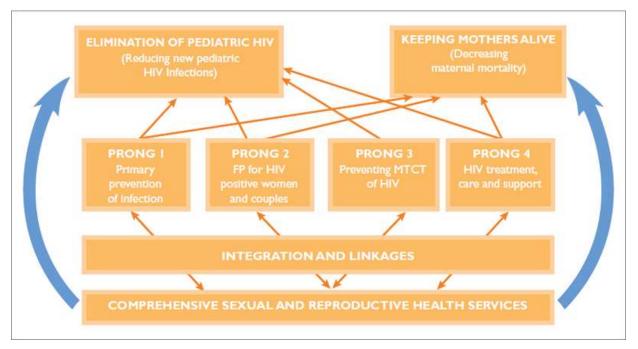
Adopting Option B+ in this setting would result in a 5-fold increase in the number of HIVinfected pregnant women being placed on lifelong triple ART (Takow et al. 2015).

#### 2.2 Cost effectiveness of option B+

According to the business case for an improved elimination of mother to child transmission (eMTCT) protocol in Zambia (2012), the initial cost of providing eMTCT through Option B+ compared to the current Option A was expected to rise from \$50 million (option A and B) to

\$70 million (option B+) during the three year period from 2013 to 2015. This substantial increase in the cost requires an adequate follow up of the benefits that would be accrued owing to the immense investment. The increase would be owing to the increase in drugs, members of staff as well as infrastructure required to effectively manage the program. The research gap that may exist especially in understanding adherence as well as monitoring the increase in the general

# **2.3 Conceptual Frameworks**



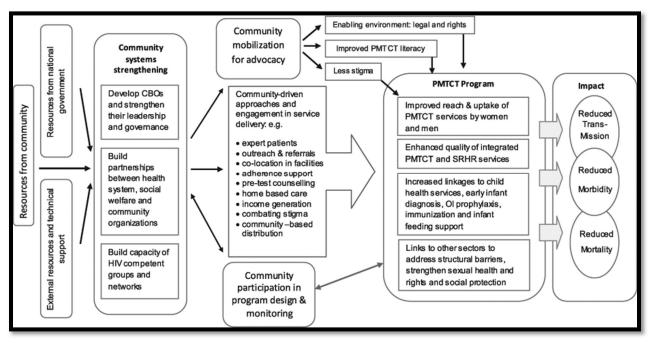
#### Figure 1: The Integration and Linkages program model

#### Source: United Nations, 2012

The above framework is a program model developed by the United Nations (U.N) in 2001. In the context of this research, the four strategies in the framework above ought to be met to ensure effective implementation of a PMTCT strategy. There is, therefore, need to assess the quality of a program so as to understand attrition (LTFU) rates that are important in ensuring completion of intervention and thus success of the program. Each of the four "prongs" represents a stage at which program services work to:

- Prevent HIV in women of reproductive age
- Prevent unintended pregnancy in women with HIV
- Prevent HIV transmission from mother to child, and

• Provide ongoing care and support to mothers, their children, and families.



# Figure 2: Link between community and socio-economic factors that contribute to PMTCT

# Source: AIDS STAR, 2012

The above framework aids the study in fully understanding the link between community and socio-economic factors that contribute to the prevention of mother-to-child transmission of HIV (PMTCT). The challenge in most parts of sub-Saharan Africa is the low coverage of PMTCT service, leading to unacceptably high rates of morbidity among mothers and new infections among infants. Other than coverage, tracking of default clients and adherence to life saving medication remains another enormous challenge in fighting transmission to infants (Regass, 2012).

ART uptake resulting from the introduction of option B+ requires to be filled. Routine reviews of monitoring data at a PMTCT setting is of supreme value in informing stakeholders and policy makers on the effectiveness of the initiative.

The other school of thought supports the foregoing idea above that despite the spike in budget requirements at the onset, over 18,000 lives would be saved by the year 2015. This will in-turn bring about a huge saving owing to more infant infections averted through simplifying operations and fewer males expected to become infected with HIV because of the viral load suppression of a triple-combination ARV regimen (Ishikawa et al. 2014). The general

expectation is that option B+ would ensure women initiate their own treatment earlier, improving their health outcomes, and averting their in-patient hospital costs, and other expenses such as drugs for opportunistic infections.

In further arguing for the new initiative other writers indicate that infant HIV infections under Option A were expected to be around 390,000 by the year 2025, whereas under Option B+ would bring about a reduction to 290,000. This represents a reduction of 100,000 infant infections averted as a result of option B+ (Ishikawa et al. 2014).

Women who are on Option B+ are expected to have less opportunistic infections and have an increased life expectancy compared to Option A, leading to dramatically improved maternal and infant health outcomes, higher economic productivity and fewer orphans. In addition, male HIV infections are expected to be significantly lower in Option B+ compared to Option A. Further modeling is required to estimate the potential male infections averted (VanDeusen et al. 2015).

The Zambian government is committed to treating HIV positive patients and announced that the budget for ARVs in 2013 was to triple to a total of \$35 million (Resch et al. 2015).

#### 2.4 Global commitment in eliminating new HIV infections

There is considerable interest and commitment globally to eliminating new pediatric HIV infections by 2015 and thereby improving maternal, newborn, and child health and survival in the context of HIV (Paredes et al. 2013). This requires not only international donor interest, but host government commitment of resources and planning so that ambitious objectives involved in preventing of mother-to-child transmission (pMTCT) can be attained. One school of thought further highlights the importance of planning because there exists enormous obstacles such as low rates of adherence to ART which may hinder reaching desired outcomes reducing transmission.(Paredes et al. 2013)

Globally, WHO highlights the limited experience available at present in handling and managing implementation of option B+. This possess questions on the pace at which implementation of this initiative should be accelerating considering the need for more research and adoption of best

practices. The need for close monitoring of the implementation of Option B+ to rapidly identify implementation issues was emphasized by WHO and others(Kieffer et al. 2014).

In the case of countries such as Tanzania, there are more than 90% health facilities providing PMTCT services, with about 230,000 children below the age of 15 years living with HIV in the year 2012. The country records an estimate of 43,000 new pediatric infections per year.(Ngarina et al. 2014). Such a scenario therefore, requires prudent case management programs and adequate resources that can aid achievement of goals and objectives. Further, the estimated fertility rate in Tanzania is among the highest in the world, (5.7), and with about 119,000 HIV-positive women giving birth every year (Ngarina et al. 2014).

#### **CHAPTER THREE**

# **3.0 METHODOLOGY**

# 3.1 Study setting

The study was conducted in predominantly low-income, high-density urban clinics' setting of Lusaka, Zambia. The setting of Lusaka comprises multilingual ethnic groups, with *Bemba* and *Nyanja* being the most widely spoken local languages. The socio-economic status and housing conditions of the residents are mixed, but predominantly poor. The majority of the residents are either in the informal sector of the economy or in lowly paid jobs of the public and private sectors. A lot more other people are not in any form of employment (Musheke et al. 2012).



#### Figure 3: Map of Lusaka District

# **3.2 Study Population**

The study targeted HIV+ pregnant women who live in Lusaka district who were enrolled on either option A or B in the period 1<sup>st</sup> January, 2012 to 31<sup>st</sup> December, 2012. The other target cohort included HIV+ pregnant women, who were enrolled on option B+ during the period 1<sup>st</sup> January 2014 to 31<sup>st</sup> December, 2014. Live infants born from HIV+ pregnant women from the selected cohorts were also included in the study.

# 3.2.1 Inclusion criteria

- HIV positive pregnant women were included in the option A and B cohorts if they started on ART within 1<sup>st</sup> January 2012 to 31 December 2012, per guidelines applicable at that time, which included initiation at CD4 count < 350 cells/mm3 or a World Health Organization (WHO) stage 3 or 4 clinical condition
- HIV positive pregnant women were included in the Option B+ cohort if they started ART after the implementation of the new Option B+ treatment guidelines, regardless of CD4 count or clinical stage (1<sup>st</sup> January 2014 to 31<sup>st</sup> December 2014)
- For Options A,B and B+ cohorts, pregnant women were included if they had transferred into the clinic and met the inclusion criteria, regardless of where they were initiated on ART
- The infants of HIV positive mothers tested at six weeks and received their results, were also included in the study.

# 3.2.2 Exclusion criteria

- HIV positive pregnant women not commenced on option B+ during the new implementation phase
- Women who has a CD4 count ≥ 350 cells/mm3 received single or dual short course antiretroviral for PMTCT were excluded from this cohort

# 3.3 Study Design

A retrospective cohort study was adopted. A retrospective cohort study, also called a historic cohort study, generally means to take a look back at events that already have taken

place. For example, the term is used in medicine, describing a look back at a patient's medical history or lifestyle. Routinely collected health facility cohort reports and medical records that are validated quarterly were used to review rate of HIV infant infection from HIV+ positive mothers at 6 weeks among three options in PMTCT, (Options A, B and B+). Data collection focused on the periods 1<sup>st</sup> January 2012 to 31 December 2012 for either the option A or B cohorts and 1<sup>st</sup> January 2014 to 31<sup>st</sup> December 2014 for the option B+ cohort. Attrition, (LTFU) was defined as HIV positive pregnant women who upon initiation on long-life ART or short term regimens did not return for continued services for over a period of three (3) months or 90 days.

#### 3.4 Sampling

#### 3.4.1 Sampling method

A frame/list of the entire population of pregnant women in the clinical catchment areas was subsequently narrowed down to those that were HIV positive. A one-to-one comparison was attained by selecting the same number of infant-mother pairs from the two cohorts. Drawing from a total number of 23 government owned health facilities that reported their PMTCT 2014 annual program results (APR) to PEPFAR Zambia, five health facilities which implemented prior to the commencement of option B+ and started the new initiative were selected using systematic sampling. Systematic random sampling is a type of probability sampling technique. With the systematic random sample, there is an equal chance (probability) of selecting each unit from within the population when creating the sample.

#### **3.4.2** Sample size and selection procedure

A two-stage sample design was adopted where the first stage health facilities were selected from a frame of 23 facilities. At the second stage persons/medical records were selected from each of the selected Health facility.

In this regard, sampling started by selecting an element (health facility) from the list at random from the health facility. The random start was the number randomly selected between 1 and k thereafter every *kth* element in the frame was selected until the required sample size was reached, where k, is the sampling interval: This was calculated as k=N/n; where n is the sample size, and N is the population size. Therefore, with 23 facilities k was every 5<sup>th</sup> healthy facility until a

sample size of 6 was reached. The selected health facilities were **Bauleni**, **Chelstone**, **Kabwata**, **Mandevu**, **Matero Reference** and **Kanyama**.

The formula used for calculating the sample size of individual medical records is shown below:

Where:
n= sample size
z= standard score
ME= Margin of error
P= proportion of sample elements that have a particular attribute.
q= proportion of sample elements that do not have a particular attribute, so $q = 1 - p$ .
N=Total population

$$\mathbf{n} = [(\mathbf{z}^2 * \mathbf{p} * \mathbf{q}) + \mathbf{M}\mathbf{E}^2] / [\mathbf{M}\mathbf{E}^2 + \mathbf{z}^2 * \mathbf{p} * \mathbf{q} / \mathbf{N}]$$

The margin of error plus or minus 4% or 0.04, the confidence level 95% or 0.95, at alpha = 1 - 0.95 = 0.05, at standard score (Z) of 1.96, p set at 0.5, q set at 0.5 and Population estimate at 6836 (Total from all PMTCT facilities in Lusaka district). Using the above formula, the sample size was 553 HIV-positive pregnant women. Taking into consideration, the possibilities of not finding correct medical records at facilities, a success rate of 80% was anticipated, thus taking into account a non-response rate of 20%, the sample size was adjusted as follows 553/0.80=691. This sample size was considered adequate to yield reliable results. At the second stage the sample elements were allocated proportionately to health facilities. The first three (Chelstone, Mandevu and Kanyama) facilities with the highest number of HIV-positive pregnant women each contributed 25% to the sample size and the last three each contributed 8.3% respectively (Bauleni, Matero reference and Kabwata). The first three facilities each contributed 173 persons/records and the last three each contributed 86, bringing the total to 691. This represented

infant mother pairs of 691 cases (option B+) and 691 controls (options A and B) with the sole aim of ensuring a one to one comparison. It is important to note here that some of the facilities were over sampled to cover those that had very limited available records.

#### 3.4.3 Statistical Analysis

Data analysis was conducted using STATA version 12 (12.0 Copyright 1985-2011 StataCorp LP Statistics/Data Analysis, StataCorp, 4905 Lake ay Drive, College Station, Texas 77845 USA). The analysis was done at two steps. The first step involved a bi-variate analysis in order to generate the average percentages of children who tested positive at 6 weeks. In addition, the relationship between attrition and PMTCT options (Options A, B and B+) was analyzed. In addition, multivariate logistic regression was used to measure the effect of independent variables on the dependent variable of positivity of children at 6 weeks. The logistic model is as described by a logit function below:

$$Logit(y) = \beta 0 + \beta 1 X 1 + \beta 2 X 2 \dots \beta n X n$$

To estimate the probability of the child being infected or not the function is denoted as:

$$p(y=1) = \frac{\exp(\beta_0 + \beta_1 x_1 + \beta_2 x_2 \dots + \beta_n x_n)}{1 + \exp(\beta_0 + \beta_1 x_1 + \beta_2 x_2 \dots + \beta_n x_n)}$$

Where y= the dichotomous dependent variables called logit defined as:

a) 1=positive 0=Negative

The Intercept in the model is the value of (y) when the value of all independent variables is zero. Coefficients describe the size of the effect of independent variables to the dependent variable. The positive regression coefficient meant that the explanatory variable increased the probability of the outcome (y), whereas negative regression coefficient meant that the explanatory variable (x) decreased the probability of the outcome (y), big regression coefficient meant that the explanatory factor strongly influenced the chance of the outcome and near-zero or zero regression coefficient means that the explanatory factor had little or no influence on the probability of that outcome.

#### 3.5 Variables

Table	1:	Variables

NO	ТҮРЕ	VARIABLE	INDICATOR	MEASUREMENT
. 1	Dependent Variables	Infant HIV Status	Number of infants tested for HIV and received their results	Cumulative number of reported new HIV diagnoses minus deaths
2.	Independent Variables	Option (A, B, B+)	The PMTCT option administered to each respondent	
		Age	Age of respondents	Years
		Education	Education levels of respondents	
		Toxicity	Change in regimen due to toxicity	µg/g
		Attrition	Attrition levels for any reason	Months
		Marital status	The marital status of each respondent	
		Defaulted	Number who defaulted from care	Percentage
		Adherence	Number who show adherence in accordance to national guidelines	Percentage

We abstracted the following treatment variables one year after ART initiation for all women: 1) alive and on ART; 2) died for any reason; 3) defaulted (defined in the national guidelines as not seen in the ART clinic and off ART for more than 90 days, and not known to have died or transferred out); 4) Infants alive and their HIV status. Other treatment variables recorded included switching (one or more medication changes) of ART to another regimen due to toxicity.

# **3.6 Limitations**

The availability of complete records at the chosen sites was a major challenge which resulted in over sampling in those that represented better records so as to meet the desired sample size. The

sites sampled were all in the Lusaka district of Zambia and thus the results are not sufficient to generalize the outcomes as a true picture of the country wide situation.

# **3.7 Ethical Considerations**

The protocol was reviewed by the University of Zambia Biomedical Research and Ethics Committee (UNZABREC) and permission to undertake the study was granted. Permission was also sought from the Ministry of Health as well as the Lusaka district medical office. To ensure confidentiality, medical records were reviewed at the sites without moving them to other locations. Names and other personal identifiable information were not collected during the study. This study will help in adding value to the limited body of knowledge on Option B+ in Zambia and will thus help in ensuring evidence based decision making that save lives.

#### **CHAPTER FOUR**

#### 4.0 RESULTS

The objectives of the study were to compare the number of infant infections between options A, B and B+ cohorts at six (6) weeks and an analysis of the attrition levels at 3 months among HIV+ pregnant women in options A, B and B+. The results of the study aimed at responding to both the research questions and the set objectives. Being a retrospective cohort study, the three PMTCT option results would help in ensuring meaningful responses to the research questions and the objectives.

#### 4.1 Description of the study population

This section presents the age distribution of the mothers involved in the study as well as analyzing the baby mother pair positivity by age category. In understanding the determinants and distribution of disease, basic epidemiology demands that we understand the age distribution and the influence it has on disease. Such knowledge of prevalence helps program implementers and stakeholders to pivot their focus and resources to locations and populations with the highest disease burden.

Infant HIV	Coef.	OIM	Z	P>z	[95% Conf.	Interval]
Status		Std. Err.				
Option	0.025	0.005	-4.61	<0.001	-0.035	-0.014
Age	0.084	0.008	-10.46	<0.001	-0.1	-0.068
Education	0.026	0.006	-4.26	<0.001	-0.038	-0.014
Toxicity	0.467	0.015	-31.22	<0.001	-0.496	-0.44
Attrition	0.012	0.004	-2.97	0.003	-0.020	-0.004
Marital status	0.063	0.007	8.82	<0.001	0.049	0.076
Defaulted	0.039	0.014	-2.74	0.006	-0.067	-0.011
Adherence	0.089	0.015	-6.07	<0.001	-0.118	-0.061

Table 2 show high statistical significance as all the independent variables of age, education levels, Toxicity of drugs, Attrition, defaulting and adherence had a strong influence on infant HIV results.

# 4.1.1 Mothers age distribution

Population characteristics such as age are vital in helping to understand disease burden in age categories, thereby helping to guide age appropriate intervention.

Age <15	Count	percentage
<15	213	8.6
15-24	1013	41.1
25-34	1063	43.2
35+	174	7.1
Total	2463	100.0

Table 3: Distribution of Respondents age (mothers)

Table 2 shows the age distribution of women that met the inclusion criteria and results show that the highest number was obtained from the 25-34 years at 43.2 percent. The lowest age group was that of above 35 at 7.1 percent. This is in line with the Zambia demographic and health survey of 2013-2014 which shows that ages 25-34 belong in the high reproductive age category. Since this age group is most productive, the probability of finding more positive mothers is also high.

# 4.1.2 Mothers age and HIV test results of the infant at 6 weeks

Table 3 brings out a higher infant positivity of 71.4 among infants of mothers who were below the age of 15 across all the cohorts. This shows that age is an important factor in determining the influence of disease and designing appropriate interventions. Mothers who are below the age 15 are adolescents who may have limited understanding of the importance of PMTCT and thus this may explain the reason behind having high infant positivity in this age category.

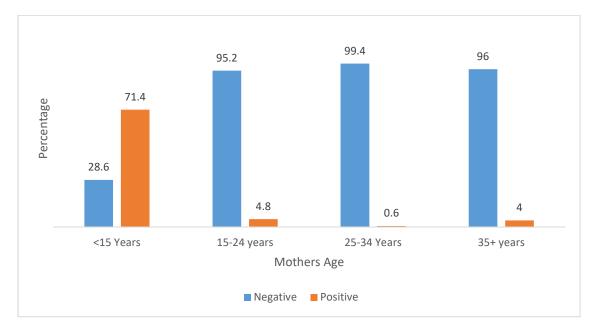
Table 4: Mothers age and HIV test results of infants at 6 weeks

	Child's HIV Status at 6 Weeks				
Childs HIV Status at 6 weeks	Positive		Negative		
	Count	%	Count	%	Total
Mother's Age					
<15 Years	152	71.4	61	28.6	100%
15-24 years	49	4.8	964	95.2	100%
25-34 Years	6	0.6	1057	99.4	100%
35+ years	7	4	167	96	100%
Total	214		2249		

#### P < 0.001

The findings have shown that there is a highly statistical significant association between the mother's level of education and the Child's HIV status at 6 weeks of survival (p<0.001). It is also prudent to realize that some of the adolescent mothers may have been born with HIV themselves and at reproductive age have a greater chance of transmitting the virus to their babies. Programs and initiatives that are aimed at providing support in a PMTCT setting need to be strategic in targeting to ensure more focus on this important age group.

Figure 4 further highlights that the age group 24-35 despite being the majority in the sample of all the cohorts, showed the lowest infant positivity rate at 0.6%. This indicated that PMTCT programs seem to have the highest impact in this age group compared to the others. The age groups 15-24 and above 35 recorded infant positive rates of 4.8% and 4% respectively.



#### Figure 4: Showing Mother's age against infant HIV test results

Figure 4 highlights the need to conduct cohort monitoring in HIV/AIDS programs so as to ensure that prevention initiatives produce results that contribute to epidemic control. Therefore, the number of women tested in a PMTCT setting is important, but it is now crucial to also measure the positivity yield by age and location for effective epidemic control. For example, the age group of women above 35 may be neglected in prevention education and activities but further analysis may help to understand the disease burden and aid in developing age appropriate initiatives.

#### 4.1.3 Education of mother and their infant HIV test results

Table 4 helps to evaluate the influence of the education of a mother on the HIV results of their infants at 6 weeks. Women with no education recorded the highest rate of 43.6% infant positivity rate across all the cohorts.

	Child's Status at 6 Weeks				
Childs HIV Status at 6 weeks	Positive		Negative		
	Count	%	Count	%	Total
Mother's Education Level					
No Education	199	43.6	257	56.4	100%
Primary	5	0.6	813	99.4	100%
Secondary	10	1	1014	99	100%
Total	214		2084		

Table 4: Mothers education and their infants HIV results

P<0.001

The results from Table 4 above clearly bring out the importance of an educated population in understanding the importance of disease transmission prevention. Further, this evidence implies that women who are not educated are more likely to transmit HIV to the infants compared to their educated counterparts. From table 1, it is clear that comparing education to infant HIV results we got a significant relationship.

#### 4.2 Attrition levels

The results from figure 5 shows that Option A recorded the least deaths at 21% compared to 39% in option B and 37% in option B+. Option B+ recorded 39.6% transfer outs compared to 24.7% in option B and 30.9% in option A. This shows that option B+ does not show superior results in reducing death among HIV positive pregnant. It also shows higher levels of women being lost to follow up owing to transferring out of the facilities.

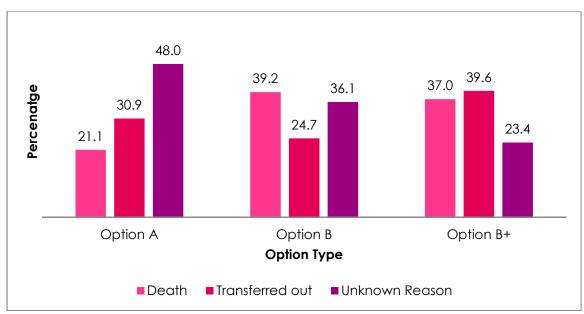


Figure 5: PMTCT Options and attrition

Transferring out of facilities does not necessarily determine the success of a program because people may move to another facility for perceived better services, convenience or may have relocated. Option B+ recording loss to follow of 37% as a result of death shows that administering of medication alone is not a panacea to reducing attrition in HIV prevention initiatives.

# 4.3 HIV status of Infants

In exploring whether we can confidently rank Option  $B^+$  as the most effective method of preventing infant HIV infections from HIV positive mothers, the results from table 5 show that Option A was just as effective as that of option  $B^+$ , because both options A and  $B^+$  had a 6% infant positivity rate with option B yielding a 13% infant positivity at 6 weeks.

Table 5: PMTCT Options and corresponding infant HIV status

Decults (Chature		OPTIONS					
Results/Status	Op	Option A		Option B		Option B+	
Negative	766	94%	741	87%	742	94%	2249
Positive	48	6%	115	13%	51	6%	214
Total	814	100%	856	100%	793	100%	2463
P<0.001			-				

# The challenges with options A and B would arise from monitoring of CD4 to ensure women stopped taking medication if they recorded a CD4 that was <350 because this would require

prudent investments in CD4 monitoring equipment. In spite of bringing out equal results to option A, option B+ proved to be a competitively good initiative in prevention of MTCT of HIV.

#### **CHAPTER FIVE**

#### **5.0 DISCUSSION**

#### 5.1 Overview

The main drive behind the research was to help in learning the effectiveness of option B+ in comparison to options A and B. Options A and B also focused on eliminating MTCT with administering of medication stopped after birth if the mother's CD4 count was above 350. On the other hand, Option B+ would ensure long life treatment of HIV regardless of CD4 count. The research aimed at examining HIV infant infections among the options as well as exploring attrition.

Some of the documented benefits of option B+ include:

- Protection from Mother To Child Transmission of HIV in current and subsequent pregnancies
- Protection for negative partners in sero-discordant couples
- Reduction in HIV-related maternal mortality (Hawkins et al., 2005)

The results from the research clearly show that option B+ yielded very good results in averting infant infections which are in line with other documented findings. It is however, important to also note that on its own, option B+ is not a panacea to the global strategy of an HIV free generation. Other prevention and education strategies are required to ensure effectiveness such as adherence to medication, good nutrition, use of condoms in prevention and best practices that help in averting infant infections are implemented in a PMTCT setting.

Some of the research conducted in some parts of the world show partial benefits of option B+ but this also came with concerns such as the risk of long-life ART to fetuses and infants, as well as adherence challenges for pregnant and breastfeeding mothers.(Ahmed et al. 2013). The foregoing statement is in line with the current research findings which highlighted very high levels of attrition even in option B+. A comprehensive approach to implementation of option B+ as well as other HIV prevention strategies should be adopted so as to bring about more gains in achieving the desired goals.

The Interagency Task Team on the Prevention and Treatment of HIV Infection in Pregnant Women, Mothers and Children, (2012), points out that Option B+ was first conceived and implemented in Malawi where the national ART program had already been functioning well using a public health approach which did not depend heavily on CD4 testing to determine who should initiate treatment. It is therefore prudent to ensure that consideration of other country specific contextual factors that may influence the failure or success of such an initiative are considered before implementation to ensure total gains.

From the research findings, it was clear that education and age levels are still very vital in influencing the results of initiatives such as PMTCT. A country like Zambia with high illiteracy levels requires a comprehensive approach to combating the spread of HIV from mothers to their un-born infants. Education of mothers in their local languages on the importance of ensuring an HIV free generation should be stepped up to ensure reduction of infant infection in the population with low education levels. Age-appropriate techniques are also required to ensure that the most at risk populations of adolescent girls are reached with suitable prevention message. Other countries have adopted the safe space technique that ensures environments where young women can freely express themselves and thereby helping to break the stigma and low uptake of services.

The results from the study also highlighted the need to reduce on attrition levels to acceptable levels so as to ensure effectiveness of interventions such as option B+. Some schools of thought ague that attrition from ART care is influenced by an interplay of personal, social, health system and structural-level factors. While improved corporeal health, side effects and need for normalcy diminished motivation to continue with treatment, individuals also weighed the social and economic costs of continued uptake of treatment. It is further argued that long waiting times for medical care and placing "defaulters" on intensive adherence counseling in the context of insecure labour conditions and livelihood constraints not only imposed opportunity costs which patients were not willing to forego, but also forced individuals to balance physical health with social integrity, which sometimes forced them to opt for faith healing and traditional medicine(Musheke et al., 2012)

The results from figure 5 clearly show that option B+ had attrition levels that were over 5-10% and as such this had a bearing on the acceptable aversion levels of infant HIV infections. The

results give emphasis on the importance of managing attrition to very low levels so as to bring about success of a program. The predominant factors enabling uptake of HIV testing are deterioration of physical health and/or death of sexual partner or child (Musheke et al., 2013). Therefore, the administering of medications without considering factors such as attrition levels and their management thereof may result in poor achievements even from initiatives that may have been proven to be successful in other settings.

In responding to the research questions and objectives that aimed at finding out whether option B+ had superior results in averting infant HIV infection, the results in table 3 indicated that at 6% positivity rate, option B+ was a very effective method in preventing mother to child transmission of HIV. The risk of HIV transmission from mother to child, without preventive interventions, ranges from 15% to 40% (WHO, 2013). Option B+ results from this study produced results that were below the WHO estimates and thus was effective in helping to reduce infant infections of HIV from positive mothers. Other options in the study (A and B), were also below the WHO estimates at 6% and 13% infant infections respectively. Therefore, Option B+ had results that were good enough to prove that it is a very effective initiative.

#### **CHAPTER SIX**

#### 6.0 CONCLUSION AND RECOMMENDATIONS

#### **6.1** Conclusion

The aim of the study was to evaluate the effectiveness of options A, B and B+ in eliminating mother to child infection of HIV. Further, the analysis brought out the comparisons between options  $B^+$  and the prior options so as to help the understanding of the shifts in averting infant HIV infections from their HIV positive mothers at 6 weeks. Attrition was also an important consideration in the objectives which would help to ascertain effectiveness. Results from the study showed that option  $B^+$  was very effective in reducing infant infections despite not being more superior to option A.

Notwithstanding the benefits of Option B+, this medical approach had very high attrition levels of 37% death, 40% transferred out and 23% unknown reasons which were above acceptable limits of 5-10%. The results show that to ensure effectiveness of option B+, a more comprehensive approach to PMTCT initiatives is required that focuses on promoting adherence to treatment and addressing attrition levels. This entails more intensified and personalized counselling to identify potential defaulters and promote the benefits of uptake of treatment regardless of one's physical condition. :

This means a cascade approach that ensures that programs in PMTCT cover all the key aspects of treatment, breast feeding, messaging and general prevention monitoring is needed for effective management and prevention of new infections. Without treatment, the likelihood of HIV passing from mother-to-child is 15 to 45%. However, antiretroviral treatment (ART) and other effective interventions for the prevention of mother-to-child transmission (PMTCT) can reduce this risk to below 5% (WHO, 2014). Therefore, option B+ results from the study at 6% infant infections show that the initiative has potential of reducing the HIV burden in Zambia and thereby contributing favorably to the HIV free generation dream.

# **6.2 Recommendations**

The findings have implication for policy and practice.

Practice level:

- Implementation of a prevention program such as option B+ will require consideration of combination prevention approaches that support adherence initiatives, tracking of attrition and effective clinical follow up strategies
- There is need for deliberate targeting of populations that are most affected by disease through evidence based approaches such as intensifying prevention education to uneducated mothers in the reproductive age group
- Prevention interventions ought to embrace age appropriate strategies and targeting that ensures adolescent girls and young women are reached with messages that help to reduce HIV incidence thereby reducing mother to child transmission.

At policy level:

- There is need to enhance health systems strengthening that focus on building facility and community structures that provide safe and conducive reproductive health environments in a bid to achieve an HIV free generation.
- More investment in data management from patient files, registers, training of medical staff and building electronic systems can enhance patient tracking and management as well as improve care. Increased human resource at health facility level is also crucial to ensure improved provider-client engagement given the high number of women required to be attended to under Option B+
- The introduction of new prevention intervention should be preceded by research and capacity assessments so as to ensure that the local environment is made suitable to absorb the change.

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# APPENDICES

# Appendix 1: Data extraction tool

Effectiveness of Option B+ towards elimination of mother to child transmission of HIV. A Retrospective Cohort Study of Facilities in Lusaka, Zambia						
Date:	Date:Facility code:					
Client unique ID:						
Data collector's name:						
NO.	ITEM	<b>RESPONSE OPTIONS</b>	CODES (Circle OR write)			
1	AGE	Completed Years	No. < 15			
			No. 15-24			
			No. 25-34			
			No. 35<			
2	EDUCATION LEVEL	None	Number			
		Primary	Number			
		Secondary	Number			
		Tertiary	Number			
3	MARITAL STATUS	Married	Number			
		Not married	Number			
		Widowed	Number			
		Single	Number			
4	Lost to follow up	Death	Number			
	(Defined in the national	Transferred out	Number			
	guidelines as not seen in	Un known cause	Number			
	the ART clinic and off					

	ART for more than 90		
	days)		
5	Defaulted (defined in the	Yes	Number
	national guidelines as not		
	seen in the ART clinic		
	and off ART for more		
	than 90 days, and not		
	known to have died or		
	transferred out, <b>found</b> but		
	refuses to commence on		
	treatment)		
6	Switching (one or more	Yes	Number
	medication changes) of		
	ART to another regimen	No	Number
	due to toxicity.		
7	Number of infants born	Positive	Negative
	HIV positive or negative		
	from options A, B and		
	B+ at six weeks		