RESUMEN

# VERTICAL TRANSMISSION OF HIV AND AIDS AT MALAMULO HOSPITAL, MALAWI, 2004-2008: A SUCCESSFUL CLINICAL AUDIT

by

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MASTER THESIS ABSTRACT

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Title: VERTICAL TRANSMISSION OF HIV AND AIDS AT MALAMULO HOSPITAL, MALAWI, 2004-2008: A SUCCESSFUL CLINICAL AUDIT

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## Problem

Malamulo Hospital has implemented a protocol on Prevention-of-Mother-to-Child HIV transmission (PMTCT) Program according to what was already established by the Government of Malawi. However, there are no published studies about the effectiveness (efficacy) of this specific protocol in this population.

## Background

HIV and AIDS has been a leading cause of illness and death especially for children born from infected mothers with HIV in countries with high HIV prevalence. Malawi is one of the highest countries in the world affected with these conditions. Malamulo Hospital started

the Prevention-of-Mother-to-child HIV transmission (PMTCT) Program in 2004 to help reduce this pandemic among infants.

## Method

A clinical audit was done to HIV infected mothers involved in PMTCT program at Malamulo Hospital in Malawi, during the years 2004-2008 using antenatal, delivery and nutritional counseling registries of the hospital. Only mothers who took Nevirapine during delivery and also infants who received Nevirapine and accepted exclusive breastfeeding for their infants and had attended the follow-up monthly appointments for 18 months were selected. A rapid HIV diagnostic test for antibodies was done at the end of the period.

## Findings

Transmission of HIV and AIDS from mother-to-child done on 303 infected pregnant mothers was proven using HIV rapid testing. From these mothers 14 (4.62%) children were HIV infected. It is emphasized that the difference of percentage between the HIV positive test and the administration of NVP in mothers and infants with EBF for the children was ($p$ = .000) which was statistically significant and important.

## Conclusions

The implementation of sdNevirapine for both infected mothers and infants with six months exclusive breastfeeding interventions at Malamulo Hospital were efficient strategies to reduce the vertical transmission of HIV. However, there could still be a chance of vertical transmission, therefore, it is important to look into other strategies to reduce it even more or aim for 0% transmission, if possible.

Universidad de Montemorelos

Facultad de Ciencias de la Salud

# VERTICAL TRANSMISSION OF HIV AND AIDS AT MALAMULO HOSPITAL, MALAWI, 2004-2008: A SUCCESSFUL CLINICAL AUDIT

A thesis
presented in partial fulfillment
for the requirements for the degree
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by

Gladys Yvonne Beteta Motta

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VERTICAL TRANSMISSION OF HIV AND AIDS AT MALAMULO HOSPITAL, MALAWI 2004-2008. A SUCCESSFUL CLINICAL AUDIT

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por

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## LIST OF ABBREVIATIONS

| | |
|---|---|
| 3TC | Lamivudine |
| AIDS | Acquired Immune – Deficiency Syndrome |
| ANC | Antenatal clinic |
| ART | Anti Retroviral Therapy |
| ARV | Antiretroviral (drugs) |
| AZT | Zidovudine |
| BBA | Born Before Arrival |
| CDC | Center for Disease Control and Prevention |
| CTX | Cotrimoxazole |
| EBF | Exclusive Breast Feeding |
| HAART | Highly Active Anti Retroviral Therapy |
| HIV | Human Immunodeficiency Virus |
| MBF | Mixed Breast Feeding |
| MMWR | Morbidity and Mortality Weekly Report |
| MOHP | Minister of Health and Population |
| MTCT | Mother -to-Child Transmission |
| MUAC: | Middle Upper Arm Circumference |
| NAC | National Aids Commission |
| NVP | Nevirapine (antiretroviral drug ) |
| PCR | Polymerase Chain Reaction |

| | |
|---|---|
| PEP | Post- Exposure Prophylaxis |
| PMTCT | Prevention of Mother to Child Transmission of HIV |
| PNC | Postnatal Care |
| SdNVP | Single-dose Nevirapine |
| TLC | Total Lymphocyte Count |
| UNAIDS | United Nations Programme on HIV/AIDS |
| UNICEF | United Nations Children's Fund |
| VCT | Voluntary Counseling and HIV Testing |
| WHO | World Health Organization |

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# CHAPTER I

# THE PROBLEM AND ITS BACKGROUND

## Introduction

Since the start of the Human Immunodeficiency Virus (HIV) and Acquired Immune Deficiency Syndrome (AIDS) pandemic in 1981, nearly 25 million people have died of AIDS.[1, 2] By the year 2008, it was estimated that there were 2.7 million people newly infected with HIV which is the cause of AIDS, and there were two million directly related to AIDS deaths.[3] At the end of 2010, 34 million adults and children were estimated to be living with HIV and AIDS around the world[4] (see Appendix A). According to studies and data the HIV infection spreads faster in women than in men.[5, 6]

The World Health Organization (WHO) and United Nations Program on HIV and AIDS (UNAIDS) stated in 2003, that most of the available epidemiological data indicate that the extensive spread of HIV started in sub-Saharan Africa in the late 1970s. By the early 1980s, HIV was found along geographic band stretching from West Africa across to the Indian Ocean, the countries north of the Sahara and those in the southern cone of the continent remained apparently untouched by the virus. By 1987, however, the epidemic started spreading toward the south with some of the most explosive outbreaks being seen in Southern Africa. The country of South Africa has the largest number of people living with HIV and AIDS in the world, (approximately five million). It is noteworthy that West Africa has been

relatively less affected by HIV infection compared to the other regions of sub-Saharan Africa.[7, 8]

Currently, sub-Saharan Africa is still the epicenter of what is now a pandemic, with more than 22 million people living with HIV infection and AIDS.[1, 4] Nearly 70 percent of all HIV-infections and 85 percent of all estimated deaths occur in this region (see Appendix B). In 2007 alone, there were more than two million new infections in the region and some 1.6 million deaths. It is estimated that some 2.5 million children are living with HIV and AIDS worldwide, and as with AIDS in general, there is disproportionate representation of AIDS cases in sub-Saharan Africa, since almost 90 percent of the global estimate reside in this region.[4] While AIDS and HIV are distributed across all age groups, of growing concern is the spread of AIDS to the unborn and newborn.[2] Prophylaxis and treatment of HIV and AIDS present logistical and sociocultural challenges. However, the prevention and treatment of HIV and AIDS in the yet unborn and the newborn pose even greater challenges especially in poorer countries where other factors which favor infant mortality are still not adequately controlled.

Malawi has one of the highest prevalence rates of HIV and AIDS in the world[1, 9] (see Appendix C). The UNAIDS estimated that the HIV prevalence rates in Malawi adults was 14.1 percent in 2005. HIV and AIDS are the leading cause of death in the most productive age group, resulting in 68,000 adult and child deaths annually.[1, 10] From the total population of 13.9 million in Malawi in 2008, 60 percent of adults living with HIV are women. The cumulative number of orphans, directly related to the AIDS pandemic, is approximately 700,000. Life expectancy declined to 39 years of age due to HIV related disease. More than 91,000 were children (almost 10 percent) below 15 years of age. Children are affected by the epidemic by contracting the disease from their mothers.[1]

Anticipating the approaching HIV epidemic, the National AIDS Commission (NAC) of Malawi was developed in 2001, and it has since overseen a number of AIDS prevention and care initiatives, including programs to provide treatment, increase testing, and prevention of mother-to-child transmission (PMTCT) of HIV. A national HIV and AIDS policy was developed in 2003, laying down the foundations and principles for all national HIV and AIDS programs and interventions. As a result, policies and guidelines for voluntary counseling and testing, PMTCT of HIV, antiretroviral therapy (ART), and treatment of sexually transmitted infections have been developed and implemented.[1]The National HIV and AIDS strategic framework for 2000-2004 included prevention and behavior change. An intervention to expand access to treatment and support services such as antiretroviral drugs (ARVs) was also initiated. Malawi has had impressive success in rapidly scaling up ART, having initiated more than 140,000 people into treatment by the middle of 2008. ART has been provided free of charge in the public sector since 2003.[1] Yet Mother -to- Child Transmission (MTCT) of HIV poses a unique set of challenges since the modes of transmission and infant breastfeeding create a dilemma between adequate nutrition and infection.

Globally, an estimated 420,000 children were newly infected in 2007, almost over 90 percent of them in sub Saharan Africa. MTCT is the main source of HIV infection in children. An estimated 90 percent of children acquire HIV infection during pregnancy, labor and delivery, or through breastfeeding. Approximately 50 percent of these children will die before their second birthday.[1, 11]

PMTCT programs are the primary prevention interventions of MTCT of HIV from pregnant women to infants.[4, 11] HIV is spread in three ways: via sexual intercourse, through HIV-infected blood or body fluids, and from mother to child. This transmission can occur

during pregnancy, childbirth, and via breastfeeding.[12, 13] According to WHO and United Nations International Children's Emergency Fund (UNICEF), 2007, the estimated risk of becoming infected during pregnancy, labor, and delivery is about 20-45 percent. The estimated risk of becoming infected postnatal (after delivery), through breastfeeding, is about 15 percent.[14, 15] These estimated risks are important since they may be used as reference standards to evaluate the efficacy of interventions aimed at reducing HIV transmission risk during the phases of pregnancy and delivery, and in the postpartum period.

The WHO estimates that approximately 150,000 infants are infected through breast-feeding each year. In United States, fewer than 150 newborn are infected with HIV at birth, usually by mothers who do not know they are HIV positive.[7, 8] Many women frequently discover that they are infected with HIV during pregnancy through routine screening performed in the first antenatal consultation. Several of the women are without any symptoms of AIDS and can be discovered when they are treated for sexually transmitted infections (STIs), or after their sexual partner or newborn child is found to be HIV positive.[16]

While it is possible to transmit HIV from mother to fetus at any time during the disease, there are periods of greater probability of transmission of the virus. It appears that a woman is more likely to transmit the virus to her fetus, if she becomes infected just before or during pregnancy in the first four to eight weeks since her level of HIV viral load is high. The higher the viral load, especially greater than 100,000 copies/$mm^3$, the more likely that MTCT will also occur at the same time if she is in the symptomatic stage of HIV disease. During the advance stage of the disease, women will have low CD4 lymphocyte count and are more likely to transmit HIV to their infants. Placental infection, known as infection of the chorion or the amnion, may increase the chance of MTCT. Genital infections, especially STIs, and prolonged

rupture of membranes during labor, may result in chorio-amnionitis. All these are due to the presence of larger quantities of virus in the bloodstream.[17, 18]

In recent years a better understanding of PMTCT and the ways to prevent it have developed. Vertical HIV transmission during labor can be reduced by: (a) the use of ART during pregnancy and labor; (b) giving the newborn infant ART; (c) avoiding unnecessary rupture of membranes; (d) avoiding episiotomy; (e) avoiding prolonged labor; (f) minimizing the fetal skin trauma from obstetrical procedures and (g) offering and providing caesarean section as the mode of delivery.[19, 20] Hospitals, clinics and midwives all play a part in the reduction of vertical transmission of HIV by keeping this in mind and putting them into practice.

Malamulo is a Seventh-day Adventist Mission Hospital located in southeastern Thyolo District, 65 kilometers from the city of Blantyre in Malawi, Africa. Blantyre is the second largest city in Malawi after its capital city, Lilongwe. Malamulo Hospital is located in a rural area where most of the population is poor. The hospital provides services to an area of over 84,000 inhabitants covering 74 villages. The hospital was founded in 1908 and has an inpatient capacity of 350. As part of its healthcare and medical mission, it is concerned about the great increase in AIDS in general but is especially concerned about HIV and AIDS amongst children. As a result, the hospital adopted the protocol that the Government of Malawi was implementing to decrease MTCT of HIV and initiated its PMTCT program in July 2004.

In the initial Malamulo PMTCT program, pregnant women were continuously enrolled, counseled, and after consent, tested for HIV. If the tests were positive, they were advised about medications, and breastfeeding was not continued after the first six months of

infant's life. Infant feeding in low-resource and low-socio-economic communities is a complex issue. Since there is definite HIV transmission risk to infants from breastfeeding, and there is also a potential risk to infants from gastroenteritis, pneumonia, malnutrition, and other infective conditions from not breastfeeding as well as unsafe formula feeding it is often a difficult decision for health workers and mothers to have to choose the most appropriate feeding method.

The National Institute of Children Health and Human Development (NICHD), states that breastfeeding is the ideal nutrition for the infant in the first six months of life. However, rise in HIV and AIDS cases, implicate breastfeeding as a route of transmission of the virus.[21, 22] With somewhere between 1.2 to 1.8 million children who have become HIV-infected through breastfeeding. Breastfeeding remains a leading route of HIV transmission in the developing world with roughly one-third to one-half of the 3.6 million children infected through MTCT.[7, 8, 23]

Since studies in Africa have shown that breastfeeding increases the risk of MTCT (14-29 percent), traditionally prolonged and mixed breastfeeding practices in the continent, which permit nipple biting and oral exposure of the lactating child to the mother's infected blood accompanied by decreased integrity of the child's gastrointestinal tract, are being questioned.[24]

Drug administration is another means of decreasing MTCT of HIV. In the Malamulo PMTCT program HIV infected woman received a single dose of Nevirapine (sdNVP) or if based on their clinical condition they were eligible for full antiretroviral therapy (ART). Upon establishing eligibility were referred to the antiretroviral clinic and are followed-up there. All offspring of the HIV positive mothers were to be administered sdNVP soon after birth. Both

the mothers and newborn children are followed-up in the Under Five Clinic according to a pre-established clinical protocol.

Malamulo Hospital's PMTCT program protocol was developed by the National AIDS Commission of Malawi through the Government, and was adopted as an empirical approach to the clinical management of HIV infected expectant mothers by Malamulo Hospital and other hospitals in Malawi. However, while it was evidence based in it's development, it's effectiveness and safety were not and could not be fully evaluated before implementation. The clinical audit of the PMTCT program at Malamulo Hospital joined the activities of other hospitals, governments, universities, and international agencies in evaluating the multiple facets of this intervention with the expressed intention of improving the care offered to the patients. In doing so, they were assured of a significant reduction of the rates of MTCT in the catchment population.

Clinical audit is a methodology used for evaluating and improving the quality of patient care in hospitals. It is defined in various ways by different agencies. According to National Institute of Clinical Excellence of National Health Services in Great Britain, clinical audit is "a quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria and the implementation of change".[25] It may include evaluation of the structure, process, or outcome of care. This model of evaluation is also the framework of quality improvement popularized by Donabedian.[26] The audit cycle is akin to the program evaluation cycle used in Public Health for assessing and improving community-based interventions in disease prevention and health promotion. It follows the basic steps in the "PDCA" or "PDSA" approach to quality improvement. Figure 1 schematically depicts the cycle.


*Figure 1*. The PDSA cycle.
*Source*: The Improvement Guide: A Practical Approach to Enhancing Organizational Performance.[27]

In this study, the conclusions and recommendations will be sent to the Malamulo Hospital administrative and medical personnel to close the audit loop.

## Statement of the Problem

Malamulo Hospital has implemented a protocol established by the Government of Malawi had established. However, there are no published studies about the effectiveness (efficacy) of this specific protocol in this population.

## Justification and Rationale

Evaluation of the program may help in the further development and strengthening of the health systems that are critical to the PMTCT at Malamulo.

Determination of efficacy will contribute to the health and wellness of Malamulo Hospital patients, Malawi, and possibly the rest of the world. The evaluation of this program is warranted. Every hospital and population may have subtle or even substantial differences. There was no readily identifiable solution at hand at the time that this program was developed and adapted.

## Hypothesis

$H_1$**:** There is a positive difference in outcome between HIV positive children of mothers infected by HIV who received antiviral prophylaxis and give exclusive breast feeding for six months compared with HIV positive children who received no specific intervention according to UNICEF.

$H_0$: There is no difference or a negative difference in outcome between HIV positive children of mothers infected by HIV who received antiviral prophylaxis and give exclusive breast feeding for six months compared with HIV positive children who received no specific intervention according to UNICEF.

## Scope

The scope of the study is described in terms of the boundaries of the problem and the population coverage.

The following scope is inherent in this study:

1. This study will evaluate only HIV and AIDS positive women who were registered at the Antenatal Care Unit of Malamulo Hospital.

2. The criteria for inclusion was limited to infants of HIV and AIDS infected mothers who take antiretroviral prophylaxis and exclusively breastfeed them.

## Delimitations

Expected limitations in methodology and research design are clearly pointed out and accepted in the following declarations:

1. The audit requires the use of the three registry books from the PMTCT program.

2. The data collected was obtained from the available records in the registry books.

3. The handwriting in the registry books was at times illegible.

4. Some of the participants may have been at other hospitals' PMTCT programs and may have had different outcomes.

5. Inconsistency with the participants' names when they come for consultations.

6. All information was collected manually due to the limited access to computers.

## Overall Objective

The clinical audit aimed to evaluate the effectiveness of the protocol used by Malamulo Hospital for mothers infected with HIV who receive ARV prophylaxis and give exclusive breastfeeding to the infants.

## Specific Objectives

This study aims to (a) evaluate the effectiveness of PMTCT protocol used by Malamulo Hospital and compare it with UNICEF data published in 2007, as well as other studies; and (b) close the audit cycle loop by providing feedback of the results to the Malamulo Hospital Administration and Clinical staff.

## Definition of Terms

Listed below are the most frecuently used terms in this study.

*Catchment Population***:** For a given hospital or unit and for a particular specialty the catchment population is that group of persons who would attend the hospital or unit were they to require treatment under that specialty.

*Clinical Audit***:** Is a quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria and the implementation of change.

*Exclusive Breastfeeding***:** Is a feeding practice in which an infant receives only breast milk and no other liquids or solids, including water.

*Evaluation***:** Is the use of the scientific method, and the rigorous and systematic collection of research data to assess the effectiveness of organizations, services and programs (e.g. health service interventions) in achieving predefined objectives.

*Health Care Provider*: Refers to any person providing health services in terms of any law including Allied Health Professions, Health Professions, Nursing, Pharmacy, and Dental Technicians.

*Health Care Worker***:** Refers to any person who is involved in the provision of health services to a user, but is not a health care provider as defined above. This includes lay counselors and community caregivers.

*HIV exposed Infant***:** Is an infant born to an HIV positive woman.

*HIV Negative*: Refers to patients or clients who have taken an HIV test with a negative result.

*HIV Positive*: Refers to patients or clients who have taken an HIV test with a positive result.

*HIV Status Unknown***:** Refers to patients or clients who have not taken an HIV test or who do not know the result of their test.

*Infant*: A person from birth to 12 months of age.

*Mixed Feeding*: Feeding breast milk as well as other milk (including commercial formula or home–prepared milk), foods, or liquids.

*Mother-to-Child Transmission***:** Refers to the transmission of HIV from an HIV positive woman to her child during pregnancy, delivery, or breastfeeding.

*Nutritional Status*: An individual's state as determined by anthropometric measures (height, weight, circumference etc.), biochemical measures of nutrients or their by-products in blood and urine, a physical (clinical) examination, and a dietary assessment and analysis.

*PDCA or PDSA*: The **P**lan–**D**o-**C**heck–**A**ct concept is attributed to Walter Shewhart, of the statistical process control fame, in the Bell Laboratories in the USA, 1930-940. It is often referred to as `the Shewhart Cycle'. W. Edwards Deming used it very effectively in Quality Management in the 1950s so it became known as `the Deming Wheel'. Deming preferred the "PDSA" acronym because of the analytical part of the cycle is better rendered "study" than "check". It is used to facilitate systematic coordination of continuous improvement efforts and both emphasizes and demonstrates that with careful planning and evaluation of results, new actions can be taken to improve outcomes in an iterative continuous cycle.

*Research*: Is the systematic and rigorous process of enquiry that aims to describe processes and develop explanatory concepts and theories, in order to contribute to a scientific body of knowledge.

*Traditional Birth Attendant***:** Refers to a pregnancy and childbirth care provider. Provides basic health care, support and advice during and after pregnancy and childbirth, based primarily on experience and knowledge acquired informally through the traditions and practices of the communities where they originated.

# CHAPTER II

## THEORETICAL FRAMEWORK AND REVIEW OF RELATED LITERATURE

Governments, health systems, hospitals, and physicians all recognize the need to evaluate the clinical services and the products that they offer. Governmental healthcare agencies are particularly keen to expose this need, which transcends the hospitals and clinics, and involves itself with the very fabric of the health culture of its jurisdiction. When there is a threat to the health and wellbeing of an individual or a relatively small number of individuals, society typically deals with such threats as "private". However, when the threat is to a major part of the population it squarely enters the domain of Public Health. HIV and AIDS is without a doubt a threat to the health and wellbeing of many and as such a Public Health issue.

When faced with the need to institute a systematic methodology for evaluating the healthcare services of the entire United Kingdom, the British Healthcare Services Administration searched for a scientifically validatable and statistically sound approach that was aimed at improving the existing service, offering to reach predetermined standards of excellence. While other systematic evaluations can be done in a purely "research" manner or even a "service evaluation" manner, the Clinical Audit was chosen to be the method of choice.

Research is the systematic and rigorous process of inquiry which aims to describe phenomena, develop, and test explanatory concepts and theories. Ultimately, it aims to

contribute to a scientific body of knowledge. More specifically, it aims to improve health, health outcomes and health services.[28]

While the double-blind randomized controlled trial, is the true experimental design, and most appropriate for addressing these types of questions. There are also situations in which this method is unrealistic, impractical, or inappropriate, and other well-designed analytic (as opposed to descriptive) methods have to be employed instead. For some cause-and-effect questions, the Randomized Controlled Trial may be the most appropriate research design but it would be unethical to randomize people to interventions that are unacceptable. Therefore, the issue must be addressed using other methods, such as a prospective, longitudinal survey of a population (e.g. "Does drinking spirits increase the risk of heart disease?").[29]

Health research has been defined in relation to health in general. It provides the basic information on the state of health and disease of the population; it aims to develop tools to prevent and cure illness, mitigate its effects, and it attempts to devise better approaches to health care for the individual and the community.[30]

## The Assessment of Quality

The quality of care can be defined in relation to its effectiveness with regard to improving the patient's health status. Quality is clearly relevant to health services research. Quality assurance and medical and clinical audit are all initiatives to establish and maintain quality in health care, and also involve the evaluation of structure, process and outcome in relation to quality.[31]

## Audit

Audit is directed at the maintenance and achievement of quality in health care. Audit aims to improve patient outcome, to develop a more cost-effective use of resources, and to have an educational function for health professionals. The issue addressed should be a common, significant, or serious problem.

## Clinical Audit

Quoting the 1982 statement of the Standing Committee on Postgraduate Medical Education, Ann Bowling goes on to state that "audit consists of reviewing and monitoring current practice and evaluation (comparison of performance) against agreed predefined standards" (see Figure 2).

Clinical audit is conducted by doctors (medical audit) and other health care professionals (e.g. nurses, physiotherapists, occupational and speech therapists), and is the systematic critical analysis of the quality of clinical care. It includes collecting information to review diagnosis and the procedures used for diagnosis, clinical decisions about the treatment, use of resources and patient outcome.[32]

## Methodology

The process of audit involves multiple methods, such as document searching and analysis, analysis of routine data, clinical case reviews and presentations in team meetings. It can also include the collection of information. Quantitative research methodology is usually the most appropriate for audit, but this can be supplemented with much benefit from qualitative methods such as observation. The design of audits should also aim to be scientifically and methodologically rigorous.[33]

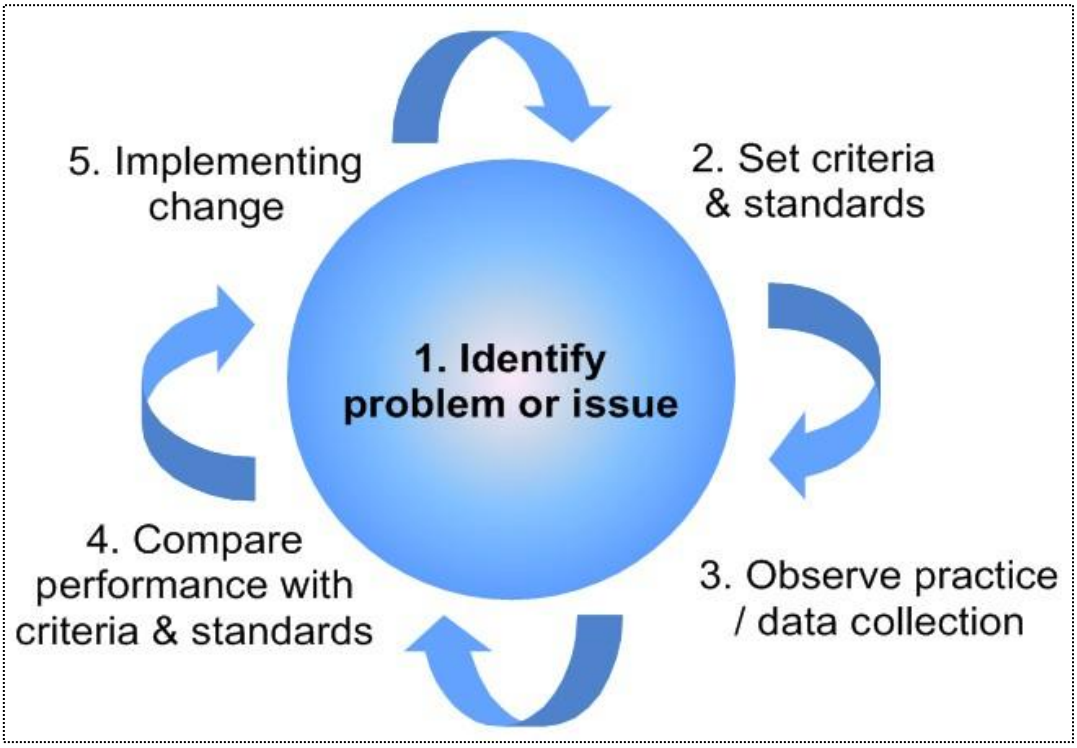



*Figure 2*. The Clinical Audit Process.

## Clinical Audit Versus Research

Research is the systematic and rigorous process of inquiry that aims to describe processes and develop explanatory concepts and theories, in order to contribute to a scientific body of knowledge.

Clinical audit is the systematic critical analysis of the quality of clinical care by all health care professionals. It is differentiated from "pure research", "service evaluation" and even quasi experimental research by its intent primarily. Nonetheless, it should be conducted with all the care and rigor of an experimental research study (see Table1).[34]

Table 1

*Differences Between Research and Clinical Audit*

| Research | Clinical Audit |
|---|---|
| Aims to establish what is best practice | Aims to evaluate how close practice is to best practice and to identify ways of improving the quality of health care provided |
| Is designed so that it can be replicated and so that its results can be generalized to other similar groups | Is specific and local to one particular patient group results are not transferable to other settings |
| Aims to generate new knowledge/increase the sum of knowledge | Aims to improve services |
| Is usually initiated by researchers | Is usually led by service providers |
| Is theory driven | Is practice-based |

*Source*: Adapted from Madden (1991) and Firth-Cozens (1993).[34]

Public health programs have as their ultimate goal, preventing or controlling disease, injury, disability, and death. Over time, this task has become more complex as programs themselves have become more complex. Increasingly, public health programs address large problems, the solution to which must engage large numbers of community members and organizations in a vast coalition. More often than not, public health problems –which in the last century might have been solved with a vaccine or change in sanitary systems– involve significant and difficult changes in attitudes and risk/protective behavior of consumers and/or providers. In addition, the context in which public health programs operate has become more complex. Programs that work well in some settings fail dismally in others because of the fiscal, socioeconomic, demographic, interpersonal, and inter-organizational setting in which they are planted. At the same time that programs have become more complex, the demands of policy makers and other stakeholders for accountability have increased. All these changes in the environment in which public health programs operate mean that strong program evaluation is essential now more than ever, but also that there is not one "right" evaluation. Rather, a host of evaluation questions may arise over the life of the program that might reasonably be asked

at any point in time. Addressing these questions about program effectiveness means paying attention to documenting and measuring the implementation of the program and its success in achieving intended outcomes, and then using such information to be accountable to key stakeholders.[35]

## Program Evaluation

Program evaluation is defined as: "the systematic collection of information about the activities, characteristics, and outcomes of programs to make judgments about the program, improve program effectiveness, and/or inform decisions about future program development."[36]

## Program Evaluation Versus Research

Academic research focuses primarily on testing hypotheses; a key purpose of program evaluation is to improve practice. Research is generally thought of as requiring a controlled environment or control groups. In field settings directed at prevention and control of a public health problem, this is seldom realistic (see Table 2).

When there exists an emergent threat of the pandemic proportions, ascribed to HIV and AIDS, it is not feasible to await all of the double blinded, randomized placebo controlled therapeutic trials of various regimens, before deciding on using the laboratory and empirical evidence in other human populations, to devise a reasonable therapeutic plan that is implemented before the human research is definitive. Such is the case with HIV and AIDS in sub-Saharan Africa.[9, 10] Guided by the counsel and collective worldwide experience of the World Health Organization and the USAIDS, Malawi, like other nations in the same situation, developed empiric protocols for antiretroviral therapy (ART), Highly Active Anti- Retroviral Therapy (HAART) and PMTCT of the HIV.

Table 2

*Distinguishing Principles of Research and Evaluation*

| Concept | Research Principles | Program Evaluation Principles |
|---|---|---|
| Planning | Scientific method<br>• State hypothesis<br>• Collect data<br>• Analyze data<br>• Draw conclusions | Framework for program evaluation<br>• Engage stakeholders<br>• Describe the program<br>• Focus the evaluation design<br>• Gather credible evidence<br>• Justify conclusions<br>• Ensure use and share lessons learned |
| Decision Making | Investigator-controlled<br>• Authoritative | Stakeholder-controlled<br>• Collaborative |
| Standards | Validity<br>• Internal (accuracy, precision)<br>• External (generalizability) | Repeatability program evaluation standards<br>• Utility<br>• Feasibility<br>• Propriety<br>• Accuracy |
| Questions | Facts<br>• Descriptions<br>• Associations<br>• Effects | Values<br>• Merit (i.e. quality)<br>• Worth (i.e. value)<br>• Significance (i.e. importance) |

*Source*: U.S. Department of Health and Human Services Centers for Disease Control and Prevention. Office of the Director, Office of Strategy and Innovation.[37]

The approach to testing their protocols included clinical trials (double blinded randomized placebo controlled interventions), open label investigative research depending upon the stage of the application of the drug in question, and local clinical audits to evaluate and improve the multiple facets of the strategic implementation of the protocols.

In the case of Malamulo Hospital, this researcher did not and could not choose or alter the intervention protocol, and the safety and effectiveness aspects of the regimen were not evaluated in that subpopulation or that hospital setting. It was deemed appropriate, by the hospital administration and the academic department of the evaluator, to use the clinical audit methodology with some specific modifications.

1. Generation of research hypotheses.

2. Quasi-experimental components regarding comparisons with external control subjects and standard based on available literature.

3. Limiting evaluations to effectiveness and safety but not cost effectiveness, process of care, etc.

The "science" behind the Malamulo PMTCT program protocol is very solid but evolving. Current evidence supports its rationale as a "reasoned" approach to prevention of vertical transmission.

In 1987, Zidovudine (AZT) became the first antiretroviral drug available and approved by the United States Food and Drug Administration (FDA). Connor et al, in February 1994, with the Pediatric AIDS Clinical Trials Group (PACTG) Protocol 076, demonstrated that a three-part-regimen of Zidovudine (ZDV) could reduce the risk for mother-to-child human immunodeficiency virus type 1 (HIV-1)-transmission by nearly 70percent. The regimen includes oral ZDV initiated at 14-34 weeks' gestation and continued throughout pregnancy, followed by intravenous ZDV during labor and oral administration of ZDV to the infant for six weeks after delivery.[38]

The claim call, to act on, was raised in 1995 after Davis showed that approximately 14,920 HIV-infected infants were born in the United States between 1978 and 1993. Of these, an estimated 12,240 children were living at the beginning of 1994; 26 percent were younger than two years old, 35percent were aged two to four years, and 39 percent were aged five years or older. Approximately 6,530 HIV-infected women gave birth in 1993, and based on a 25 percent vertical transmission rate, an estimated 1,630 of their infants were HIV infected. These results provide a basis for estimating medical and other resource needs for HIV-infected

women and their children, and for measuring the impact of interventions to reduce vertical transmission of HIV.[39]

In South Africa, Anna Coutsoudis from the Department of Pediatrics and Child Health, University of Natal, South Africa in her article "*Breast-feeding and HIV transmission",* made the following statement: HIV-1 (subsequently referred to as HIV) infection may be transmitted to the infant during breast-feeding. The risk of transmission varies with stage of maternal infection, duration of breast-feeding, type of breast-feeding (i.e. exclusive or mixed breast-feeding), and breast pathology (see Table 3).

Table 3

*Births to Human Immunodeficiency Virus (HIV)-positive Women and Incidence in Infants*

| Year | No. of States in SCBW | No. Tested in SCBW | %Vertically Acquired AIDS Cases† | Estimated No. of Births to HIV Positive Women† | Estimated Incidence of HIV Infection in Infants ‡ |
|---|---|---|---|---|---|
| 1988 | 13 | 590 128 | 81.4 | 5430 | 1360 |
| 1989 | 35§ | 1 747 561 | 94.1 | 6370 | 1590 |
| 1990 | 43§ | 2 349 661 | 96.8 | 6770 | 1690 |
| 1991 | 44§ | 2 386 430 | 99.7 | 7040 | 1760 |
| 1992 | 44§ | 2 711 603 | 99.7 | 6990 | 1750 |
| 1993 | 44§ | 2 743 767 | 99.5 | 6530 | 1630 |

*Note.* Estimates based on Survey of Childbearing Women (SCBW), United States, 1988 through 1993, all estimates are rounded to the nearest 10.
† Proportion of all vertically acquired immunodeficiency syndrome (AIDS) cases reported to the Centers for Disease Control and Prevention, Atlanta, GA, accounted for by these states.
‡ Estimates are based on 25% transmission rate, rounded to the nearest 10.
§ Value includes District of Columbia.[39]

Studies support the findings of a meta-analysis (Dunn *et al*. 1992) and indicate that when breast-feeding is practiced for over two years, the risk of infection is about 14percent. Shorter durations of breast-feeding may therefore minimize the risk of transmission. Although the risk of infection appears to be greatest in the first six months, this risk needs to be weighed

against the excess risk of morbidity and mortality if children are not breast-fed in the first six months. In resource-poor settings, any policy decision to replace breast-feeding with formula feeding in order to prevent postnatal HIV transmission needs to be balanced against the risks to the infant of malnutrition, morbidity, and death if not breast-fed. New information suggests that exclusive breast-feeding, instead of the norm of mixed breast-feeding, may not increase risk of HIV transmission at six months and suggests that exclusive breast-feeding with early cessation may be a viable option for some women (see Table 4).[40]

Table 4

*Mother-to-child Transmission Rates (%) for HIV-1 in Breast-fed and Formula-fed Infants*

| | | | Age of Infants | | | | |
|---|---|---|---|---|---|---|---|
| Study | Mode of Feeding | N | 1d | 6 Weeks | 3 Months | 6 Months | 15-18 Months | 24 Months |
| Brazil (Tess et al, 1998) | Breast-fed | 168 | | | | | 21 | |
| | Formula-fed | 264 | | | | | 13 | |
| South Africa | Breast-fed | 157 | 6.9 | | | 24.2 | 31.6 | |
| (Coutsoudis et al, 2001) | Formula-fed | 394 | 7.6 | | | 19.4 | 19.4 | |
| Kenya (Nduati et al, | Breast-fed | 191 | 7.0 | 19.9 | 24.5 | 28.0 | | 36.7 |
| 2000a) | Formula-fed | 193 | 3.1 | 9.7 | 13.2 | 15.9 | | 20.5 |

In South Africa, The Western Cape AIDS Training Information and Counseling Centre (ATICC) was one of 24 such centers brought about by the National Department of Health from 1989-1995. The Western Cape ATICC was inaugurated on July 26, 1989. The purpose was to train Health Care Providers to respond to the HIV and AIDS pandemic in the Province. As the name suggests, the functions of ATICC include Training, Information, and HIV Counseling and Testing. According to information provided by Dr. Carroll Jacobs, by following the results of some studies, relating to Nevirapine, the Department of Health,

Provincial Government of the Western Cape in 1998 decided that in order to save infants from becoming infected with HIV, the PMTCT program should be introduced. Following the training of the midwives, nurses, and lay counselors in the latter part of 1998, on January 4, 1999 the PMTCT program was initiated at two health care facilities in Cape Town, South Africa, namely the Midwife Obstetric Unit, Site B, Khayelitsha and at the Midwife Obstetric Unit at Michael Mapongwana Community Health Centre, Khayelitsha, as this was the area with the highest rates of HIV infection in the Western Cape. With the success of this program in these two sites, the implementation to the rest of the Province took place in 2001.[41]

In 2003, Suryavanshi et al., assessed factors that influence the infant feeding decisions of HIV-infected mothers in Pune, India. From December 2000 to April 2002, HIV positive (HIV (+)) pregnant women ($n$ = 101) from a government hospital antenatal clinic were interviewed pre-partum about infant feeding intention, feeding practice immediately postpartum, and feeding after a minimum of two weeks postpartum. Of the HIV (+) sample, the last 39 were interviewed more intensively to examine factors affecting feeding decision making. They found that an equal number of HIV (+) women intended to breast-feed (44%) or give *top milk* (44%) (diluted animal milk). Women who chose to *top feed* were also more likely to disclose their HIV status to family members. Mixed feeding occurred frequently in our sample (29%); however, for the majority of those (74%), it lasted only three days postpartum. The hospital counselor had an important role in assisting women in their intended feeding choice as well as actual practice. The time immediately after delivery was noted as critical for re-counseling about infant feeding and further support of the woman's decision, thus lowering the risk of mixed feeding. Lack of funds, poor hygienic conditions, and risk of social repercussions were more commonly noted as reasons to breast-feed. *Top milk*, the

alternative for breast milk was used in this population. According to the Joint United Nations Programme on HIV/acquired immunodeficiency virus (AIDS), India has more than 1.3 million estimated HIV-infected women of child-bearing age, and 160,000 infected children (aged 0-15 years). Transmission of HIV infection from mother to child is responsible for nearly all pediatric HIV cases and contributes to two percent of all HIV cases in India. With greater accessibility to antiretroviral drugs during delivery, breast-feeding is responsible for an increasingly large proportion of worldwide pediatric HIV infection. This study was conducted on women participating in a pilot study awaiting an upcoming Nevirapine trial for prevention of mother to infant HIV transmission in the out-patient antenatal clinic (ANC) of a government hospital in Pune, Maharashtra. As part of the trial preparation, ELISA HIV testing was made available to all newly enrolled women attending the antenatal clinic. Those accepting testing were asked to return after two weeks to obtain their results. They estimated that approximate 60 percent of women tested returned for their results. To obtain a sample that was representative of all women attending the ANC during the study period, data were collected every three days, thereby, giving every clinic day an equal coverage. Data were obtained from all newly registered women who were eligible and consented to be interviewed. Women were eligible for the study if they were between 18 and 44 years old, over 28 weeks gestation, identified as either HIV positive or HIV negative by ELISA (Labsystems Oy, Helsinki, Finland), and were mentally and physically healthy enough to participate in the study (as assessed by a doctor). HIV (+) pregnant women ($n$ = 101) were recruited from December 2000 to April 2002; none of the women refused to participate in the study. All women attending the ANC, on study enrollment days, whose report indicated that they tested HIV (+) were invited to participate and consented to three interviews as part of this study.[42]

In 2008, Sc, Nyunya, Siika and Rotich conducted an investigation to determine the types and modes of infant feeding practices among the HIV infected mothers on prevention of mother-to-child transmission (PMTCT), and attending maternal and child health and family planning (MCH-FP) clinic at Kitale District Hospital, Kenya. A total of 146 respondents, who had delivered 150 infants, were recruited for this study. Thirty five percent (52/150) of the infants were exclusively breastfed while 50percent (75/150) were not breastfed at all and 14percent (21/150) of the infants received mixed feeding. The length of exclusive breastfeeding ranged from one to six months with most women (53%) exclusively breastfeeding for two to three months. There were only thirteen percent of the women that exclusively breastfeed for about five to six months. There was a strong relationship between mode of infant feeding and spouse's awareness of HIV status. Mothers who had disclosed their HIV status to their spouses were more likely not to breastfeed than mothers who had not disclosed their status ($p < .05$). The choice of infant feeding method was also influenced by the socio-economic status of the mothers and Nevirapine uptake. The level of education did not influence the mode of infant feeding. Infant feeding decisions were mainly influenced by the male partner's involvement and the socio economic status of the mother. Half of the respondents did not breastfeed at all. The duration of exclusive breastfeeding rarely reached six months. To encourage women to adhere to good infant feeding practices, involvement of their partners, family members as well as the community should be encouraged.[43]

In the same year 2008, Elchalal et al. conducted a prospective analysis of all deliveries of HIV positive women in the Jerusalem district over a ten year period, between 1996 and 2006. The objective was to assess mother-to-child transmission of HIV among Ethiopian immigrants and non-Ethiopians in the Jerusalem area. Thirty five HIV (+) women gave birth

to forty five infants. Thirty-one (88%) of these women were of Ethiopian origin and gave birth to thirty nine infants. Of the thirty five HIV (+) women, thirty were aware of being HIV positive. They gave birth to forty infants. Another five women (14%) were not aware of being HIV (+) during delivery. They gave birth to five infants. Of the group of known HIV (+) women, twenty six (87%) were Ethiopian immigrants who delivered thirty four infants and four were non-Ethiopians who delivered six infants. In the group of five women not aware of being HIV (+), all were Ethiopians. Breast-feeding data were available for thirty two of the thirty five women. Only two women (6.2%) breast-fed their infants. Neither was aware of being HIV (+). In the Ethiopian immigrant group (both known and unknown HIV status), eleven deliveries (28%) were vaginal, eighteen (46%) were elective cesarean section and ten (26%) were delivered by emergency cesarean section. Of the twenty six known HIV (+) Ethiopian women, three (12%) refused antiretroviral treatment despite repeated counseling. In the non-Ethiopian group, all deliveries were elective cesarean sections. Mother to child transmission of HIV occurred in four of the total forty five deliveries (8.8%). Of the four transmission cases, two occurred among forty deliveries of known HIV (+) women (5%), and two occurred among the five deliveries of women not aware of being HIV (+) (40%, $p = .05$). In the Ethiopian group of women, HIV transmission occurred in four of thirty nine deliveries (10%), of which two occurred among thirty four deliveries (5.8%), of women known to be HIV (+), and two among five deliveries (40%), of women not aware of being HIV (+) ($p = .08$). Pregnant Ethiopian immigrants, whose HIV status was known during pregnancy, were at relatively high risk of HIV transmission despite the availability of antiretroviral drugs and counseling. This is likely due to inadequate adherence to ART preventive regimens, not dissimilar to the poor adherence observed among other immigrant groups in western countries.

The substantial proportion of women, all Ethiopians, unaware of being HIV (+) at delivery, along with the significantly higher HIV transmission in that group compared to women who knew their HIV status, call for a revision of the current Ministry of Health opt-in policy for prenatal HIV screening.[44]

Also in 2008, Kagaayi et al., in the study entitled "Survival of infants born to HIV positive mothers, by feeding modality, in Rakai, Uganda", compared the mortality and HIV negative status of breast and formula-fed infants born to HIV positive mothers in a program in rural, Rakai District in Uganda. 182 infants born to HIV positive mothers were followed at one, six, and 12 months postpartum. Mothers were given infant-feeding counseling and allowed to make choices as whether to formula-feed or breast-feed. Eligible mothers and infants received antiretroviral therapy (ART) if indicated. Mothers and their newborns received prophylaxis for PMTCT if they were not receiving ART. Infant HIV infection was detected by PCR (Roche Amplicor 1.5) during the follow-up visits. Seventy-five infants (41%) were formula-fed, while one hundred seven (59%) were breast-fed. Exclusive breast-feeding was practiced by only 25% of breast-feeding women at one month postpartum. The cumulative 12-month probability of infant mortality was 18% (95%, CI = 11%-29%) among the formula-fed compared to 3% (95%, CI = 1%-9%) among the breast-fed infants (unadjusted hazard ratio (HR = 6.1, 95%; CI = 1.7-21.4; $p < 0.01$). There were no statistically significant differentials in HIV-free survival by feeding choice (86% in the formula-fed compared to 96% in breast-fed group), adjusted (RH = 2.8, 95%; CI = 0.67-11.7; $p = 0.16$). Formula-feeding was associated with a higher risk of infant mortality than breastfeeding in this rural population. Their findings suggest that formula-feeding should be discouraged in similar African settings.[45]

In 2008, Kuhn et al conducted a randomized trial in Zambia to evaluate whether abrupt weaning at four months, compared with the standard practice has a net benefit for HIV-free survival of children. They enrolled 958 HIV-infected women and their infants in Lusaka, Zambia. All the women planned to breast-feed exclusively up to four months; 481 were randomly assigned to a counseling program that encouraged abrupt weaning at four months, and 477 to a program that encouraged continued breast-feeding for as long as the women chose. The primary outcome was either HIV infection or death of the child at or before 24 months. In the intervention group, 69% of the mothers stopped breast-feeding at five months or earlier; 68.8% of these women reported the completion of weaning in less than two days. In the control group, the median duration of breast-feeding was sixteen months. In the overall cohort, there was no significant difference between the groups in the rate of HIV-free survival among the children; 68.4% & 64.0% survived to 24 months without HIV infection in the intervention and control groups, respectively ($p$ = .13). Among infants who were still being breast-fed and were not infected with HIV at four months, there was no significant difference between the groups in HIV-free survival at 24 months (83.9% and 80.7% in the intervention and control groups, respectively; $p$ = .27). Children who were infected with HIV by four months had a higher mortality by 24 months if they had been assigned to the intervention group than if they had been assigned to the control group (73.6% vs. 54.8%, $p$ = .007). Early, abrupt cessation of breast-feeding by HIV-infected women in a low-resource setting, such as Lusaka, Zambia, does not improve the rate of HIV-free survival among children born to HIV-infected mothers and is harmful to HIV-infected infants.[46]

Kunz et al., in 2008, conducted a study in Uganda, about the persistence of Nevirapine in breast milk and plasma of mothers and their children after single-dose administration. The

antiretroviral drug Nevirapine is widely used in resource-limited areas to reduce the associated risk of intra-partum transmission. Since breastfeeding is the norm in sub-Saharan Africa, there is an additional risk of 10% to 20% for post-natal transmission. So far, Nevirapine concentrations in breast milk, after a single dose for periods longer than one week, have not been analyzed. For plasma, such data are available using assays that detect Nevirapine levels more than 50 ng/mL only. In this study in rural western Uganda, they analyzed Nevirapine concentrations in three compartments: breast milk, plasma of mothers, and plasma of children, over a period of six weeks after single-dose administration. Breast milk and plasma samples of 62 HIV positive Ugandan mother–child pairs who had received single-dose Nevirapine were collected at delivery and one, two, and six weeks postpartum. Nevirapine concentrations were quantified by LC/tandem-mass-spectrometry using a quantification limit of 15 ng/mL, and a population pharmacokinetic (PK) analysis was performed. Concentration–time profiles in breast milk, maternal plasma and child plasma showed similar shapes. At week one, median Nevirapine concentrations were 164 ng/mL in maternal plasma, 114 ng/mL in breast milk and 183 ng/mL in child plasma. The population PK model predicted Nevirapine concentrations more than 10 ng/mL (IC50 for nevirapine) for 13 days in breast milk, 14 days in maternal plasma and 18 days in child plasma in 80% of the samples. Nevirapine concentrations were present for two to three weeks in the three compartments. The concentrations are sufficiently high to protect most breastfed children from HIV transmission during the first two weeks. The long presence of slowly decreasing levels of Nevirapine is likely to induce resistance formation. Post-natal addition of antiretrovirals for one week only, as recommended in the current PMTCT guidelines, will not suffice to avoid Nevirapine resistance formation.[47]

In 2009, Maru et al. undertook a qualitative and quantitative cross-sectional survey to

identify the social determinants of mixed feeding among a subset of the 469 HIV-infected women enrolled in a MTCT prevention program in Jos, Nigeria, Formula was provided free-of-cost. Of the 91 participants, 68 (75%) exclusively formula fed, seven (8%) exclusively breastfed, and 16 (18%) practiced mixed feeding. Of the mixed feeding women, seven primarily formula fed and nine primarily breastfed. Women who primarily formula fed described family pressure as the reason for mixed feeding, while women who primarily breastfed reported insufficient breast milk. In a multivariate analysis, lack of partner support of the feeding decision predicted mixed feeding behavior (OR: 4.2, 95%; CI: 1.2-14.9; $p$ = .03). Disclosure of HIV status was significantly correlated ($p < .001$) with partner support. HIV prevention interventions aimed at reducing mixed feeding, should encourage supportive partner relationships that facilitate disclosure of HIV status. Attention should also be made to the differing pressures faced by women attempting to exclusively breast feed and exclusively formula feed. Every year, approximately 40% of HIV-infected children worldwide, become infected through breastfeeding, making breastfeeding the most prevalent mode of mother-to-child transmission (MTCT) of HIV (Kourtis, Lee, Abrams, Jamieson, & Bulterys, 2006). In those settings with poor access to clean water and sanitation, HIV-infected mothers in Sub-Saharan Africa are faced with the choice of breastfeeding, which confers an increased risk of HIV, or formula feeding, which increases the risk of malnutrition, respiratory tract infections, and diarrheal diseases. The consequences of this feeding choice have led, the WHO, to take a conservative approach, recommending avoidance of all breastfeeding only “when replacement feeding is acceptable, feasible, affordable, sustainable, and safe” (AFASS) and exclusive breastfeeding if those conditions are not met (WHO, 2001). Mixed feeding confers excess risk of mother-to-child transmission (MTCT) of HIV, as compared with exclusive breastfeeding

(EBF) and exclusive formula feeding (EFF).[48]

Arpadi et al. conducted in 2009 a trial in Lusaka, Zambia about growth faltering due to breastfeeding cessation in uninfected children born to HIV-infected mothers. HIV-infected mothers were randomly assigned to exclusive breastfeeding for four months, followed by rapid weaning to replacement foods, or exclusive breastfeeding for six months followed by introduction of complementary foods, and continued breastfeeding for a duration of the mother's choice. Weight-for-age Z score (WAZ), length-for-age Z score (LAZ), and weight-for-length Z score (WLZ), and the self-reported breastfeeding practices of 593 HIV-uninfected singletons were analyzed. Exclusive breastfeeding for six months is an important strategy for reducing postpartum MTCT of HIV in resource-poor settings when conditions do not permit safe use of breast-milk replacements. The benefits of breastfeeding regarding reductions in gastrointestinal infections, respiratory infections, middle ear infections, and improvements in neurodevelopment, and overall survival are well established. Child anthropometric measures were collected as part of the Zambia Exclusive Breastfeeding Study (ZEBS). HIV positive women attending prenatal care services from May 2001-September 2004 at two sites in Lusaka, Zambia, were recruited. Women were given single-dose Nevirapine (sdNVP) and were counseled about the risks and benefits of infant feeding options. Women who intended to breastfeed were eligible, and all those enrolled were encouraged to exclusively breastfeed until four months. When their child reached one month of age, they were randomly assigned to either a counseling program that encouraged abrupt cessation of breastfeeding at four months (intervention group), or to a program that encouraged continued exclusive breastfeeding to six months with gradual introduction of complementary foods (control group). The duration of breastfeeding after

four months in the control group was determined by personal choice. All children in the intervention group were provided with commercially available modified cow milk, infant formula, and a fortified replacement cereal for three months after early breastfeeding cessation. The replacement cereal, which provided 74 kcal/100 ml, was a product developed and tested in Zambia, by the United States Department of Agriculture and is based on the local staple maize meal and fortified with milk powder, sugar, oil, and micronutrients. Mothers were encouraged to offer replacement cereal, or formula, six to eight times per day. Education about preparation, feeding practices, and hygiene was provided. Growth monitoring was done every two weeks, between four and six months, and then monthly from six months as a safety net; any infant in either group with failure to thrive after weaning was provided with either the fortified study replacement cereal, or with high-energy protein supplements furnished by the World Food Program, Zambia. Mothers and infants were followed up at clinic visits, at least once a month for the first six months, and every three months thereafter until 24 months postpartum. Child feeding practice was assessed at each visit, by maternal self-report using a detailed questionnaire, and the exact age at which breastfeeding cessation occurred was determined. Child length and weight were measured at each study visit. Blood samples were collected at each visit to determine the child's HIV status by HIV/DNA polymerase chain reaction. Study population of 958 mother-child pairs randomly assigned in the ZEBS, 593 singleton births were included in this analysis. Flow chart detailing the number of randomized subjects excluded from the analysis, the reason for their exclusion, and the distribution of included subjects by randomization Group and actual breastfeeding (BF)status at five months (see Figure 3).[49]

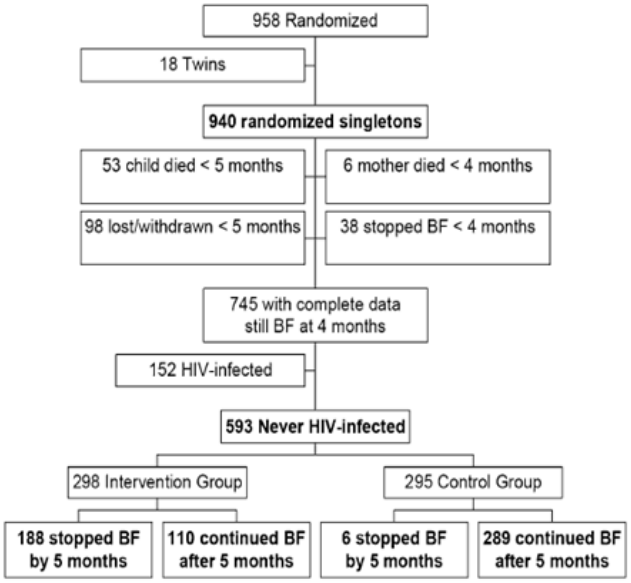



*Figure 3*. The Flow of Participants and the Inception of the Study Cohort.

Fadnes et al., in 2009 conducted a research to compare feeding practices, including breastfeeding, between infants and young children of HIV positive mothers and infants of mothers in the general population of Uganda. This study compares two cross-sectional surveys conducted in the end of 2003 and the beginning of 2005 in Eastern Uganda using analogous questionnaires. The first survey included 793 randomly selected general-population mother-infant pairs with unknown HIV status from urban and rural areas in Mbale district, the infants were 0-11 months old, 30 had non-responses, and 36 had incomplete data, 727 mother-infant pairs remained in the analysis. They did not collect information about the mothers' HIV status. These participants are referred to as "general-population mothers." The second survey was conducted in 2005 and included 240 mother-child pairs. This study was performed in collaboration with The Aids Support Organization (TASO). TASO is a non-governmental organization working for HIV positive people in Uganda. It provides counseling, information,

support, and medical treatment for HIV positive people. The mothers were approached through TASO-Mbale, including their outreach clinics in Mbale district and adjacent areas. The children were 0-23 months old. Comparisons of infants were made with corresponding age-groups in the general population. Five mother-infant pairs were excluded from analysis because of missing information or the child being at least 24 months old. All women recruited through TASO were known to have HIV positive status and are described as HIV positive mothers in this study. In this article, they compare early feeding practices, breastfeeding duration, feeding patterns with dietary information and socio-economic differences in the two groups of mothers (see Figure 4).

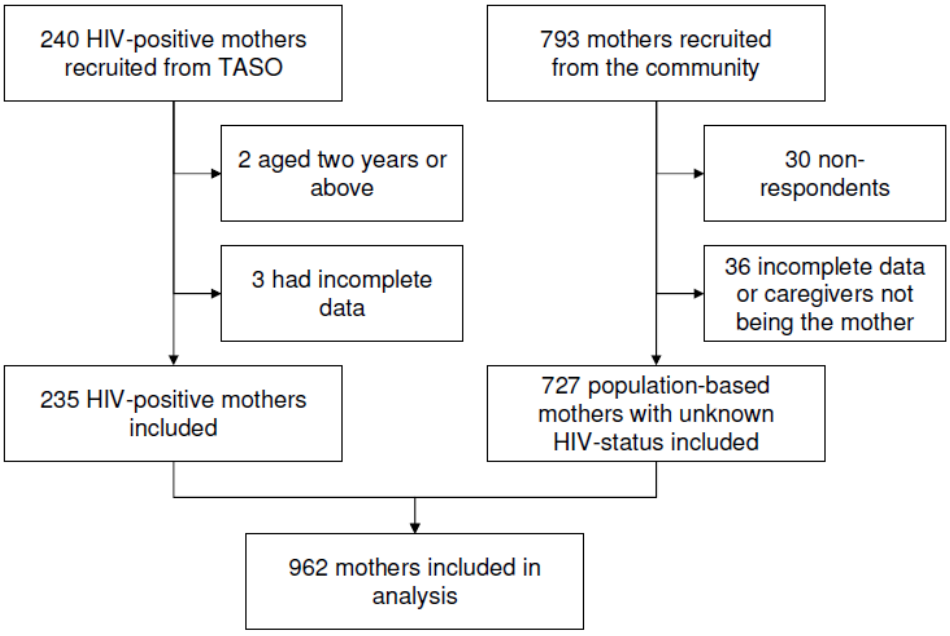



*Figure 4.* Study Enrolment Overview.

Pre-lacteal feeding was given to 150 (64%) infants of the HIV positive mothers and 414 (57%) infants of general-population mothers. Exclusive breastfeeding of infants under the age of six months was more common in the general population than among the HIV positive mothers, 186 [45%] vs. nine [24%] respectively, according to 24-hour recall. Mixed feeding was the most common practice amongst both groups of mothers. Solid foods were introduced to more than half of the infants less than six months old, among the HIV positive mothers, and a quarter of the infants in the general population. Among the HIV positive mothers with infants below 12 months old, 24 of 90 (27%) had stopped breastfeeding in contrast to nine of 727 (1%), in the general population. The HIV positive mothers were poorer and had less education than the general-population mothers. In many respects, HIV positive mothers fed their infants less favorably than mothers in the general population, with potentially detrimental effects on both the child's nutrition and the risk of HIV transmission. Mixed feeding and pre-lacteal feeding were widespread in this study. Breastfeeding duration was shorter among HIV positive mothers. Higher educational level and being socioeconomically better off were associated with more beneficial infant feeding practices.[50]

Rollins et al., in 2009, completed a study to determine the late HIV transmission and survival risks associated with early infant feeding practices. HIV-infected pregnant women attending rural and semi-urban antenatal clinics in Kwa Zulu Natal (KZN), South Africa, were enrolled into a non-randomized intervention cohort study. The dilemma of how to best feed infants and young children of HIV-infected mothers living in prevalent HIV communities remains complex. Exclusive breastfeeding carries a lower risk of HIV transmission over the first six months of life but is infrequently practiced by mothers, or effectively supported by health systems. Replacement feeding avoids all postnatal HIV transmission but carries the risk

of death, when given in household circumstances that are not ideal. Early data suggest that highly active antiretroviral treatment (HAART), given to HIV-infected mothers during the period of breastfeeding, can reduce transmission risks even if she is already immune-deficient. The quality of counseling to guide women in their choice of infant feeding practice, and the practical support to enable these choices, is frequently deficient. Due to this fact, sub-optimal feeding practices have resulted in higher mortality of HIV-exposed infants. While there is substantial research regarding the transmission risks of infant feeding practices of HIV-infected mothers, in the first six months of life, the pattern of feeding beyond this period is equally important in determining child survival. This particular study, describes the outcome of infants that were part of an intervention cohort study in which feeding practices were intensively supported. The data showed an 18 month HIV-free survival of HIV-exposed infants, according to infant feeding practices implemented at birth, and secondly, by infant feeding practices between zero to six months of age and subsequent feeding practices beyond six months of age. Mothers were visited at home by infant feeding counselors, three or four times in the first two weeks of life and every two weeks thereafter, until the infant was six months of age. Mothers who chose to replacement feed, and who encountered problems, were principally supported by the infant feeding supervisor or study nurses when referred by infant feeding counselors, following a home visit or when they visited the study clinic. Mothers and infants were given continuous follow up appointments at the study clinic beginning at six weeks of age, and every month thereafter until the infant reached 18 months of age. At each visit a dried blood spot sample was collected for determination of HIV status by quantitative HIV/RNA assay (Nuclisens HIV-1 QT, Organon Teknika, Boxtel, The Netherlands and Nuclisens Easy Q HIV-1, Biomerieux, Boxtel, The Netherlands). HIV status was determined

at five months of age to guide counseling on infant feeding practices after six months. An independent group of field monitors visited mothers, at home, every week from birth until the infant was nine months of age, and documented all feeds and morbidity episodes for each day. When HIV negative infants were five months old, the mothers were counseled to stop breastfeeding (at six months). Mothers were counseled to continue breastfeeding infants who were already confirmed HIV positive. All mothers were counseled regarding the introduction of complementary feeds. Single-dose Nevirapine was provided to all HIV-infected women, and their infants, for use during labor and delivery, and Cotrimoxazole was provided to all HIV exposed infants. A six months' supply of commercial infant formula was offered free through the KZN PMTCT program at the end of 2002. CD4 counts were performed on HIV-infected women, antenatally but were not routinely considered in infant feeding counseling. At each clinic visit, all mothers were checked for symptoms and weight, and referred to the local hospital for diagnostic services if indicated. At the time of the study, HAART was not available through the provincial health services. 1,193 live-born infants were included. Overall, 18-month probability of death 95% CI was 0.04 (0.03-0.06) and 0.53 (0.46-0.60) for HIV-uninfected and infected children, respectively. 18-month probability of survival was not statistically, significantly different for HIV- uninfected infants breastfed or replacement fed from birth. In univariate analysis of infant feeding practices, the probability of HIV-free survival beyond the first six months of life, in children alive at six months was 0.98 (0.89-1.00) amongst infants replacement fed from birth, 0.96 (0.90-0.98; $p$ = .25) and 0.91 (0.87-0.94; $p$ = .03) in those breastfed for less or more than six months, respectively. In multivariable analyses, maternal unemployment and low, antenatal CD4 counts were independently associated with more than three-fold increased risk of infant HIV infection or

death. Breastfeeding and replacement feeding of HIV uninfected infants were associated with similar mortality rates at 18 months. However, these findings were amongst mothers and infants who received excellent support to first make, and then practice, appropriate infant feeding choices.[51]

AIDS has been reported in all the states of the Mexican Republic. 55 percent of AIDS cases are concentrated in the Federal District, State of Mexico, and in Jalisco.[52] The highest number of infections occur in the 25 - 44 years of age group. Thus, AIDS has become the third most common cause of death in men, and the sixth cause of death in women, within this age group.[53] Pediatric AIDS represents 2.6 percent of the cumulative number of cases in Mexico, of these 50 percent were infected prenatally.[54]

The major elements of the PMTCT protocol of Malamulo Hospital are:

1. sdNVR to mother and offspring of HIV (+) (not AIDS) women.
2. Cotrimoxazole prophylaxis therapy daily for pregnant women.
3. Recommendation of strict exclusive breastfeeding.
4. Recommendation of breastfeeding for only six months.
5. Follow up of mother-offspring pair monthly for 18 months (see Figures 5, 6, 7, 8 and 9).

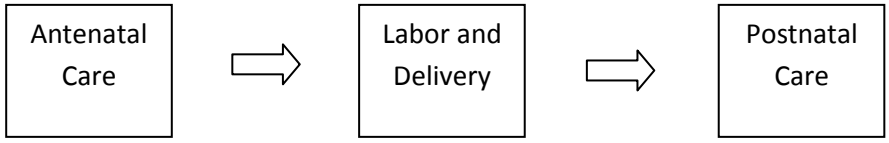



*Figure 5*. PMTCT Processes at Malamulo Hospital.

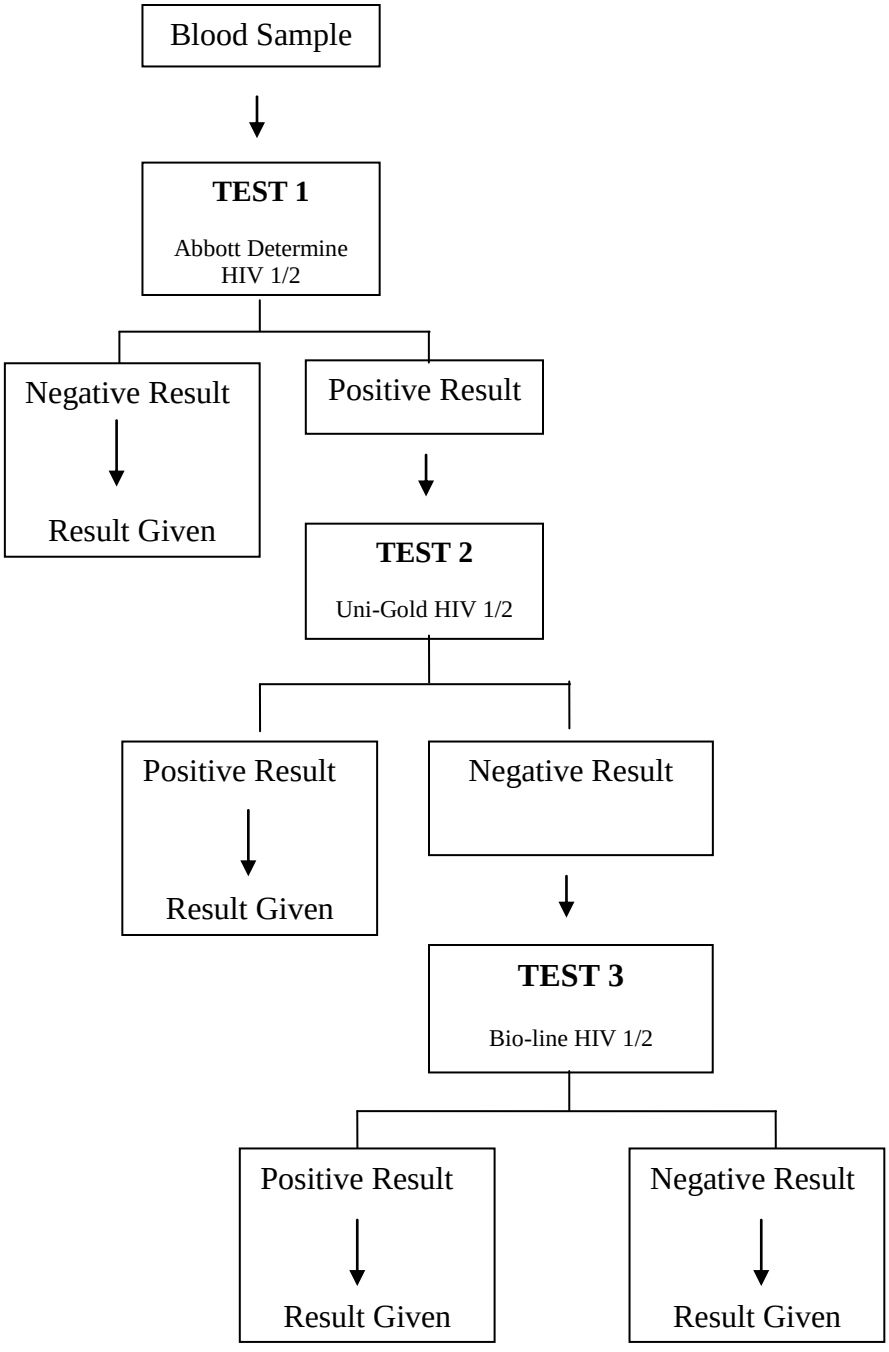



*Figure 6*. HIV Screening Test.

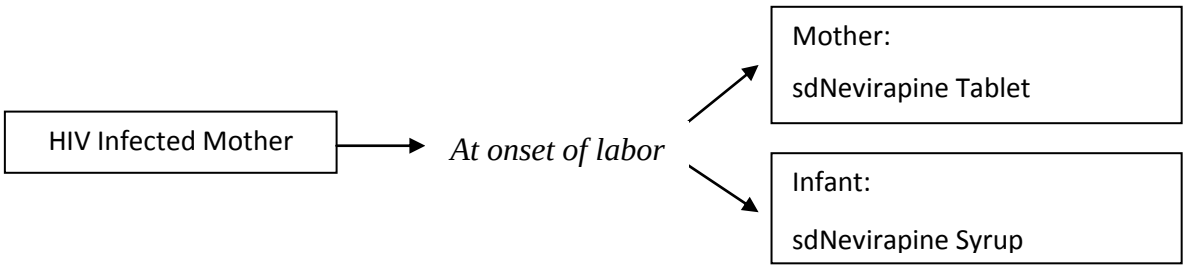



*Figure 7*. PMTCT Algorithm.

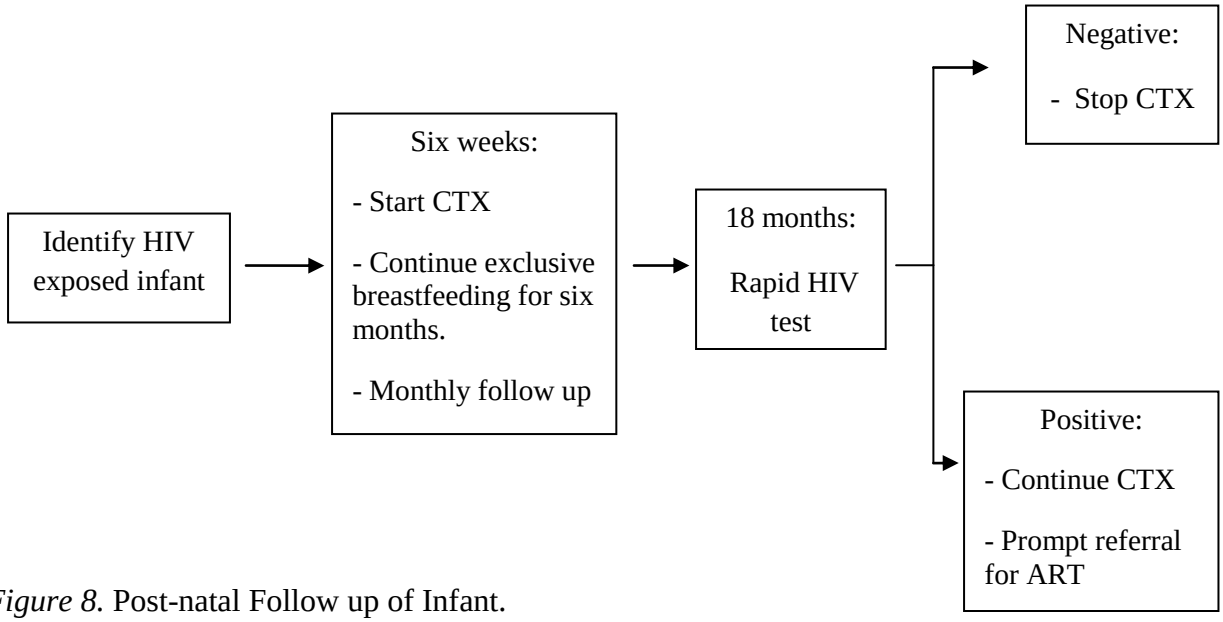



*Figure 8.* Post-natal Follow up of Infant.

.

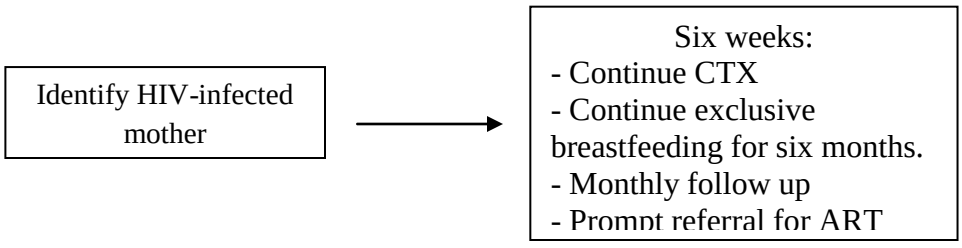



*Figure 9***.** Post-natal Follow up of Mother.

All are supported by prior studies or information that was available at the time of the implementation of the program. This clinical audit will evaluate how effective the empiric protocol has been and how safe it has been with respect to infant mortality and Stevens Johnson Syndrome.

# CHAPTER III

# METHODOLOGY AND PROCEDURES

## Research Design

This study is a retrospective clinical audit of the, then existing, clinical program for the prevention or abatement of MTCT (Vertical Transmission) of the HIV adopted by the Malamulo Hospital in Malawi, Africa. It is a retrospective study because the audit/ research were conducted after the fact.

### Population and Sampling

The study was conducted at Malamulo Hospital in Makwasa, Malawi. The universe of patients consisted of all pregnant women seen at the hospital during the study period. The population of interest consisted of all women diagnosed as pregnant, from July 2004 - June 2008. Of this population, the study cohort consisted of only pregnant HIV (+) mothers and their children who were alive until 18 months of age, and were tested for HIV. All subjects were participants of the PMTCT program at Malamulo Hospital.

As a clinical audit it did not require approval by an Institutional Review Board or Bioethics Committee[25]. It is classified as a clinical audit because of the intent of the study, and because the researcher did not participate in the selection of the intervention nor could modify it for research purposes. It can also be classified as a retrospective program evaluation as is the custom in the Public Health[27].

The detailed process for selection and the Malamulo PMTCT Program protocol is as follows (see Figure 10):

All pregnant women who came to Antenatal Clinic (ANC) and gave consent to participate in the PMTCT program at Malamulo Hospital were registered, between July 1, 2004 and June 30, 2008, following the Guidelines of 2004 by the Government of Malawi through the Ministry of Health, National AIDS Commission, and representatives of local and international non-governmental organizations (NGOs) and development partners guided by WHO on PMTCT and Pediatric HIV Care of HIV prevention.

All registered pregnant women were then counseled for HIV testing. Upon obtaining consent for testing, the Determine®for HIV1-2 (Abbott Laboratories), a rapid HIV screening test was performed. This test is a visual read, qualitative immunoassay for the detection of antibodies to HIV- 1 and HIV- 2. All pregnant women who were HIV (+), according to this test, were subjected to a confirmatory HIV test, Uni-Gold™(Trinity Biotech) for the rapid detection of antibodies to HIV-1 and HIV-2 virus in serum, plasma or whole blood. If this test was also positive then the subject was considered and labeled HIV (+). If the results of the Determine® and Uni-Gold™ were discordant, a third rapid test, Bio-line® (Standard Diagnostic Laboratories) was applied to determine HIV status by preponderance of evidence.

All HIV (+) pregnant women were further checked for CD4 count. If the result was below 350cell/$mm^3$, the woman was referred to the antiretroviral therapy (ART) clinic, to start the Antiretroviral (ARV)'s therapy. All HIV (+) pregnant women were followed up during the pregnancy. Cotrimoxasol prophylaxis therapy (CPT), for opportunistic super infection, was given at various times during pregnancy.

Pregnant HIV (+) women who dropped out of the program were not candidates for the audit. Women who had abortions or stillbirths were also not considered candidates since they did not deliver a viable child.

Towards the last trimester of the pregnancy, Nevirapine (NVP) was given to the expectant woman to take home: one tablet 200 mg, single dose for the woman, to take at onset of labor and 0.6 ml of single dose NVP (2 mg/kg) for the anticipated newborn in case for any reason the woman could not return to the hospital on time for her delivery. Instructions were given regarding the timing for dose administration to the neonate if return to the hospital was unachievable. Nonetheless, if the woman was able to return to the hospital for delivery, she was instructed to carry the NVP tablets and syrup so that the midwife or nurse could take charge of its administration for both the mother and the infant.

After delivery, counseling regarding breastfeeding were given to the mothers. When the infant reached six weeks of age, the mothers brought their infants in for the commencement of CPT. Mother and infant were to return a monthly follow up for nutritional assessment of both mother and infant. This evaluation included, weight, measuring of middle upper arm circumference of the infant, and if mothers has evidence of mastitis or cracked bleeding nipples. CPT for both the mother and the infant were also supplied at the time of this monthly visit. Data were collected on the children who died before reaching 18 months of age. All live infants, at 18 months of age, were tested for rapid HIV screening test following the same system as the mothers. If the infants were tested positive, ART was started and CPT was continued. If the infant was HIV negative, CPT was stopped.

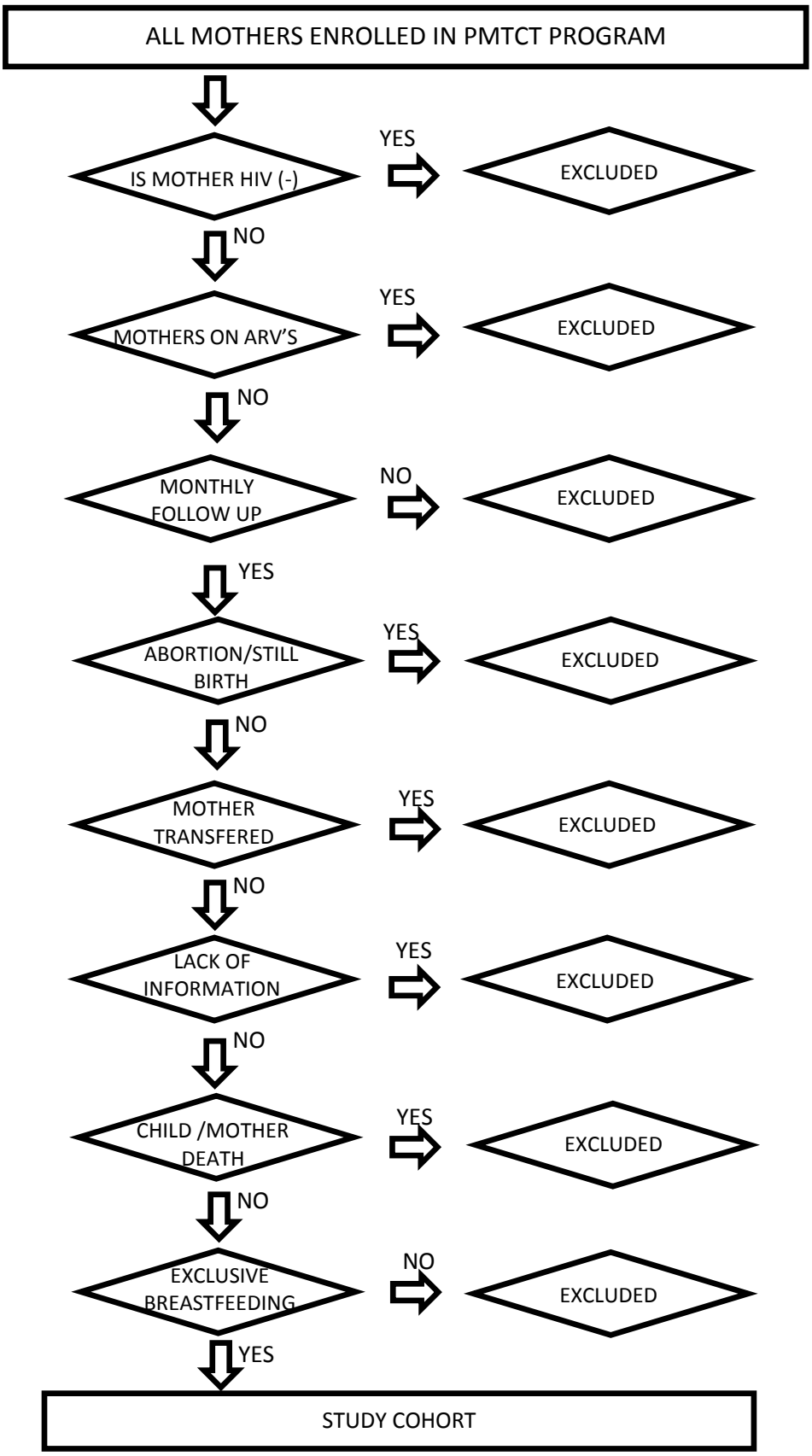



*Figure 10*. Procedure for Exclusion.

## Data Gathering Procedures

Data were collected from three physical registries at Malamulo Hospital: the *Antenatal Clinic Register Book*; *Delivery Register Book*; and the *PMTCT's Follow up- Nutrition Register Book*. The *Antenatal Clinic Register Book* contained records of the first prenatal visit, weight, parity, last menstrual period, and the screening test for HIV along with monthly appointments from entry into the program until the time of delivery. The *Delivery Register Book* in the Maternity Ward, contained information about the date of delivery, mode of delivery, gender and weight of the infant, and the administration of Nevirapine to mother and newborn. The third register book used was the *PMTCT's Follow up- Nutrition* for children in the Under Five Clinic. This phase of the program started six weeks after birth, and involved the results of the monthly visits, including weight of the infant, nutrition evaluation, measurement of middle upper arm circumference and CPT monthly supply. At the age of 18 months the rapid HIV screening test was performed to check the children's HIV infection status using the test procedure as described previously.

Data were cross tabulated, checked and rechecked for consistency. When there was doubt as to the accuracy or reliability of an entry or when corroborating evidence was lacking, that subject was excluded from analysis. The cross referencing scheme is described in Table 5.

Table 5

*Patients' Registry Books Data Collection*

| Data | Registry 1<br>Antenatal Clinic | Registry 2<br>Delivery Book | Registry 3<br>PMTCT's Follow-up Nutrition |
|---|---|---|---|
| Pregnancy | Inclusion | Verification | Selection |
| Delivery Date | ----- | Verification | Verification |
| HIV status | Identification | Verification | Verification |
| ARV | Identification | Exclusion | ----- |
| Breastfeeding | ----- | ----- | Verification |

## Characterization

We define the efficacy of this intervention, in this audit, as the lack of transmission of HIV from mother- to- child at 18 months postdelivery. To account for these children, the data mining was set at an 18 months offset from July 1, 2004. Due to this fact only offspring of HIV (+) mothers who were alive at 18 months, after July 1, 2004, were candidates for audit. This resulted in a retrospective review of mother and infant records from April 2006 - December 31, 2009.

For the purpose of this study, efficacy was evaluated as the percentage of offspring who were in Malamulo program and who with full adherence to the protocol were free of HIV at 18 months. This number was then compared with that reported in the literature by UNICEF as a comparative standard. Mothers or children, who were deceased or not in the follow up group were not included in the evaluation of efficacy.

However, the evaluation of safety considered all children who were delivered viably and received prophylaxis but were not alive at 18 months. For the purpose of the audit we defined the safety of the Malamulo protocol as the infant survival rate at 18 months (infant viability at 18 months). This is calculated as (100-mortality rate at 18 months) and is expressed as a percentage.

## Variables

Dependent Variable

**Transmission of HIV**

1. HIV (+) pregnant mothers who receive Nevirapine as ART prophylaxis during delivery.

2. Exposed newborns from infected HIV mothers who receive Nevirapine as ART Prophylaxis 72 hours after delivery.

3. Mothers who accepted to breastfeed their newborns with Exclusive Breastfeeding (EBF) program for six months only and then cessation.

4. A follow-up on the children in study until the age of 18 months old and tested for rapid HIV screening test.

5. The variable was used as a metric. For this reason, the “0” value was assigned to children who were infected and “1” to uninfected children. Based on the coding, the variable is considered a "dummy", so that an average close to unity is reached indicating a higher proportion of uninfected children.

6. Infant survival at 18 months.

Independent Variables

**Use of Antiretroviral Therapy (Nevirapine)**

Pregnant mothers who are tested HIV positive, give birth to live infants and receive NVP as prophylaxis to ARV’s therapy were considered independent variables for this study. Exposed infants who receive NVP prophylaxis immediately after delivery or during 72 hours after delivery.

**Breastfeeding**

Mothers who accepted to give exclusive breastfeeding to their infants are also noted and observed. Follow-up evaluations were also completed with these infants until the age of 18 months after which they were tested for rapid HIV screening test.

**Statistical Treatment of the Data**

All data were coded with unique identifiers and the names of mother and infant were omitted for confidentiality.

The effectiveness data sets were analyzed by t-test, using Statistical Package for the Social Sciences SPSS version 19.0

# CHAPTER IV

# RESULTS

## Description of Sample

There were a total of 5,283 pregnant women enrolled at Malamulo's PMTCT program. After consenting to do HIV testing, 4,465 women were negative and 818 were positive.

Of the 818 women who were reported as HIV positive, seven were already taking ARV's for a life time dose; these mothers were excluded from this study. Another 451 did not come in for a follow up and were also excluded. Of the 360 remaining women, nine requested to be transferred to another institution, and were also excluded. An additional eight mothers who had abortions or still birth were also excluded from this study. They were nine cases which lacked information regarding the mothers or infants took sdNVP were also excluded. During the study 22 children died before the age of 18 months. Among a group of seven women, two decided not to exclusively breastfeed their infants: one gave only formula milk while the other provided mixed feeding, and both were excluded from this study.

After screening for eligibility only 303 women were accepted into this study, with a total of 305 infants due to a pair twin births. For the purpose of this study, only one infant per mother was considered, because there were no discordant results on vertical transmission of HIV among the twins.

Thus the audit cohort for effectiveness consisted of 303 mother-infant pairs.

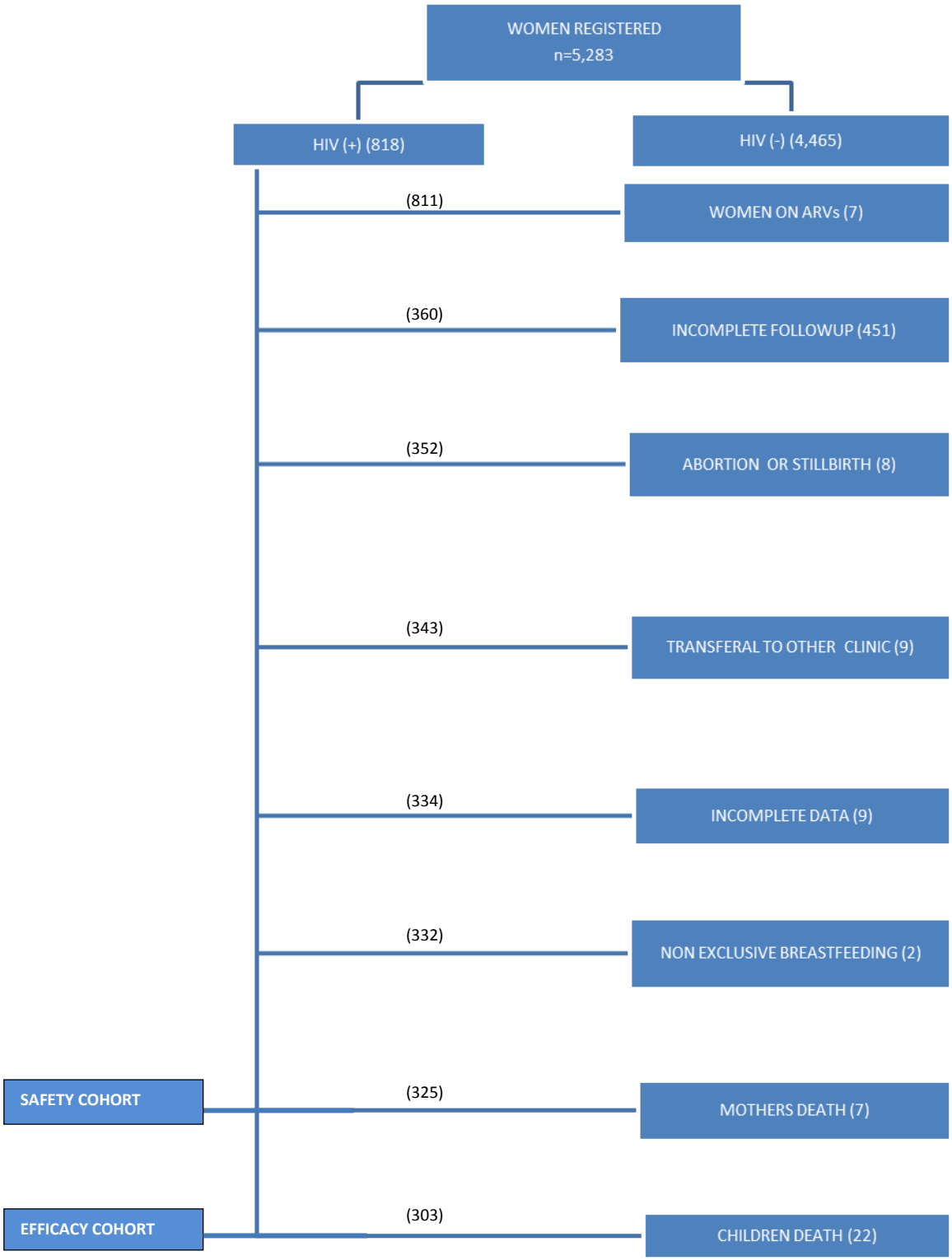



*Figure 11.* Audit's Sampling Data.

## General Findings and Demographic Descriptions

The majority of the pregnant women preferred to deliver their infants at home attended by midwives or traditional birth attendants due to financial constraints. However, with the hospital's PMTCT program, all delivery costs were subsidized by financial aid from the Ministry of Health through the district headquarter in Thyolo. There were 300 vaginal deliveries and three caesarean sections performed. There was an increase in the number of hospital deliveries (269) versus home deliveries (34), showing a significant change in the community norms.

The location of delivery shows that those infants born at the hospital had a higher incidence of being HIV negative than those born at home. (Chi Square (1) = 12.731, $p$ = .000). 18.5% of children born at home were HIV positive, compared to only 3.3% of children born in the hospital (see Appendices D and E).

Pregnant women who were enrolled in the PMTCT program belong to the 16-41 years of age demographic group. The majority were classified as multipara (272), while 31 were classified as primigravida.

## Description of the Dead Infants Group

Causes of death among some children in the clinical audit were: malaria, anemia, pneumonia, and malnutrition. Other causes of death were unknown. The average age of death was seven months. Three were neonatal deaths and one died at 14 months of age. 21 were born vaginally and one by caesarean section. The average birth weight was 2.9 kg.

## Description of the 14 HIV(+) Infants

From the 303 infants, 14 (4.62%) were HIV positive while 289 (95.38%) were HIV

negative. From the 14 HIV positive infants six were masculine and eight were feminine. Five of those infants were born at home and the other nine were born at the hospital (see Table 6). Of the HIV negative infants, 263 were born at the hospital, 22 at home, and four were BBA (born before arrival). The majority of mothers delivered their infants at the hospital vaginally (see Figure 12).

Table 6

*Number of HIV Positive Children (*n = *14)*

| | Sex | | | | |
|---|---|---|---|---|---|
| Child No. | Masculine | Feminine | Weight kg | Birthplace | Mode of Delivery |
| P26 | | X | 2.7 | Hospital | Normal |
| P69 | X | | 2.9 | Hospital | Normal |
| P113 | X | | 0.0 | Home | Normal |
| P152 | | X | 3.0 | Hospital | Normal |
| P160 | X | | 0.0 | Home | Normal |
| P165 | | X | 0.0 | Home | Normal |
| P204 | X | | 0.0 | Home | Normal |
| P211 | | X | 3.2 | Hospital | Normal |
| P217 | X | | 2.9 | Hospital | Normal |
| P224 | | X | 3.1 | Hospital | Normal |
| P230 | | X | 3.2 | Hospital | Normal |
| P247 | | X | 0.0 | Home | Normal |
| P254 | X | | 3.5 | Hospital | Normal |
| P266 | | X | 3.0 | Hospital | Normal |

There were other covariates such as maternal age, infant's birth weight, infant's gender, and mother's parity but they did not make any significant relevance to the study.

The dependent variable is the transmission of HIV in mothers and infants who received sdNevirapine as ARV prophylaxis and mothers who gave EBF, showing a significant and important difference (see Appendices F, G, and H).

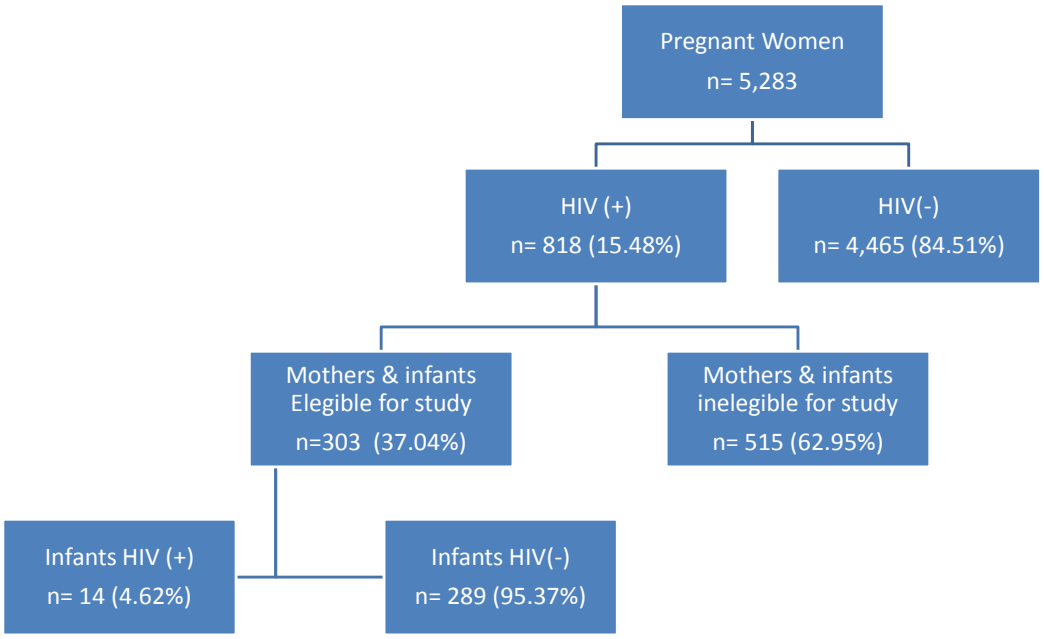



*Figure 12.* HIV (+) Results in the Audits.

# CHAPTER V

# DISCUSSION, CONCLUSION AND RECOMMENDATIONS

## Discussion

Mother-to-child transmission (MTCT) of HIV can occur antenatally (in utero), intrapartum (labor and delivery), and postpartum (breastfeeding). The PMTCT program at Malamulo, with sdNevirapine for mother and infant, along with exclusive breastfeeding for six months, had reduced this burden of pediatric morbidity and the prevalence of HIV in the community. Earlier, this option for preventing HIV was limited to sdNevirapine, but now with the emergence of other ARV's it has improved the strategies of MTCT. This study was done with the aim of evaluating the efficacy of sdNevirapine which is the only available resource during the time of study and EBF for six months.

The pregnant women at Malamulo Hospital continued their follow up on monthly bases upon beginning their prenatal control at Malamulo Hospital. However when the time of deliver came they preferred to go to another hospital or a home delivery by Traditional Birth Attendant due to the lower cost. In response to these events, the Hospital Administration signed an agreement with the Ministry of Health (MOH) through the Thyolo District Hospital allowing all the pregnant women, registered in the PMTCT program, coverage by the government. With this provision the number of hospital deliveries increased. Despite the provision made by the MOH there were still some cases of pregnant women delivering at home. The place of delivery showed that there was a higher incidence of HIV negative cases .from infants born at the hospital versus

those infants born at home. The reason of this incidence is due to the fact that the nurses make certain that the patients take the NVP drug.

Previous studies had shown that performing cesarean section to infected women would reduce the transmission of HIV but at Malamulo Hospital this was not a routine procedure.

The nurses who received citation carried out training sessions with those mothers who implemented cessation of breastfeeding at six months. When the infants reached five months, the mothers came to the clinic to learn how to express the milk from their breasts into a clean cup. Afterwards, the mothers gave the milk to their infants, via the cup, in this way the infants will be ready to accept the cup directly from their mothers. Mothers were advised to breastfeed for six months only, because the infants can cause lesions on the nipple of the mother's breast due to their protruding teeth, which can increase the risk of infection.

Exclusive breastfeeding was advised because studies had shown that mixed feeding can cause lesions on the infants' digestive tract, increasing the risk of acquired infection.

After cessation of breastfeeding, the mother are more susceptible to becoming pregnant again, therefore, the nurses give counseling for family planning, and prompt them to start a lifelong intake of ARV drugs.

In 2009, Goya et al. implemented a prospective observational cohort study at three routine prevention of MTCT sites in South Africa where they studied operational feasibility and predictors of complete breast-feeding cessation (CBC) to reduce MTCT of HIV. At programmatic level, CBC by 24 weeks is uncommon, and success seems unrelated to predetermined social, economic, and environmental (acceptable, feasible, affordable, sustainable, and safe AFASS) criteria. Thus, at this level, activities that encourage CBC (amongst women meeting AFASS criteria) need to be identified and tested. The study was

conducted at three government PMTCT sites: Paarl, Umlazi, and Rietvlei, purposively selected to reflect different socioeconomic contexts, rural–urban locations, and HIV prevalence rates. In summary, HIV prevalence was 9% in Paarl, 28% in Rietvlei, (rural site), and 47% in Umlazi, and infant mortality rates (per 1000 live births) were 40, 99, and 60, respectively. The study shows that completely stopping breastfeeding, by 24 weeks, was not feasible amongst most EBF/PBF (Predominant Breast-feeding) HIV positive women-only 39%-44% reported NBF or complete cessation of BF.[55]

## Rejection of the Null Hypothesis

$H_o$. There is no difference in outcome between HIV positive children of mothers infected by HIV who received antiviral prophylaxis and exclusive breast feeding for six months compared with HIV positive children who received no specific intervention according to UNICEF.

To prove the null hypothesis the *t- test Student for a group* was applied. The mean of the distribution of uninfected children in the sample ($M$ = 0.95) with the mean provided by the UNICEF ($M$ = 0.8) were compared. Null hypothesis was rejected because the probability level was below the established level of significance ($t(302) = 12.731$, $p = .000$) which means that there is a sufficient evidence to accept that the HIV transmission in children is considered significantly less than the data provided by UNICEF about infants without medical intervention. The effect size of the difference is 0.73. This value indicates that the difference is important in magnitude since it is greater than 0.3.

## Conclusion

The study shows efficacy of the PMTCT program protocol implemented at Malamulo Hospital because the MTCT of HIV from mother-to-child had been reduced using ART prophylaxis (for mothers and infant) and EBF for six months, compared to not implementing any protocol.

The use of sdNevirapine demonstrated reliability due to a lack of side effects amongst the participants and a high tolerance rate since nobody ceased using the medication.

In this population, compliance was very high suggesting that the regimen was simple enough that women can follow.

The researcher concludes that this type of audit was useful. Even though the hospital did not request a follow up of this investigation, this kind of evaluation was considered to be helpful for other programs in the future.

Additional benefits concluded from this study was the use of Cotrimoxasol given to mothers and children due to the fact that they did not acquired any opportunistic infections.

The study shows that the number of HIV infected children decreased; however, there were still quite a few of the children who were HIV positive. A contributing factor is the use of single dose prophylaxis making these isolated cases resistant to NVP. Related studies regarding NVP prophylaxis have also shown resistance. At the conclusion of this study Malamulo was in the process of adopting another regimen of ARV prophylaxis for its PMTCT program, adding Zidovudine (AZT) to the infants, and AZT plus Lamivudine to mothers.

It is recommended that another clinical audit will be implemented with this new protocol to compare with sdNevirapine.

## Recommendations

Malamulo Hospital has accomplished a meaningful effort in the PMTCT program, but it needs a continuous follow up and scale up. Some of the recommendations are as follows:

1. Improve the records by completing the information on each column of the registry books and making them legible.

2. Complete additional effort with the follow up of those mothers who are dropping out.

3. To procure more antiretroviral drugs available in the country.

4. To improve the pre and post HIV laboratory screening tests using confirmatory tests such as Western blot and ELISA.

5. Perform repeated HIV tests with mothers just before delivery. This is done because the HIV test at the beginning of the prenatal check up could be negative but those mothers could be in window period.

6. To check on the viral load of each patient before and after taking the ARV drugs.

7. To develop other investigations exploring same variables with other populations and compare the results of this study. The comparative study it should determine if the findings will be similar.

8. To include other variables that could have strong association with the HIV disease such as the use of urban region.

9. Include a pilot group in another study to compare the results.

## APPENDIX A

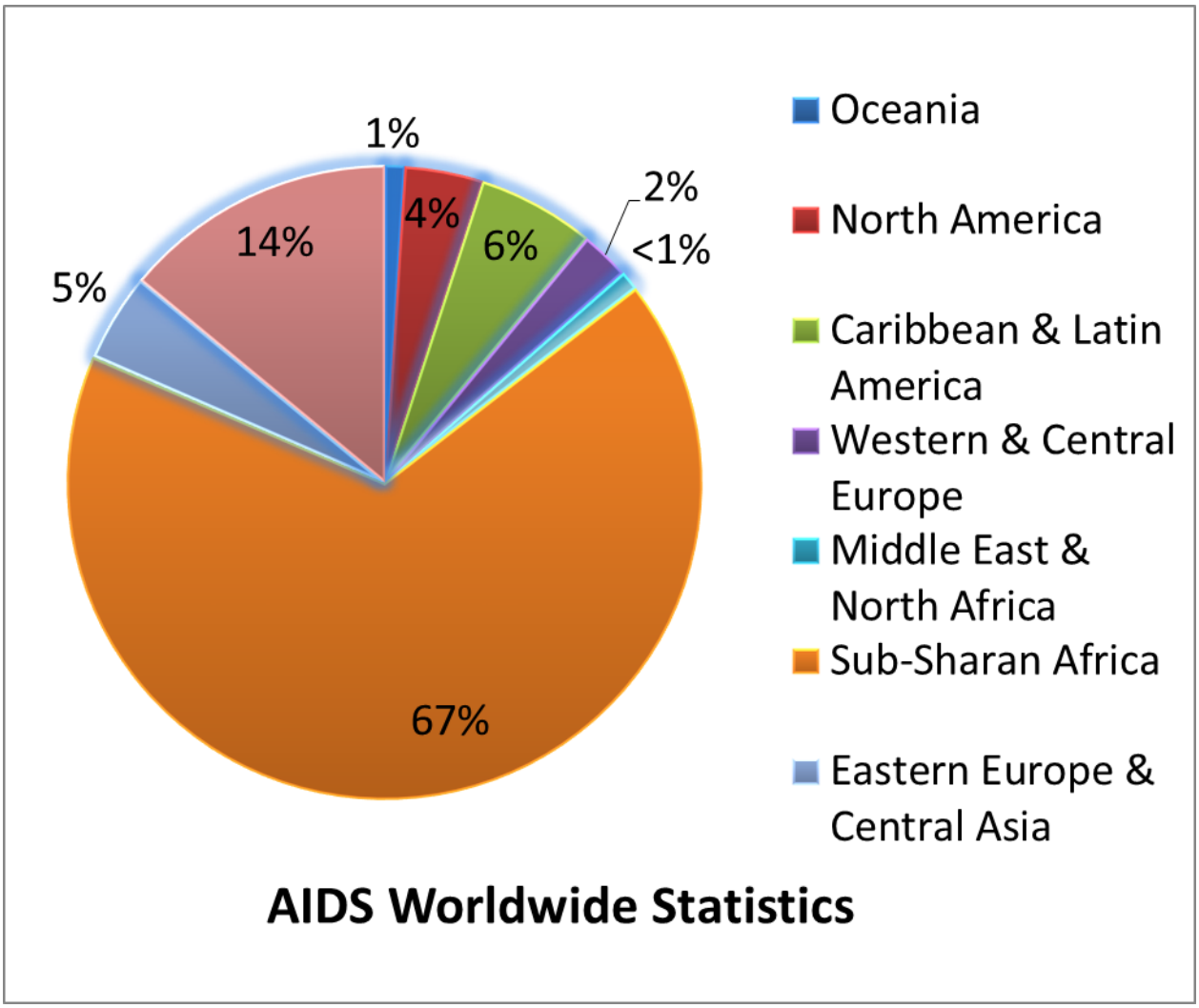
## GLOBAL SUMMARY OF THE AIDS EPIDEMIC

| Global summary of the AIDS epidemic, 2010 | |
|---|---|
| **Number of people living with HIV in 2010** | |
| Total | 34.0 million [31.6–35.2 million] |
| Adults | 30.1 million [28.4–31.5 million] |
| Women | 16.8 million [15.8–17.6 million] |
| Children under 15 years | 3.4 million [3.0–3.8 million] |
| **People newly infected with HIV in 2010** | |
| Total | 2.7 million [2.4–2.9 million] |
| Adults | 2.3 million [2.1–2.5 million] |
| Children under 15 years | 390,000 [340,000–450,000] |
| **AIDS deaths in 2010** | |
| Total | 1.8 million [1.6–1.9 million] |
| Adults | 1.5 million [1.4–1.6 million] |
| Children under 15 years | 250,000 [220,000–290,000] |

WHO & UNAIDS, 2010

**APPENDIX B**

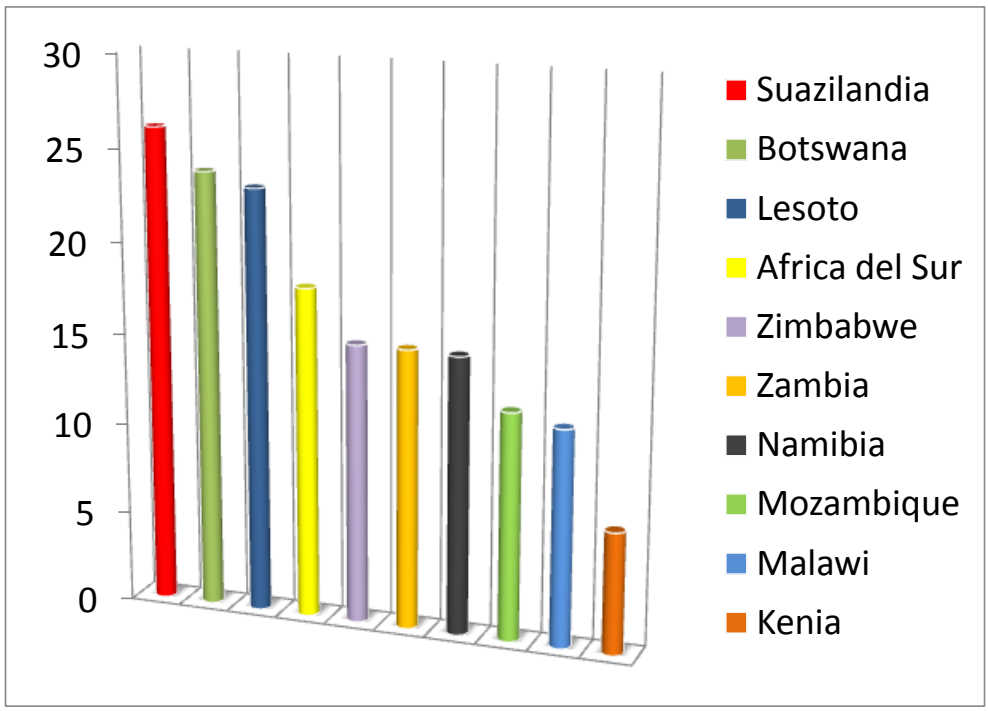
**AIDS WORLDWIDE STATISTICS**




The latest statistics of the global HIV and AIDS epidemic were published by UNAIDS, WHO and UNICEF in November 2011, and refer to the end of 2010.

## APPENDIX C

## ESTIMATED HIV PREVALENCE IN TEN COUNTRIES AROUND THE WORLD WITH THE HIGHEST PREVALENCE



# APPENDIX D

## T-TEST

**One-Sample Statistics**

| | N | Mean | Std. Deviation | Std. Error Mean |
|---|---|---|---|---|
| Infant HIV | 303 | .95 | .210 | .012 |

**One-Sample Test**

| | Test Value = .8 | | | | | |
|---|---|---|---|---|---|---|
| | | | | | 95% Confidence Interval of the Difference | |
| | t | df | Sig. (2-tailed) | Mean Difference | Lower | Upper |
| Infant HIV | 12.731 | 302 | .000 | .154 | .13 | .18 |

# APPENDIX E

## PLACE DELIVERY CROSS TABULATION

**Case Processing Summary**

| | Cases | | | | | |
|---|---|---|---|---|---|---|
| | Valid | | Missing | | Total | |
| | N | Percent | N | Percent | N | Percent |
| Infant HIV * Place delivery | 299 | 98.7% | 4 | 1.3% | 303 | 100.0% |

**Infant HIV * Place Delivery Cross Tabulation**

| | | | Place delivery | | |
|---|---|---|---|---|---|
| | | | 0 Home | 1 Hospital | Total |
| Infant HIV | 0 HIV positive | Count | 5 | 9 | 14 |
| | | % within Place delivery | 18.5% | 3.3% | 4.7% |
| | 1 HIV negative | Count | 22 | 263 | 285 |
| | | % within Place delivery | 81.5% | 96.7% | 95.3% |
| Total | | Count | 27 | 272 | 299 |
| | | % within Place delivery | 100.0% | 100.0% | 100.0% |

**Chi-Square Tests**

| | Value | df | Asymp. Sig. (2-sided) | Exact Sig. (2-sided) | Exact Sig. (1-sided) |
|---|---|---|---|---|---|
| Pearson Chi-Square | 12.731[a] | 1 | .000 | | |
| Continuity Correction[b] | 9.551 | 1 | .002 | | |
| Likelihood Ratio | 8.125 | 1 | .004 | | |
| Fisher's Exact Test | | | | .005 | .005 |
| Linear-by-Linear Association | 12.689 | 1 | .000 | | |
| N of Valid Cases | 299 | | | | |

**Chi-Square Tests**

| | Value | df | Asymp. Sig. (2-sided) | Exact Sig. (2-sided) | Exact Sig. (1-sided) |
|---|---|---|---|---|---|
| Pearson Chi-Square | 12.731[a] | 1 | .000 | | |
| Continuity Correction[b] | 9.551 | 1 | .002 | | |
| Likelihood Ratio | 8.125 | 1 | .004 | | |
| Fisher's Exact Test | | | | .005 | .005 |
| Linear-by-Linear Association | 12.689 | 1 | .000 | | |
| N of Valid Cases | 299 | | | | |

a. 1 cells (25.0%) have expected count less than 5. The minimum expected count is 1.26.

b. Computed only for a 2x2 table

# APPENDIX F

## CORRELATIONS

**Correlations**

| | | Infant weight | Mother Age | Parity | Gravida | Infant HIV |
|---|---|---|---|---|---|---|
| Infant weight | Pearson Correlation | 1 | .070 | .067 | .091 | -.002 |
| | Sig. (2-tailed) | | .251 | .269 | .137 | .968 |
| | N | 270 | 270 | 270 | 270 | 270 |
| Mother Age | Pearson Correlation | .070 | 1 | .506** | .514** | .015 |
| | Sig. (2-tailed) | .251 | | .000 | .000 | .798 |
| | N | 270 | 303 | 303 | 303 | 303 |
| Parity | Pearson Correlation | .067 | .506** | 1 | .973** | .076 |
| | Sig. (2-tailed) | .269 | .000 | | .000 | .187 |
| | N | 270 | 303 | 303 | 303 | 303 |
| Gravida | Pearson Correlation | .091 | .514** | .973** | 1 | .063 |
| | Sig. (2-tailed) | .137 | .000 | .000 | | .274 |
| | N | 270 | 303 | 303 | 303 | 303 |
| Infant HIV | Pearson Correlation | -.002 | .015 | .076 | .063 | 1 |
| | Sig. (2-tailed) | .968 | .798 | .187 | .274 | |
| | N | 270 | 303 | 303 | 303 | 303 |

**. Correlation is significant at the 0.01 level (2-tailed).

# APPENDIX G

## INFANT SEX CROSS TABULATION

**Case Processing Summary**

| | Cases | | | | | |
|---|---|---|---|---|---|---|
| | Valid | | Missing | | Total | |
| | N | Percent | N | Percent | N | Percent |
| Infant HIV * Infant sex | 303 | 100.0% | 0 | .0% | 303 | 100.0% |

**Infant HIV * Infant sex Cross Tabulation**

| | | | Infant sex | | |
|---|---|---|---|---|---|
| | | | 0 Masculine | 1 Femenine | Total |
| Infant HIV | 0 HIV positive | Count | 6 | 8 | 14 |
| | | % within Infant sex | 4.7% | 4.5% | 4.6% |
| | 1 HIV negative | Count | 121 | 168 | 289 |
| | | % within Infant sex | 95.3% | 95.5% | 95.4% |
| Total | | Count | 127 | 176 | 303 |
| | | % within Infant sex | 100.0% | 100.0% | 100.0% |

**Chi-Square Tests**

| | Value | df | Asymp. Sig. (2-sided) | Exact Sig. (2-sided) | Exact Sig. (1-sided) |
|---|---|---|---|---|---|
| Pearson Chi-Square | .005[a] | 1 | .942 | | |
| Continuity Correction[b] | .000 | 1 | 1.000 | | |
| Likelihood Ratio | .005 | 1 | .942 | | |
| Fisher's Exact Test | | | | 1.000 | .575 |
| Linear-by-Linear Association | .005 | 1 | .942 | | |
| N of Valid Cases | 303 | | | | |

**Chi-Square Tests**

| | Value | df | Asymp. Sig. (2-sided) | Exact Sig. (2-sided) | Exact Sig. (1-sided) |
|---|---|---|---|---|---|
| Pearson Chi-Square | .005[a] | 1 | .942 | | |
| Continuity Correction[b] | .000 | 1 | 1.000 | | |
| Likelihood Ratio | .005 | 1 | .942 | | |
| Fisher's Exact Test | | | | 1.000 | .575 |
| Linear-by-Linear Association | .005 | 1 | .942 | | |
| N of Valid Cases | 303 | | | | |

a. 0 cells (.0%) have expected count less than 5. The minimum expected count is 5.87.

b. Computed only for a 2x2 table

# APPENDIX H

## DELIVERY CROSS TABULATIONS

**Case Processing Summary**

| | Cases | | | | | |
|---|---|---|---|---|---|---|
| | Valid | | Missing | | Total | |
| | N | Percent | N | Percent | N | Percent |
| Infant HIV * Delivery | 303 | 100.0% | 0 | .0% | 303 | 100.0% |

**Infant HIV * Delivery Cross Tabulation**

| | | | Delivery | | |
|---|---|---|---|---|---|
| | | | 0 Delivery by C/S | 1 Normal delivery | Total |
| Infant HIV | 0 HIV positive | Count | 0 | 14 | 14 |
| | | % within Delivery | .0% | 4.9% | 4.6% |
| | 1 HIV negative | Count | 20 | 269 | 289 |
| | | % within Delivery | 100.0% | 95.1% | 95.4% |
| Total | | Count | 20 | 283 | 303 |
| | | % within Delivery | 100.0% | 100.0% | 100.0% |

**Chi-Square Tests**

| | Value | df | Asymp. Sig. (2-sided) | Exact Sig. (2-sided) | Exact Sig. (1-sided) |
|---|---|---|---|---|---|
| Pearson Chi-Square | 1.037[a] | 1 | .308 | | |
| Continuity Correction[b] | .218 | 1 | .640 | | |
| Likelihood Ratio | 1.959 | 1 | .162 | | |
| Fisher's Exact Test | | | | .610 | .376 |
| Linear-by-Linear Association | 1.034 | 1 | .309 | | |
| N of Valid Cases | 303 | | | | |

**Chi-Square Tests**

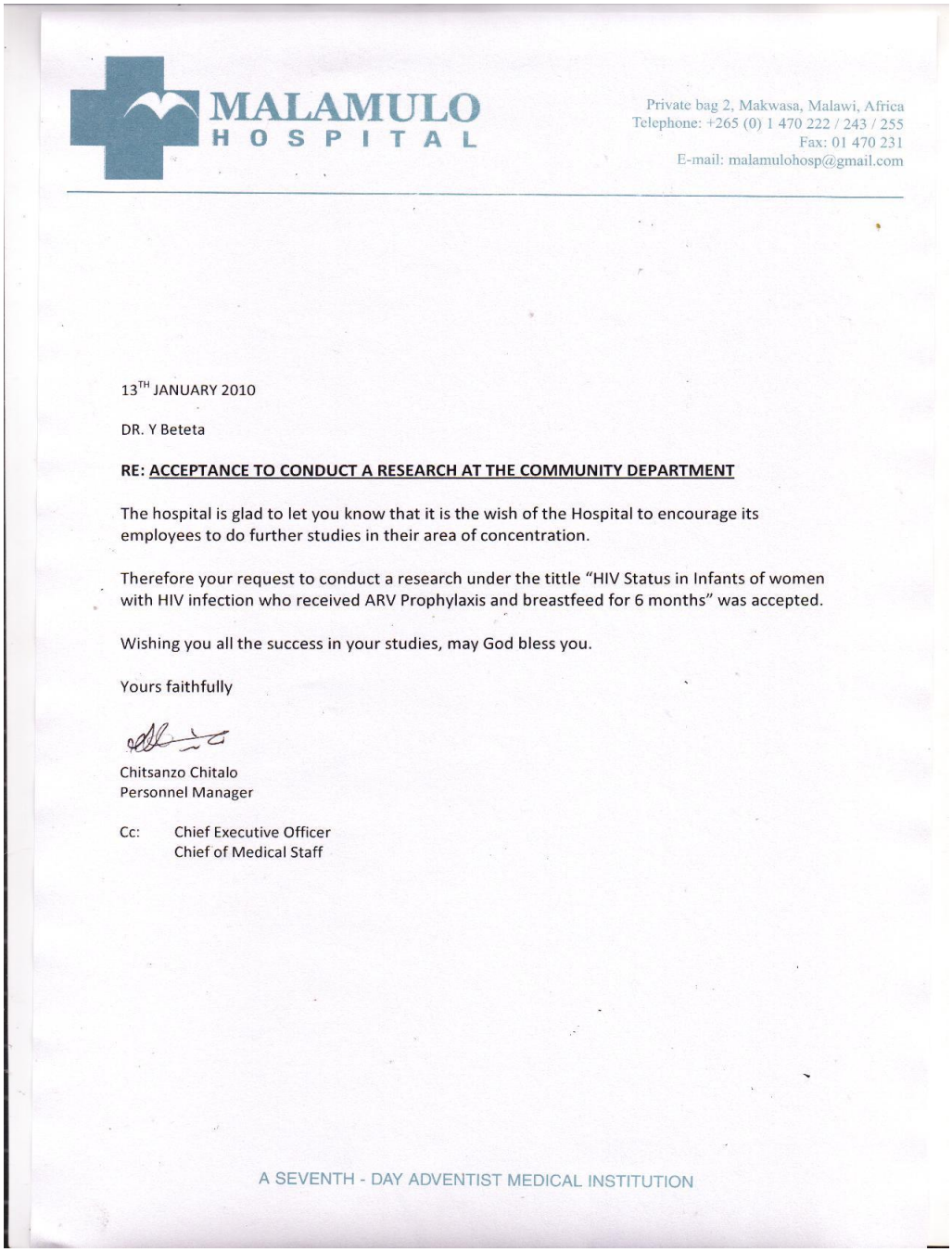
| | Value | df | Asymp. Sig. (2-sided) | Exact Sig. (2-sided) | Exact Sig. (1-sided) |
|---|---|---|---|---|---|
| Pearson Chi-Square | 1.037[a] | 1 | .308 | | |
| Continuity Correction[b] | .218 | 1 | .640 | | |
| Likelihood Ratio | 1.959 | 1 | .162 | | |
| Fisher's Exact Test | | | | .610 | .376 |
| Linear-by-Linear Association | 1.034 | 1 | .309 | | |
| N of Valid Cases | 303 | | | | |

a. 1 cells (25.0%) have expected count less than 5. The minimum expected count is .92.

b. Computed only for a 2x2 table

# APPENDIX I

## LETTER FROM MALAMULO HOSPITAL FOR AUTHORIZATION



MALAMULO HOSPITAL

Private bag 2, Makwasa, Malawi, Africa
Telephone: +265 (0) 1 470 222 / 243 / 255
Fax: 01 470 231
E-mail: malamulohosp@gmail.com

13TH JANUARY 2010

DR. Y Beteta

**RE: ACCEPTANCE TO CONDUCT A RESEARCH AT THE COMMUNITY DEPARTMENT**

The hospital is glad to let you know that it is the wish of the Hospital to encourage its employees to do further studies in their area of concentration.

Therefore your request to conduct a research under the tittle "HIV Status in Infants of women with HIV infection who received ARV Prophylaxis and breastfeed for 6 months" was accepted.

Wishing you all the success in your studies, may God bless you.

Yours faithfully

Chitsanzo Chitalo
Personnel Manager

Cc: Chief Executive Officer
Chief of Medical Staff

A SEVENTH - DAY ADVENTIST MEDICAL INSTITUTION

## APPENDIX J

## GLOSSARY

**AIDS**: Acquired immune-deficiency syndrome. It is the most advanced stage of infection with HIV.

**Antibodies**: Special protein produced by B-cells that is used by the immune system to identify and neutralized foreign objects such as bacteria, fungi, parasites and viruses.

**Antigen**: An antigen is any substance that causes your immune system to produce antibodies against it.

**Anti-retroviral**: Drugs which suppress or prevent replication of HIV

**CD4 cells**: CD4 cells or T-helper cells are a type of lymphocytes (white blood cell) with CD4 receptors that fights infections.

**CD4 count**: The laboratory test most commonly used to measure the number of CD4 cells in a sample of your blood to estimate the level of immune-deficiency in HIV infection.

**EBF**: Exclusive breast feeding. Feeding practice in which an infant receives only breast milk and no other liquids or solids, including water.

**ELISA test**: Enzyme-Linked ImmunoSorbent Assay. A laboratory technique to detect antibodies in the blood.

**False Positive**: A test result that is positive when the person is actually or truly negative.

**False Negative**: A test result that is negative when the person is actually or truly positive.

**HIV**: Human immuno-deficiency virus which causes AIDS.

**HIV Positive**: Refers to a person who was tested HIV positive and therefore has been exposed to the HIV virus and is infected with the virus.

**HIV P24 Antigen**: (HIV antigen test). A core protein found in the virus. The presence of this antigen is evidence of the HIV virus and is usually detectable in the early and very late state of the HIV infection.

**Immune System**: The immune system is a network of cells, tissues, and organs that work together to defend the body against attacks by "foreign" invaders. These are primarily microbes-tiny organisms such as bacteria, parasites, and fungi and viruses that can cause infections.

**Immune-Deficiency**: Is a disorder of the immune system can result in autoimmune diseases, inflammatory diseases and cancer. Immunodeficiency occurs when the immune system is less active than normal, resulting in recurring and life-threatening infections.

**MTCT**: Mother-to-Child HIV Transmission. Also known as vertical transmission. Is the overwhelming source of HIV infection when HIV, the virus that causes AIDS, is passed from a mother to her unborn baby during pregnancy, during birth or during breastfeeding.

**NNRTI**: Non-nucleoside reverse transcriptase inhibitor- a class of anti-retroviral drugs.

**NRTI**: Nucleoside reverse transcriptase inhibitor- a class of anti-retroviral drugs.

**PMTCT**: Prevention of Mother-to-Child Transmission of HIV. strategies to reduce the risk of mother-to-infant transmission during pregnancy, labor and post partum, during infant feeding.

**PCR**: Polymerase chain reaction – a method of testing for the presence of HIV in the body. The polymerase chain reaction (PCR) is a scientific technique in molecular biology to amplify a single or a few copies of a piece of DNA across several orders of magnitude, generating thousands to millions of copies of a particular DNA sequence.

**Retrovirus**: A group of viruses, which replicate by changing genetic RNA into the DNA of host's cells, using the reverse transcriptase enzyme to produce DNA from its RNA genome.

**RDT**: Rapid diagnostic tests are available for detection of the two types of HIV,HIV-1 and HIV-2, or both.

**Sero-conversion**: Is the development of detectable specific antibodies to microorganisms in the blood serum as a result of infection or immunization. The word seroconversion is often used in reference to blood testing for anti-HIV antibodies. In particular, "seroconverted" has been used to refer to the process of having "become HIV positive.

**WB**: Western Blood Test. A highly accurate blood test for antibodies to HIV infection, usually use to confirm a positive HIV ELISA test.

**Window Period**: The time between the initial (first) HIV infection and the development of detectable HIV antibodies. During this time the antibody test will be falsely negative. The test will be negative even though the person is actually infected with HIV.

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**CURRICULUM VITAE**

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**OBJECTIVE** To serve the less fortunate anywhere around the world and promote prevention of diseases through proper health hygiene and education.

**WORK EXPERIENCE**

May 2010 – Present — Private practices, Tecpatán, Chiapas, México

1997 – 2000 — Tecpatán, Chiapas, México

- Performs deliveries and minor surgeries to patients in the community
- Attends to medically related cases of patients 24/7
- Does home visits to patients

July 2003 – May 2010 — Malamulo Hospital, Malawi, África

**Medical Director / Chief of Medical Staff**

- Administers the hospital's medical affairs attending to all administrative issues
- Supervises and attends to the daily routine patient care in all the wards of the hospital
- Chairs the Administrative Council meetings on regular schedule of once a week
- Conducts and coordinates continuing education of clinical officers and physicians working in the hospital

December 2002 – June 2003 — Malamulo Hospital, Malawi, África

**Family Medicine and General Practice**

- Assists in general surgeries, pre-natal care, deliveries and post-natal care
- Attends to in-patients and out-patients in the general and private wards
- Attends to patients at the satellite clinic in Limbe

August 2000 – December 2002 — Linda Vista University, Chiapas, México

**University Physician / Lecturer, Faculty of Nursing**

- Attends to all medical needs of the students, faculty & staff and their families
- Conducts lectures to students of the Faculty of Nursing

1997 – 2000 — Tecpatán, Chiapas, México

**Private Medical Practitioner**

- Performs deliveries and minor surgeries to patients in the community
- Attends to medically related cases of patients 24/7
- Does home visits to patients
- Attends to all medical needs of teachers and their families from the ISSTECH government institution
- Assists the monthly meetings of actualization at the Colegio de Medicos Generales del Estado de Chiapas, Mexico

1990 – 1996 — Davis Memorial Hospital, Georgetown, Guyana

**Missionary Physician / General Practitioner**

- Attends to the medical needs of the patients at the outpatient and inpatient wards
- Attends to emergency cases and intensive care unit cases of patients
- Assists in general surgeries
- Acts as the Medical Superintendent attending to the administrative issues and medical issues of the patients, health workers and other colleagues
- Assists in monthly meetings of actualizations at Guyana Medical Association.

1987 – 1900 — Tecpatán, Chiapas, México

**Private Medical Practitioner**

- Practices general medicine attending to all out-patients, in-patients, deliveries and minor surgeries that comes to the clinic

| | |
|---|---|
| 1983 – 1986 | Cadereyta, Nuevo León<br>México |

**Private Medical Practitioner**

♦ Practices general medicine attending to all patients, deliveries and minor surgeries

## EDUCATION & PROFESSIONAL TRAINING

| | |
|---|---|
| 2012 | Master in Public Health<br>Universidad de Montemorelos, México |
| 2008 – 2010 | Certificate in Family Life Education<br>Universidad de Montemorelos, México |
| 1982 – 1983 | Social Service Public Health Center<br>Cadereyta, Nuevo León, México |
| 1980 – 1981 | Internship Rotation, General Roosevelt Hospital<br>Guatemala |
| 1975 – 1980 | Doctor of Medicine, Universidad de Montemorelos<br>México |
| 1973 – 1975 | BA in Education, Normal Central de Managua<br>Nicaragua |
| 1970 – 1972 | High School, Normal Central de Managua<br>Nicaragua |
| 1967 – 1969 | Secondary School, Colegio Vocacional de<br>América Central, Alajuela, Costa Rica |
| 1961 – 1966 | Primary School, Colegio "El Alba''<br>Guatemala |

## PROFESSIONAL MEMBERSHIP

| | |
|---|---|
| 2001 – 2006 | El Consejo Nacional de Medicina General del<br>Estado de Chiapas, A.C., México |
| 2000 – 2005 | Colegio de Médicos Generales del Estado de<br>Chiapas, A.C., México |

## SEMINARS / CONVENTIONS ATTENDED

| | |
|---|---|
| 2012 | *XV Seminario de Medicina General*<br>Tuxtla Gutiérrez, Chiapas, México |
| 2009 | *Workshop on Local Anesthesia in Surgery, CHAM*<br>Lilongwe, Malawi<br>*Workshop on Basic Trauma Life Support, CHAM*<br>Lilongwe, Malawi<br>*Workshop on Bandages and POP Techniques, CHAM*<br>Lilongwe, Malawi |

| | |
|---|---|
| 2008 | *Workshop on Skin Grafting, CHAM*<br>Lilongwe, Malawi |
| | *Obstetrical Ultra Sound Course (Advanced)*<br>University of Malawi, Blantyre, Malawi |
| 2007 | *V Simposio de Educación y IV Jornadas de Creacionismo,* Universidad de Montemorelos, México |
| | *5$^{o}$ Congreso Internacional Nutriología y Obesidad*<br>Universidad de Monterrey, México |
| 2006 | *Seminar on Managing Problems during ART*<br>University of Malawi, College of Medicine, Malawi |
| | *Short Course in Advanced Life Support in Obstetrics*<br>Soche Hotel, Blantyre, Malawi |
| 2005 | *Obstetrical Ultra Sound Course (for Beginners)*<br>University of Malawi, College of Medicine, Malawi |
| 2004 | *Classroom Training in Antiretroviral Therapy*<br>Ministry of Health, Lilongwe, Malawi |
| 2002 | *Segundo Curso Annual de Dermatologia en el Sureste*<br>Tuxtla Gutiérrez, Chiapas, México |
| | *Taller de RCP Avanzado*<br>Tuxtla Gutiérrez, Chiapas, México |
| | *Taller de RCP Básico*<br>Tuxtla Gutiérrez, Chiapas, México |
| | *2do. Congreso Estatal de Medicina General*<br>Tuxtla Gutiérrez, Chiapas, México |
| | *II Simposium Estatal de Urologia*<br>Tuxtla Gutiérrez, Chiapas, México |
| | *Seminario de Alteraciones en la Esfera Bio-Psico-Social del ser Humano*<br>Universidad Linda Vista, Chiapas, México |
| 2001 | *1er. Congreso Internacional de Médicos Generales*<br>Acapulco, México |
| | *El Programa de Educación Médica Continua 2001, Tópicos Selectos en Cardiología*<br>Tuxtla Gutiérrez, Chiapas, México |
| | *El Programa de Educación Médica Continua 2001 Manejo de las Enfermedades Diarreicas*<br>Tuxtla Gutiérrez, Chiapas, México |
| | *Primer Curso Anual de Dermatología en el Sureste*<br>Tuxtla Gutiérrez, Chiapas, México |
| | *1er Congreso Estatal de Medicina General*<br>Tuxtla Gutiérrez, Chiapas, México |
| | *El Programa de Educación Médica Continua 2001 Actualizaciones en Traumatología y Ortopedia*<br>Tuxtla Gutiérrez, Chiapas, México |
| | *El Programa de Educación Médica Continua 2001 Académica y Clínica* |

| | |
|---|---|
| | Tuxtla Gutiérrez, Chiapas, México |
| | *El Programa de Educación Médica Continua 2001* |
| | *Clínica y Bibliográfica* |
| | Tuxtla Gutiérrez, Chiapas, México |
| 1996 | *Microbiology* Course |
| | White Memorial Hospital, Los Angeles, USA |
| | California, USA |

**INTERESTS**
Traveling around the world, reading, computers, yarn-stitch, photography

**HOBBIES**
Computer Software Literate in MicroSoft (Word, Excel, Powerpoint)

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