A PROCESS EVALUATION OF NURSES' IMPLEMENTATION OF AN INFANT FEEDING COUNSELING PROTOCOL FOR HIV-INFECTED MOTHERS: THE BREASTFEEDING, ANTIRETROVIRAL AND NUTRITION (BAN) STUDY IN LILONGWE, MALAWI

By

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ABSTRACT

YVONNE OWENS FERGUSON: A Process Evaluation of Nurses' Implementation of an Infant Feeding Counseling Protocol for HIV-infected Mothers: The Breastfeeding, Antiretroviral and Nutrition (BAN) Study in Lilongwe, Malawi
(Under the direction of Eugenia Eng)

In prevention of mother to child HIV transmission programs, nurses are responsible for counseling HIV-infected mothers about infant feeding. Studies of nurses' infant feeding counseling in African countries suggest that counseling quality is often poor and may be associated with nursing culture, inadequate training, and health system factors. Few studies, however, have conducted theory-informed process evaluations to assess nurses' implementation of an infant feeding counseling protocol.

This study conducted the process evaluation of an infant feeding counseling protocol for the Breastfeeding, Antiretroviral and Nutrition (BAN) Study, an ongoing clinical trial in Lilongwe, Malawi. Six nurses, trained on World Health Organization recommendations, counseled HIV-infected mothers to exclusively breastfeed for 6 months and stop breastfeeding at 6 months. This study adapted and applied patient-provider communication theoretical concepts to assess nurses' counseling behaviors through: (1) direct observation and audio-taping of 123 infant feeding counseling sessions (30 antenatal and 93 postnatal) using a checklist to document nurses' adherence to specific protocol items; and (2) in-depth interviews with each nurse to document adherence perceptions and attitudes toward the protocol. Analysis included calculating a percent adherence of checklists and constant comparison techniques and visual display matrices for the observation and interview data.

Results indicate that nurses were implementing the protocol at an average adherence level of 90% or above. Adherence to protocol items during the antenatal sessions was 100%. During postnatal sessions, adherence ranged from 92.7% to 97.8%. Nurses' implementation inconsistencies occurred when addressing breast health and breastfeeding cessation issues. An unexpected finding was nurses counseling mothers on proper infant formula preparation, although not detailed in the protocol. Interviews revealed a high nurse to mother ratio and additional counseling training on infant formula and complementary feeding preparation as perceived barriers toward complete protocol adherence.

Findings illustrate that with minimal training, nurses implemented the BAN Study infant feeding counseling protocol as designed. The process evaluation results will help to interpret the BAN Study's impact and health outcomes related to evaluating mother's feasibility to follow infant feeding recommendations. The implication for HIV/AIDS clinical trials is to conduct process evaluations to identify and address potential implementation inconsistencies and, thereby, improve protocol implementation adherence.

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TABLE OF CONTENTS

Page

LIST OF TABLES

LIST OF FIGURES

LIST OF ABBREVIATIONS

AIDS	Acquired immunodeficiency syndrome
ARV	Antiretroviral
BAN	Breastfeeding Antiretroviral and Nutrition
BF	Breastfeeding
CDC	Centers for Disease Control and Prevention
EBF	Exclusive breastfeeding
GDP	Gross domestic product
GNI	Gross national income
HIV	Human Immunodeficiency Virus
LPT	Late postnatal transmission
MTCT	Mother-to-child transmission
PMTCT	Prevention of mother-to-child transmission
RNA	Ribonucleic acid
STI	Sexually transmitted infection
UNAIDS	Joint United Nations Program on HIV/AIDS
UNC	University of North Carolina at Chapel Hill
UNICEF	United Nations Children's Fund
UNDP	United Nations Development Programme
WHO	World Health Organization

CHAPTER I

INTRODUCTION

Problem Statement

Since it was first reported in 1981 (Sepkowitz, 2001), AIDS has been one of the world's most complex and challenging epidemics. With approximately 25.8 million adults and children living with HIV and approximately 2.4 million of them dying of AIDS in 2005 (UNAIDS/WHO, 2005), sub-Saharan Africa is experiencing the worst HIV/AIDS epidemic in the world (UNAIDS/WHO, 2005). Malawi, along with other sub-Saharan Africa countries, has been seriously affected by the HIV/AIDS epidemic. The adult HIV prevalence rate in Malawi is approximately 14.2% (UNAIDS/WHO, 2004), compared to 7.4% for the sub-Saharan Africa region (UNAIDS/WHO, 2005). Further, women in Malawi are disproportionately represented in the HIV/AIDS epidemic, accounting for 56% of the adult HIV prevalence (UNAIDS/WHO, 2004). Approximately 18.5% to 28.4% of pregnant women in Malawi's urban areas are infected with the virus, contributing to the 83,000 children (age 0 to 15 years) living with HIV/AIDS in the country (UNAIDS/WHO, 2004). Although heterosexual contact with an infected partner is the predominant mode of HIV transmission in Malawi, mother-to-child-transmission (MTCT) accounts for 10% of all HIV infections in the country (Malawi Global Fund Coordinating Committee, 2002; National Statistical Office [Malawi] & ORC Macro, 2001). MTCT of HIV can occur during the: (1) antenatal stage; (2) labor and delivery stage; and (3) post-partum stage via breastfeeding (Newell, 2001a). In the absence of preventive measures, such as anti-retroviral (ARV) therapy, high quality

obstetric care and avoidance of breastfeeding, the risk of MTCT ranges from 25% to 42% in developing countries such as Malawi (Malawi Global Fund Coordinating Committee, 2002; BHITS Group, 2004). Although the country has received financial assistance to implement ARV therapy to prevent MTCT (The Global Fund, 2003) during pregnancy and delivery, the risk of HIV transmission to the infant during breastfeeding among the population is still present because of socio-cultural, economical and environmental issues (Coutsoudis, Goga, Rollins, & Coovadia, 2002; Luo, 2000; Newell, 2001a; Nicoll et al., 2000; Piwoz et al., 2003; Piwoz et al., 2006).

Although HIV-infected mothers who breastfeed are putting their infants at risk for HIV transmission (WHO, 2004), avoidance of breastfeeding contradicts the cultural norm in Malawi (National Statistical Office [Malawi] & ORC Macro, 2001). Prolonged breastfeeding is common in the country, with the median duration of exclusive breastfeeding being just two months and most infants are still breastfed at 24 months of age (National Statistical Office [Malawi] & ORC Macro, 2001). Qualitative research results in Malawi suggest that compared to formula feeding, breastfeeding is more affordable, feasible, acceptable, sustainable and safer for HIV-infected women in Malawi (Piwoz et al., 2003). In these circumstances, the World Health Organization (WHO) recommends that HIV-infected mothers exclusively breastfeed (i.e. feeding an infant breast milk and no other liquids or solids) their infant for the first six months of life and stop breastfeeding soon after the first six months (WHO, 2001). Although research supporting these policy recommendations is ongoing, current studies suggest that for HIV-infected mothers, where replacement feeding is not a viable option, the benefits of breastfeeding exclusively for the infant's first six months of life may outweigh the risks of infant morbidity and mortality during that time period (WHO, 2004b). Further, early breastfeeding cessation soon after exclusive breastfeeding reduces exposure and risk of

HIV transmission to the infant (WHO, 2004b). However, as mentioned earlier, usual infant feeding practices in Malawi pose challenges for implementing these recommendations. Despite these infant feeding cultural norms, formative research results in Malawi suggested that HIV-infected mothers would adhere to the WHO (2001) infant feeding recommendations if nurses explained why and how these practices would decrease the risk of mortality and HIV transmission to their infant (Piwoz et al., 2003).

In Malawi, mothers trust health care providers and often take their recommendations as the final word (Corneli et al., 2003). WHO (2001) infant feeding recommendations for HIV-infected mothers state that these mothers should receive counseling about the risks and benefits of different infant feeding options as well as guidance and support to choose the most appropriate option for their situation. Evidence from one Zambian study credited the infant feeding counseling by trained nurses with HIV-infected mother's adherence to three months of exclusive breastfeeding (Piwoz et al., 2005). Results from a formative research study indicated that nurses in Malawi were knowledgeable about optimal breastfeeding practices recommended for the general population, but not aware of the infant feeding practices recommended for HIV-infected mothers (Piwoz et al., 2006). Further, Malawian nurses also appeared to hold cultural beliefs and attitudes toward breastfeeding practices and HIV-infected mothers that would not promote the implementation of WHO infant feeding recommendations among resource-poor mothers (Piwoz et al., 2006). Nurses in this formative study also indicated that they need additional training on how to counsel HIV-infected mothers on infant feeding (Piwoz et al., 2006).

The Breastfeeding, Antiretroviral and Nutrition (BAN) Study, conducted by the School of Medicine at the University of North Carolina at Chapel Hill (UNC) and funded through a cooperative agreement with the U.S. Centers for Disease Control and

Prevention (CDC), is a clinical trial evaluating the safety and efficacy of antiretroviral and nutrition interventions to reduce MTCT among breastfeeding mothers in Lilongwe, Malawi (Galliard et al., 2004; van der Horst, Jamieson & Kazembe, 2005). The three main objectives of the BAN Study are to evaluate: (1) the benefit of nutritional supplementation given to women during breastfeeding; (2) the benefit and safety of antiretroviral medications given either to infants or to their mothers to prevent HIV transmission during breastfeeding; and (3) the feasibility of mothers exclusively breastfeeding their infant, followed by early, rapid breastfeeding cessation (van der Horst, Jamieson & Kazembe, 2005). An infant feeding counseling protocol was developed to address the third study objective and BAN Study nurses were trained to counsel HIV-infected mothers on practicing exclusive breastfeeding for six months and early, rapid breastfeeding cessation at six months (van der Horst, Jamieson & Kazembe, 2005).

Research Questions & Rationale

This study was designed to assess nurses' implementation adherence to the BAN Study infant feeding counseling protocol. Documenting and analyzing nurses' implementation of this protocol would help to interpret the BAN Study's behavioral impact and health outcomes related to evaluating the BAN Study's objective to evaluate the feasibility of HIV-infected mothers exclusive breastfeeding their infant, followed by early, rapid breastfeeding cessation (Israel et al., 1995; van der Horst, Jamieson & Kazembe, 2005). Further, evidence suggesting that Malawian nurses' attitudes toward WHO (2001) infant feeding recommendations for HIV-infected mothers in resource-poor areas may influence their infant feeding counseling practices (Piwoz et al., 2006), supports investigating how these attitudes may influence the implementation of the BAN Study infant feeding counseling protocol. Thus, the purpose of the study was to investigate:

1) What task and socio-emotional domain behaviors of the protocol were consistently implemented as designed?
2) What were nurses' patterns of adherence to the task and socio-emotional domain behaviors of the protocol?
3) What were nurses' attitudes toward the protocol?

A social ecological perspective, which situates health behavior within the context of multiple levels of influence, provided the framework to view the determinants of nurses' infant feeding counseling behavior. Additionally, theoretically-derived patient-provider communication and relationship concepts (Roter & Hall, 1997) provided the conceptual basis for the BAN Study infant feeding counseling protocol and this study. Because of its emphasis on program implementation, a process evaluation approach (Steckler & Linnan, 2002), using primarily qualitative methods, was used to investigate BAN Study nurses' implementation adherence of and attitudes toward key elements of the BAN Study infant feeding counseling protocol. The primary data collection methods included direct observations of infant feeding counseling sessions between BAN Study nurses and HIV-infected mothers and interviews with BAN Study nurses. Analysis of transcripts included a combination of a case-oriented and variable-oriented approach (Miles & Huberman, 1994). An average implementation adherence percentage was calculated from implementation checklists completed during direct observations of counseling sessions to assess nurses' patterns of implementation adherence to key BAN Study infant feeding counseling elements.

Significance of the Study

The study findings contribute to public health research, policy and practice. Currently, no studies have used direct observations, an effective approach to assess program implementation (Patton, 1990; Walsh et al., 2000), to observe nurses'

implementation adherence to an infant feeding counseling protocol within the context of an HIV/AIDS clinical trial, but in the context of country-wide pilot Prevention of Mother to Child Transmission (PMTCT) programs (Chopra et al., 2005; Horizons Program, 2002). Because clinical trial treatment and procedures are conducted under optimum conditions, compared to other non-experimental study environments (Flay, 1986), the study results may provide a view of how and to what extent nurses, in optimal research conditions, are able to implement an infant feeding counseling protocol in a high HIV prevalence, resource-poor setting. Thus, these study findings potentially contribute new and innovative findings to the HIV/AIDS clinical trial and the HIV and infant feeding research fields.

The implementation checklist tool used when observing nurses' implementation adherence to the infant feeding counseling protocol could potentially be used by the BAN Study co-investigators, other HIV and infant feeding studies in sub-Saharan Africa with an infant feeding counseling component, or the Malawi Ministry of Health and Population as a performance tool for nurse counselors. Previous research on the Malawi nursing system identified lack of nurse performance reviews, among other things, as contributing to the deterioration of the quality of care and low morale among nurses (Chirwa, 2000). Thus, the results from observing nurses' implementation of the BAN Study infant feeding counseling protocol and assessing their adherence to key infant feeding counseling elements could be used as a performance tool to identify nurses' counseling strengths, weaknesses and give guidance on areas of improvement.

Finally, without understanding the processes by which nurses implement their infant feeding counseling skills, it may be difficult to attribute the BAN Study's evaluation results on the feasibility of HIV-infected mothers to exclusively breastfeed for six months, followed by rapid, early breastfeeding cessation, to the BAN Study's infant

feeding counseling protocol. Hence, the results of this study could help interpret the BAN Study's behavioral impact and health outcomes (Israel et al., 1995; Linnan & Steckler, 2002).

Organization of this Dissertation

Chapter II reviews several bodies of literature related to the study's research questions. The chapter reviews literature on the HIV/AIDS epidemic in Malawi and how its physiological, behavioral and socio-cultural manifestations have affected women in the country. Literature specific to HIV and infant feeding research, policies and practices, with a focus on nurses, is also presented in the next chapter. Chapter III describes the BAN Study infant feeding counseling protocol, presents a social ecological perspective of determinants related to nurses' infant feeding counseling behavior and the study's theoretically-derived conceptual model and re-states the research questions. Chapter IV describes the methods used to assess the study's research questions. Chapter V presents the study findings specific to BAN Study nurses' implementation adherence of and attitudes toward key elements of the BAN Study infant feeding counseling protocol and Chapter VI discusses the study findings and their implications for public health theory, research, policy and practice.

CHAPTER II

REVIEW OF THE LITERATURE

Overview

To understand the context and rationale of this study, this chapter presents a review of the relevant literature on: (a) the HIV/AIDS clinical trial with which this study is associated; (b) Malawi, the study setting; (c) epidemiological, psycho-social, healthcare delivery and cultural determinants of HIV and mother-to-child transmission; (d) nurses' infant feeding counseling behavior for HIV-infected women; and (e) HIV and infant feeding research, policy and practice. The conclusions drawn on the current state of knowledge are synthesized at the end of this chapter. Finally, the study aims are presented with regard to monitoring Malawian nurses' implementation of and attitudes toward an infant feeding counseling protocol intended to reduce mother-to-child transmission (MTCT) of HIV infection.

Breastfeeding Antiretroviral and Nutrition (BAN) Study

This study was conducted within the Breastfeeding Antiretroviral and Nutrition (BAN) Study, a randomized controlled clinical trial conducted by the University of North Carolina at Chapel Hill (UNC) through a cooperative agreement with the U.S. Centers for Disease Control and Prevention (CDC) (van der Horst, Jamieson, & Kazembe, 2005). The study was conducted in Lilongwe, Malawi and consisted of a sample of HIV-infected mothers and their infants (van der Horst, Jamieson, & Kazembe, 2005). The BAN Study was designed to evaluate two clinical interventions using a factorial design. A two-arm clinical nutritional intervention to assess the benefit of a nutritional supplement

administered to mothers during breastfeeding and a three-arm antiretroviral intervention, with drugs administered to the mother, the infant, or neither, to assess the benefit and safety of this antiretroviral regimen are being implemented (Gaillard et al., 2004; van der Horst, Jamieson, & Kazembe, 2005). In addition to these two clinical interventions, an infant feeding counseling protocol was developed to address the BAN Study's third objective, which is to assess the feasibility of mothers exclusively breastfeeding their infants followed by early, rapid breastfeeding cessation (Gaillard et al., 2004; van der Horst, Jamieson, & Kazembe, 2005). A final sample of 2,418 HIV-infected mothers will be enrolled and followed for 48 weeks after delivery to evaluate the study objectives (van der Horst, Jamieson, & Kazembe, 2005).

The BAN Study consists of researchers from UNC, CDC and Malawi and is divided into six work teams: (a) administration, (b) antiretroviral drugs, (c) data and statistics, (d) health economics, (e) laboratory, and (f) nutrition. This dissertation research study was developed as the result of the dissertation author's three-year tenure as a research assistant with the nutrition work team. The nutrition work team consisted of public health researchers with extensive research and international expertise in HIV and infant and maternal nutrition (Adair & Popkin, 1992; Bentley, Dee & Jensen, 2003; Bentley et al., 1994; Bentley et al., 1991; Piwoz, Huffman & Quinn, 2003; Piwoz et al., 1994; Piwoz et al., 1996; van der Horst, Jamieson, & Kazembe, 2005). With their expertise in conducting empirical nutrition studies in developing nations, the nutrition work team developed an infant feeding counseling protocol for nurses to follow while counseling HIV-infected mothers enrolled in the BAN Study (van der Horst, Jamieson, & Kazembe, 2005). BAN Study nurses completed an infant feeding counseling training course that focused on the following topics: the state of HIV/AIDS and infant feeding practices in Malawi, how to counsel HIV-infected mothers on issues relevant to the BAN

Study objectives, WHO infant feeding recommendations for resource-poor HIV-infected women, and risk estimates and factors for MTCT via breastfeeding (WHO/UNICEF, 1993; WHO/UNAIDS/UNICEF, 2000). The following sections review the literature relevant to these training topics.

Malawi & HIV/AIDS

Malawi is a small, landlocked country east of Zambia and west of Tanzania and Mozambique (see Figure 1) that is home to 12.3 million people (UNAIDS/WHO, 2004). Colonized by the British in 1880, Nyasaland gained its independence in 1964 and was renamed Malawi (Electionworld, 2004). Lilongwe is the capital of Malawi and has approximately 646,738 people (World-Gazetteer, 2005). Although English and Chichewa are the country's official languages (Electionworld, 2004), other languages are spoken by various ethnic groups, including the Lomwe, Chewa, Ngoni, Yao, Tumbuka and Sena tribes (Malata, 2000).

With a gross national income (GNI) per capita of $170.00, Malawi is one of the poorest and indebted countries in sub-Saharan Africa (UNICEF, 2004; The World Bank Group, 2004). Malawi's economy is heavily dependant on agriculture, which accounts for over 90% of its export earnings and supports 90% of the population (The World Bank Group, 2004). Cash crops include tobacco, tea, coffee, cotton and sugar (The World Bank Group, 2004). Tobacco accounts for 60% of Malawi's export earnings, while maize is the principal food crop (Garbus, 2003). A severe drought in the 2001-2002 agricultural season, and subsequent sporadic rainy seasons, have resulted in a famine that continues to threaten the country today (Garbus, 2003; Moloya, 2005).

Women head 25% of Malawian households, with the average household size being 4.4 persons (National Statistical Office [Malawi] & ORC Macro, 2001). Gender disparities are evident in the low educational attainment among women (3.1 years)

compared to men (5.1 years) (Garbus, 2003). The United Nations Development Programme (UNDP) measures gender inequality with its Gender-related Development Index (GDI), a composite index measuring average achievement in living a long and healthy life, knowledge and a decent standard of living-adjusted to account for inequalities between men and women, where values range from 0 (lowest gender equality) to 1 (highest gender equality) (UNDP, 2002). In 2000, Malawi's GDI was 0.389, ranking it 137 out of the 146 countries on the index (for comparison, GDI values range from 0.263 [Niger] to 0.956 [Australia]) (UNDP, 2002).

Malawi's health system is structured around eight service delivery levels ranging from small community and health posts to large district and regional level hospitals (Garbus, 2003). Overall, access to health care is limited, with only 3.0% of Malawians living in a village with a health center (Government of Malawi, 2002). Most of the country's health resources are located in urban areas, whereas 80% of Malawians live in rural areas (Garbus, 2003; National Statistical Office [Malawi] & ORC Macro, 2001). Further, there is a severe shortage of physicians and nurses in the country resulting in high patient to health worker ratios (Chirwa, 2000; Garbus, 2003). The Malawi government provides 60% of health services with the Christian Health Association of Malawi (CHAM) providing the remaining percentage of health care (Garbus, 2003). Non-governmental organizations (NGOs) and other private facilities provide about 3.0% of health services in the country (Garbus, 2003).

In 1998, approximately 2.8% of Malawi's gross domestic product (GDP) was spent on health care (Garbus, 2003). The government's low health care budget is evident in the country's health status. The median childbearing age is 19 years, with 20-24 years of age being the peak childbearing period for Malawian women (National Statistical Office [Malawi] & ORC Macro, 2001). Malawi's total fertility rate is 6.1 births per

woman and the infant mortality rate is 112 per 1,000 live births, one of the highest in sub-Saharan Africa (WHO, 2004a; UNICEF, 2004). Malawi's under-five mortality rate of 178 per 1,000 live births is high, ranking 19th in the world (UNICEF, 2004). Although there are no specific data on the leading cause of infant mortality in Malawi, communicable disease, poor maternal health and living conditions of infants, and nutritional deficiencies account for the majority of infant deaths in Africa (WHO/UNICEF, 2003). These poor health status rankings are partially due to Malawi's food shortage and poor environmental conditions (National Statistical Office [Malawi] & ORC Macro, 2001; UNICEF, 2004). For example, food shortages continue to threaten the country due to a sporadic rainy season (Moloya, 2005). Furthermore, 35% of Malawian households lack a clean water source and 95% are without electricity (National Statistical Office [Malawi] & ORC Macro, 2001).

Nonetheless, pregnant women in Malawi generally attend antenatal clinics. In the urban areas, antenatal attendance is high (97.7%), with 68.3% of pregnant women having at least four prenatal care visits (van der Horst, Jamieson, & Kazembe, 2005). Moreover, a very high proportion of infants in urban areas (81.5%) are delivered by nurses and other skilled health providers in a hospital or clinic, as compared to the national rate of 55.6% (National Statistical Office [Malawi] & ORC Macro, 2001; UNAIDS/WHO, 2004). For example, at Bottom Hospital in Lilongwe, approximately 13,000 infants were delivered annually (van der Horst, Jamieson, & Kazembe, 2005).

HIV prevalence among pregnant women who attend the antenatal clinics in the Kamuzu Central Hospital and Bottom Hospital system was approximately 20.1% (UNAIDS/WHO, 2004). UNAIDS/WHO (2004) estimated that Malawi's adult HIV prevalence rate of 14.2% (estimated range: 11.3% to 17.7%) ranks among the highest in the world. An estimated 810,000 adults (age 15 to 49 years) and 83,000 children (age 0

to 15 years) are living with HIV/AIDS in Malawi (UNAIDS/WHO, 2004). Of the 810,000 adults infected with HIV, 460,000 (56.7%) are women (UNAIDS/WHO, 2004). HIV sentinel surveillance data estimated that between 18.5% to 28.4% of pregnant women who attend antenatal clinics in urban areas, and 4.4% to 35.7% in rural areas, are infected with HIV (UNAIDS/WHO, 2004).

HIV/AIDS Epidemiological Factors & Mother-to-Child Transmission

The two primary routes for HIV transmission in sub-Saharan Africa are heterosexual contact and mother-to-child transmission (MTCT) (Guay et al., 1999; Quinn et al., 2000; Wiktor et al., 1999). In sub-Saharan Africa, including Malawi, heterosexual transmission accounted for a majority of the HIV infections (UNAIDS/WHO, 2004). For example, among the 810,000 adults and 83,000 children infected with HIV in Malawi, heterosexual transmission accounted for approximately 90% of HIV infections, while MTCT accounted for 9% (National Statistical Office [Malawi] & ORC Macro, 2001). These transmission routes have contributed to the disproportionate burden of HIV among Malawian women, who comprise 56% of this country's adult HIV prevalence rate (UNAIDS/WHO, 2004).

Many studies that have reported on this gender disparity in HIV/AIDS transmission have focused on the lower social status of women in sub-Saharan Africa countries (Ackerman & de Klerk, 2002; Gilbert & Walker, 2002; Lawson, 1999; MacDonald, 1996). Malawian culture positions boys and men in a dominating role over girls and women (Garbus, 2003). This male dominance may leave females in the position of not having the ability to negotiate sexual intercourse or condom use (Garbus, 2003). Further, Malawian women have lower educational attainment and limited employment opportunities compared to men, which has resulted in women being economically dependent on men (Garbus, 2003; UNAIDS/WHO, 2004). For example, widow's

inheritance (where the husband's male relative marries the deceased's wife) and "grabbing" (where relatives forcefully take possession of the deceased's household goods, land, livestock, clothes and other assets) are psycho-social and economical factors that can increase women's vulnerability to HIV (Garbus, 2003).

In addition to societal and behavioral factors, studies have reported that women, globally, are more vulnerable than men to HIV infection for physiological reasons (Vuylsteke, Sunkutu, & Laga, 1996). Specifically, research has shown that the transmission of sexually transmitted infections (STIs), including HIV, from men to women is more efficient than from women to men (European Study Group on Heterosexual Transmission of HIV, 1992). STIs, which enhance the transmission of HIV from men to women, are more likely to go undetected and untreated in women compared to men, thus, making women more vulnerable to HIV infection (Gelmon & Piot, 1996). This increased physiological vulnerability to HIV infection among women can also increase the risk of MTCT of the virus.

With approximately 20% of clients receiving antenatal services in Lilongwe infected with HIV (UNAIDS/WHO, 2004), the potential risk of mothers transmitting the virus to their infant is high. MTCT of HIV can occur before (intrauterine), during (intrapartum) and after delivery (postpartum) (Newell, 2001a). The overall absolute risk of HIV transmission during these three stages has ranged from 5-20%, with the intrapartum stage found to have highest risk for MTCT (De Cock et al., 2000). There are effective interventions that reduce MTCT of HIV. These are the reduction of maternal viral load through antiretroviral (ARV) therapy (Guay et al, 1999), avoidance of exposure to contaminated maternal secretions through delivery by elective caesarean section and avoidance of breastfeeding (Newell, 2001a; Preble & Piwoz, 1998). Countries that have implemented these interventions, such as the United States and Europe, have experienced

a dramatic decline in MTCT of HIV to a rate of less than 2% of infants being infected with the virus (Connor et al., 1994; Davis et al., 1995; European Collaborative Study, 2001; Mofenson & McIntyre, 2000). However, these interventions have been difficult to implement in resource-poor countries, such as Malawi, because of unsanitary conditions, a deficit in skills among health providers and lack of technical resources to perform elective caesarean sections. Additionally, avoidance of breastfeeding contradicts the cultural norm in most sub-Saharan African countries that predominately supports prolonged breastfeeding (Luo, 2000; Mofenson & McIntyre, 2000). Although Malawi, with assistance from The Global Fund and other local and international agencies, is offering ARV therapy to HIV-infected pregnant women to reduce MTCT of HIV during the in utero and intrapartum stages (John & Kreiss, 1996; Peckham & Gibb, 1995; The Global Fund, 2003; van der Horst, Jamieson & Kazembe, 2005) the use of ARV therapy has not been shown to reduce MTCT of HIV through breastfeeding (Dunn et al., 1992; Miotti et al., 1999).

Epidemiology of HIV Transmission via Breastfeeding

The following sections examine available epidemiological evidence on HIV transmission through breastfeeding. The focus is on (a) current risk estimates and (b) maternal and infant risk factors that may be modified through infant feeding counseling by nurses.

Risk estimates. Findings from an early meta-analysis of nine studies estimated that breastfeeding increased the overall risk of MTCT of HIV by 14% for infants of mothers with established HIV infection (Dunn et al., 1992). A more recent study in Malawi estimated the cumulative risk of HIV transmission via breastfeeding to be 3.5% for infants at six months of age, 7% at 12 months of age, and 10.3% at 24 months of age (Miotti et al., 1999). In a critical review of the available data on MTCT of HIV, De Cock

and colleagues (2000) estimated the relative proportion of MTCT of HIV among infants during the first six months of breastfeeding to be 20-25% during the first two months of breastfeeding and 5-10% after two months of breastfeeding. However, they suggested caution when interpreting these risk estimates because technological limitations did not permit the study to determine if an infant was infected with HIV during delivery or during the first weeks of life through early breastfeeding (De Cock et al., 2000; John-Stewart et al., 2004; Preble & Piwoz, 1998). Further, these studies used non-standardized definitions of early and late postnatal transmission (LPT) (BHITS Group, 2004; Preble & Piwoz, 1998).

Acknowledging the technological limitations and applying these standardized definitions for early and LPT, leading international HIV/AIDS and infant feeding researchers and policy makers (i.e. the Breastfeeding and HIV International Transmission Study Group [BHITS Group]) conducted a meta-analysis from nine MTCT international trials to estimate the rate of HIV transmission via breastfeeding (BHITS Group, 2004). The BHITS Group (2004) concluded that LPT could represent 24% - 42% of the overall rate of MTCT of HIV among children (birth to 24 months old), which was higher and more precise than previous estimates (De Cock et al., 2000; Dunn et al., 1992; Ekpini et al., 1997).

In sum, the majority of breastfed infants born to HIV-infected women do not become infected with HIV (Dabis et al., 1993). Explanations regarding why some infants become infected and others do not are complex. The following is a review of risk factors found to be associated with HIV transmission through breastfeeding.

Risk factors for HIV transmission via breastfeeding. Both maternal and infant factors have been found to contribute to the risk of HIV transmission through breastfeeding. Maternal factors include RNA viral loads in plasma and breast milk, CD4

cell count, maternal nutrition and breast health (John-Stewart et al., 2004; WHO, 2004b). Infant factors include duration of breastfeeding, infant morbidity and mode of infant feeding (John-Stewart et al., 2004). The following section reviews each of these factors. Since research in the area of HIV transmission via breastfeeding is in its early stages (WHO, 2004b), the risk factors described below are not an exhaustive list.

Maternal Factors

Maternal factors related to HIV transmission through breastfeeding include: (a) RNA viral load in plasma and in breast milk; (b) CD4 cell count; (c) maternal nutrition; and (d) breast health. Studies have reported that these risk factors are inter-related (John-Stewart et al., 2004; Piwoz & Preble, 2000; Willumsen et al., 2003). High levels of maternal RNA viral load in plasma have been shown to be the most important independent risk factor of MTCT of HIV (Garcia et al., 1999; Mofenson et al., 1999; Shaffer et al., 1999). Increased risk of MTCT of HIV via breastfeeding is associated with raised levels of RNA viral load in both plasma and breast milk (John et al., 2001; John-Stewart et al., 2004; Leroy et al., 2003; Semba et al., 1999; Willumsen et al., 2003).

Immunosuppression, defined as low CD4 cell count, is strongly associated with plasma RNA viral load and is an independent risk factor for HIV transmission through breastfeeding (Embree et al., 2000; John-Stewart et al., 2004; Leroy et al., 2003; Semba et al., 1999). In a West African clinical trial, Leroy and colleagues (2003) reported that the cumulative postnatal transmission risk of HIV among infants two years of age was higher (16-22%) among nursing mothers with CD4 cell counts of <500 cells/mL than among nursing mothers with CD4 cell counts of >=500 cells/mL (2-5%). Similarly, based on a meta-analysis of data from nine international trials, the BHITS Group (2004) reported that overall risk of LPT among infants was significantly higher among nursing mothers with low CD4 cell counts.

Malnutrition among mothers and infants has been found to increase the progression of HIV and facilitate the risk of HIV transmission from mothers to their infants (Piwoz & Preble, 2000). Researchers hypothesize that the increased metabolic demands of breastfeeding for HIV-infected mothers could result in malnutrition (van der Horst, Jamieson & Kazembe, 2005). Results of randomized trials of vitamin A and multivitamin (B, C, and E) supplementation found that multivitamin supplementation (excluding A) among breastfeeding HIV-infected mothers significantly reduced HIV transmission through breastfeeding among mothers with poor nutrition status (Fawzi et al., 2002). Hence, HIV and infant feeding counseling courses include a session on maternal nutrition, highlighting the importance of good nutrition for breastfeeding HIV-infected mothers to reduce HIV transmission to infants (LINKAGES, 2004; WHO/UNAIDS/UNICEF, 2000).

Mastitis, abscesses and cracked nipples are common breast health pathologies that have been reported to increase the risk of MTCT of HIV via breastfeeding (Ekpini et al., 1997; John-Stewart et al., 2004; John et al., 2001; Ogundele & Coulter, 2003; Semba et al., 1999; WHO, 2004b). They may occur when (a) the milk first comes in after birth; (b) there is inadequate milk drainage from the breast; (c) infant attachment to the breast is poor; (d) an ill infant practices less vigorous suckling; or (e) the infant is weaned rapidly (WHO, 2004b). The WHO HIV and infant feeding counseling training course focuses on proper management of these breast health problems (WHO/UNICEF, 1993; WHO/UNAIDS/UNICEF, 2000). One study found that nurses trained with the WHO course model knew how to manage breastfeeding problems more correctly when compared to those without this training (Owoaje, Oyemade and Kolude, 2002).

Infant Factors

Infant risk factors found to be associated with HIV transmission through breastfeeding include duration of breastfeeding, infant morbidity, and mode of infant feeding (John-Stewart et al., 2004). Transmission of HIV to the infant can occur throughout the breastfeeding period (Embree et al., 2000; Miotti et al., 1999) and studies have concluded that the longer an infant is breastfed, the greater the risk of HIV transmission (Leroy et al., 1998; Miotti et al., 1999; Petra Study Team, 2002). A study conducted in Malawi concluded that this risk is cumulative and highest during the early months of breastfeeding (Miotti et al., 1999). To minimize this risk, WHO (2001) recommendations for HIV-infected mothers, who decide to exclusively breastfeed, advise the discontinuation of breastfeeding as soon as feasible (see Table 1) (Ekipini et al., 1997; WHO, 2001).

Some studies have identified infant morbidity as a risk factor, which can lead to less vigorous suckling by infants and consequently mastitis and increased leakage of HIV across breast milk ducts (John-Stewart et al., 2004; Ryder et al., 1991). Early research in the Democratic Republic of Congo reported that the rate of morbidity among infants born to HIV-infected mothers may be decreased by exclusive breastfeeding during the first six months of life (Ryder et al., 1991). The WHO HIV and infant feeding counseling training course dedicates training exercises on how to assess and manage infant morbidity and counsel mothers on how to maintain optimal infant feeding practices (WHO/UNICEF, 1993; WHO/UNAIDS/UNICEF, 2000).

Mode of infant feeding: A key infant risk factor for HIV transmission. For HIV-infected mothers, the practice of mixed feeding (i.e. feeding infants breast milk in addition to other liquids and solids) may be detrimental to infants. Researchers have reported that this infant feeding practice may disturb an infant's tonsils and/or immature

gastrointestinal tract, increasing the permeability of these areas to HIV infection during breastfeeding (Coutsoudis et al., 1999; Nicoll et al., 2000; Rollins et al., 2001; WHO, 2004b). Two major HIV and infant feeding studies sparked much debate in the HIV/AIDS field because of their contradictory findings concerning mode of infant feeding and its association with risk of HIV transmission among infants and maternal mortality (Coutsoudis et al., 1999; Coutsoudis et al., 2001a; Nduati et al., 2000; Nduati et al., 2001).

A South African prospective cohort study reported that the proportion of infants infected with HIV, who were exclusively breastfed for three months, was significantly lower than those who were given mixed feeds (14.6% vs. 24.1%) and was not significantly different from those exclusively formula-fed (18.8%) (Coutsoudis et al., 1999). At 15 months, there was still a significant difference in HIV transmission rates between infants who were exclusively breastfed for three months or more (24.7%) and mixed fed infants (35.9%) (Coutsoudis et al., 2001a).

In Kenya, a clinical trial randomized HIV-positive mothers to breastfeed or formula-feed their infant (Nduati et al., 2000). At 24 months, 36.7% of infants in the breastfeeding arm and 20.5% of infants in the formula arm were infected with HIV (Nduati et al., 2000). Nduati and colleagues (2001) also found that breastfeeding among HIV-infected mothers placed them at higher risk for maternal mortality, reporting deaths of 10.5% in the breastfeeding arm and only 3.8% in the formula-fed arm at 24 months. In response to these findings on maternal mortality and breastfeeding by Nduati and colleagues (2001), Coutsoudis and colleagues (2001b) examined maternal mortality data from their study and found no associated risk with mode of infant feeding.

Both studies have their limitations. The Nduati et al (2000, 2001) studies were criticized by researchers ethically and methodically for randomizing mothers to either

formula feed or breast feed their infants (Newell, 2001b; Tompson, 2001). Further, the Nduati et al (2001) study was also criticized for not differentiating between exclusive breastfeeding and mixed feeding within the breastfeeding group (Tompson, 2001).

For their studies on HIV-infected mothers breastfeeding and risks associated with maternal mortality, the primary limitations of the Coutsoudis et al. (2001a) analysis included its small sample size to detect adequate power (WHO, 2004b). However, neither the Nduati et al. (2001) nor the Coutsoudis et al. (2001a) studies provided detailed information on the mode, duration and quantity of breastfeeding and the associated risk with maternal mortality (WHO, 2001). Although results from these studies sparked much debate within the HIV/AIDS community (Florin, 2001; Latham & Preble, 2000; Newell, 2001b; Sachs et al., 2000; Tompson, 2001; Wise, 2001), the WHO (2001) did not change its infant feeding recommendations for HIV-infected mothers.

WHO Recommendations & Infant Feeding Practices

To address HIV and infant feeding issues, the WHO (2001) developed recommendations to guide public health research, policy and practice. The following section reviews the relevant literature supporting these recommendations and ways in which infant feeding practices by mothers and counseling practices by nurses in Malawi pose a challenge to its implementation.

In general, breastfeeding is considered beneficial for infants for many reasons. Specifically, breastfeeding has been shown to: provide optimal nutrition (WHO/UNICEF, 2003); protect against common childhood infections and illnesses, such as diarrhea and pneumonia (Habicht et al., 1986; Victora et al., 1987; WHO Collaborative Study Team, 2000); and decrease infant mortality (WHO Collaborative Study Team, 2000). Infants experience these benefits when they are breastfed exclusively during the first six months of life (Feachem & Koblinsky, 1984; Smith & Kuhn, 2000). Thus, the WHO

recommends that infants be exclusively breastfed for the first six months of life to achieve the optimal benefits of breastfeeding (World Health Assembly, 2001). In Malawi, breastfeeding is a cultural norm and a cost effective infant feeding method for most families (Piwoz, et al., 2006).

Evidence citing breast milk as a mode of HIV transmission (Preble & Piwoz, 1998; Thiry et al., 1985; Ziegler et al., 1985) has led to public health policies suggesting that HIV-infected mothers avoid breastfeeding (CDC, 1985; Preble & Piwoz, 1998; WHO, 2001). WHO (2001) guidelines currently state that when replacement feeding is acceptable, feasible, affordable, sustainable and safe, avoidance of all breastfeeding by HIV-infected mothers is recommended to prevent postnatal transmission of HIV (see Table 1). Otherwise, exclusive breastfeeding during the first months of life should be followed by early, rapid breastfeeding cessation (WHO, 2001). WHO (2001) recommendations further state that HIV-infected mothers should receive counseling on the risks and benefits of different infant feeding options and given guidance and support to choose the most appropriate option for their situation. The Malawi Ministry of Health and Population (2003) also supported these infant feeding recommendations for HIV-infected mothers.

Additionally, the WHO HIV and infant feeding counseling course offers other infant feeding options for HIV-infected mothers, such as replacement feeding with locally available milks, including cow's milk, evaporated milk, powdered milk and commercial infant formula (WHO/UNAIDS/UNICEF, 2000). Findings from focus groups with mothers, fathers, grandmothers and individual interviews with breastfeeding mothers, health providers and community leaders suggested that exclusive breastfeeding for six months would be the most affordable, feasible, acceptable, sustainable and safe infant

feeding option for HIV-infected mothers in Malawi (Corneli et al., 2003; Piwoz et al., 2003).

Although the recommendation for HIV-infected mothers to avoid all breastfeeding is implemented in countries such as the United States and Europe (Mofenson & McIntyre, 2000), it is difficult to implement in resource-poor countries, such as Malawi, where access to sanitary water to prepare safe replacement feedings is limited and socio-cultural norms support breastfeeding (Luo, 2000; National Statistical Office [Malawi] & ORC Macro, 2001; Piwoz et al., 2003). Results from the BAN formative study in Malawi concluded that the WHO recommendation to exclusively breastfeed for six months followed by early, rapid breastfeeding cessation would be more acceptable, feasible, affordable, sustainable and safer for HIV-infected mothers to practice in their community than formula-feeding (Corneli et al., 2003; Piwoz, et al., 2003). However, the formative results did conclude that stopping breastfeeding over the course of one month, versus a few days to one week, would be a culturally appropriate option for HIV-infected mothers in their community (Piwoz et al., 2003). Thus, the BAN Study nutrition team designed the study's infant feeding counseling protocol based on these formative research findings (van der Horst, Jamieson & Kazembe, 2005).

Malawi Infant Feeding Practices

Usual infant feeding practices in Malawi pose challenges for implementing WHO (2001) infant feeding recommendations for HIV-infected mothers. Although prolonged breastfeeding is common in Malawi, long duration of exclusive breastfeeding is not the norm (National Statistical Office [Malawi] & ORC Macro, 2001). The 2000 Malawi Demographic and Health Survey reported that more than half of all infants were still breastfed at 24 months of age; however, the median duration of exclusive breastfeeding was just two months (National Statistical Office [Malawi] & ORC Macro, 2001).

Moreover, the survey found that 31% of two to three month old children and 80% of four to five month old children were already consuming solid foods (National Statistical Office [Malawi] & ORC Macro, 2001). However, formative research results in Malawi indicated that HIV-infected mothers would exclusively breastfeed for six months and practice early, rapid weaning, when nurses explained why and how this practice would decrease the risk of HIV transmission to their infant (Piwoz et al., 2003).

In sum, it may be difficult for HIV-infected mothers in Malawi to adhere to the WHO (2001) recommendations to exclusively breastfeed for six months and discontinue breastfeeding at six months to minimize their infant's risk of HIV infection. However, recent evidence indicates that infant feeding counseling by trained nurses may lead to improved adherence to these recommendations by HIV-infected mothers (Piwoz et al., 2005).

Nurses and Infant Feeding Counseling for HIV-Infected Women

The WHO (2001) infant feeding recommendations for HIV-infected women state that HIV-infected mothers should receive counseling about the risks and benefits of different infant feeding options as well as guidance and support to choose the most appropriate option for their situation (see Table 1). Hence, counseling for a mother's infant feeding decision-making process is an important component of interventions designed to reduce MTCT of HIV. In fact, the preliminary results of one Zambian study credited the infant feeding counseling by trained nurses with HIV-infected mothers' adherence to three months of exclusive breastfeeding (Piwoz et al., 2005).

In many sub-Saharan Africa countries, including Malawi, it has been reported that communities trust health care providers and often take their recommendations as the final word (Corneli et al., 2003; de Paoli, Manongi & Klepp, 2002; Seidel, Sewpaul & Dano, 2000). At the same time, in Malawi, studies have noted that the quality of nursing care is

deteriorating and its impact is apparent in low morale among nurses and patient dissatisfaction with health care (Chirwa, 2000; Malata, 2000; Namate, 1992). This deterioration has occurred for many reasons, including: a shortage of trained nurses and resources, lack of nursing standards, lack of performance reviews, long working hours, poor working conditions and an increase in nurse to patient ratios (that can be has high as 1:50) (Chirwa, 2000; Muula, Mfutso-Bengo, Makoza & Chatipwa 2003; Namate, 1992). Chirwa (2000) found that without a performance review, nurses did not know their strengths, weaknesses or ways to improve their quality of care.

Despite the deterioration of quality nursing care, nurses remain as key gatekeepers in influencing HIV-infected mothers' infant feeding decisions (Seidel et al., 2000; Semega-Janneh et al., 2001) and can serve a vital role in preventing postnatal HIV transmission by counseling these mothers and communicating accurate and current infant feeding information (Piwoz et al., 2005). There is evidence that nurses can effectively increase rates of exclusive breastfeeding in their communities with formal counseling training and supportive supervision (Davies-Adetugbo & Adebawa, 1997; Davis-Adetugbo et al., 1997; Haider et al., 2000; Morrow et al., 1999; Owoaje, Oyemade & Kolude, 2002; Piwoz et al., 2005). At the same time, research has indicated that nurses' counseling practices may compromise the health and well-being of HIV-infected mothers and their infants (Chopra et al., 2002; Programme Review Team et al., 2002). Infant feeding advice by nurses with no formal infant feeding counseling training has contributed to sub-optimal feeding practices in some communities (Akuse & Obinya, 2002; Bradley & Meme, 1992; Ojofeitimi et al., 1999; Owoaje, Oyemade & Kolude, 2002) and among HIV-infected populations (Chopra et al., 2002; Programme Review Team et al., 2002). Even among nurses with formal training, post-training surveys reported an increase in infant feeding knowledge (Bradley & Meme, 1992; Davies-

Adetugbo, 1996; Owoaje, Oyemade & Kolude, 2002), but their infant feeding counseling practices did not improve (Bradley & Meme, 1992). Evidence of no improvement in counseling skills may be due to nursing culture. In Malawi, the nursing schools taught students to "give their patients instructions" which did not allow patients the opportunity to ask the nurse questions (W. Msungama, personal communication, April 13, 2005). However, with the advent of HIV/AIDS in the country, many nurses are moving toward a counseling approach, which requires nurses to listen and answer their patient's questions related to HIV/AIDS (W. Msungama, personal communication, April 13, 2005). This incorporation of counseling skills into the current nursing culture may allow BAN Study nurses to better implement the BAN Study infant feeding counseling protocol elements.

Most previous studies assessing infant feeding counseling practices among African nurses have relied on self-report survey methods (Bradley & Meme, 1992; Davies-Adetugbo, 1996; Owoaje, Oyemade & Kolude, 2002) and only two studies reported using direct observation methods by trained observers (Chopra et al., 2005; Horizons Program, 2002). No study has used direct observation methods, an effective approach to assess program implementation (Patton, 1990; Walsh et al., 2000), to observe nurses' implementation of infant feeding protocols within the context of an HIV/AIDS clinical trial.

In general, nurses in sub-Saharan African countries are not aware of the WHO (2001) infant feeding recommendations for HIV-infected mothers (Chopra et al., 2002; de Paoli, Manongi & Klepp 2002; Piwoz, et al., 2006). For example, BAN Study co-investigators found that nurses in Malawi were knowledgeable about optimal breastfeeding practices recommended for the general population, but not aware of the infant feeding practices recommended for HIV-infected mothers (Piwoz et al., 2006). However, unlike the nurses in the BAN Study, none of the nurses interviewed in the study

by Piwoz and colleagues (2006) had received formal HIV and infant feeding counseling training.

In addition to having no formal counseling training, Malawian nurses also appeared to hold cultural beliefs and attitudes toward breastfeeding practices and HIV-infected mothers that would not promote WHO the infant feeding recommendations for HIV-infected women (Piwoz et al., 2006). Results from the BAN Study formative research indicated that nurses without experience counseling HIV-infected mothers had more negative attitudes about the ability of HIV-infected mothers to follow WHO infant feeding recommendations than those nurses with experience counseling HIV-infected mothers (Piwoz et al., 2006). Specifically, those nurses without experience counseling HIV-infected mothers did not believe that HIV-infected women should breastfeed at all (Piwoz et al., 2003). Further, although HIV-infected mothers expressed confidence in their ability to exclusively breastfeed for six months and stop breastfeeding soon after this time if nurses counseled them to do so, some nurses doubted these mothers' ability to follow WHO recommendations citing local infant feeding cultural norms as a major barrier (Piwoz et al., 2003). Based on the BAN Study formative research findings on the HIV and infant feeding counseling knowledge, attitudes and skills of Malawian nurses, all BAN Study nurse counselors completed a week-long HIV and infant feeding counseling training course (Piwoz et al., 2006).

Summary

This chapter provided context for this study by presenting an overview of the BAN Study, the HIV/AIDS epidemic in Malawi, the literature specific to MTCT via breastfeeding and determinants for nurses' HIV and infant feeding counseling behaviors. Figure 2 provides a conceptual model summarizing the determinants associated with

MTCT of HIV via breastfeeding among HIV-infected mothers in Malawi, while Table 2 summarizes the determinants that influence nurses' infant feeding counseling behavior.

Nurses and their implementation of the BAN Study infant feeding counseling protocol are the focus of this study. The review of the literature presented the determinants specific to nurses and their HIV and infant feeding counseling behavior which included their HIV and infant feeding counseling knowledge, attitudes and skills, traditional nursing communication and relationships with patients, nurses' working environment and the Malawi health system (see Table 2). These determinants provided the foundation for this study to assess BAN Study nurses' implementation of the BAN Study infant feeding counseling protocol. The next chapter will describe the theoretical concepts and present the conceptual models used to investigate the study's research objective.

Figure 1

Map of Malawi

Source: www.maps.com (2003)

Table 1
WHO (2001) Recommendations Regarding Infant Feeding for HIV-Infected Mothers

Topic area	Recommendations
Risk of breastfeeding and replacement feeding	• When replacement feeding is acceptable, feasible, affordable, sustainable and safe, avoidance of all breastfeeding by HIV-infected mothers is recommended. • Otherwise, exclusive breastfeeding is recommended during the first months of life. • To minimize HIV transmission risk, breastfeeding should be discontinued as soon as feasible, taking into account local circumstances, the individual woman's situation and the risks of replacement feeding (including infections other than HIV and malnutrition). • When HIV-infected mothers choose not to breastfeed from birth or stop breastfeeding later, they should be provided with specific guidance and support for at least the first 2 years of the child's life to ensure adequate replacement feeding. Programs should strive to improve conditions that will make replacement feeding safer for HIV-infected mothers and families.
Breastfeeding cessation	• HIV-infected mothers who breastfeed should be provided with specific guidance and support when they cease breastfeeding to avoid harmful nutritional and psychological consequences and to maintain breast health.
Infant feeding counseling	• All HIV-infected mothers should receive counseling, which includes provision of general information about the risks and benefits of various infant feeding options, and specific guidance in selecting the option most likely to be suitable for their situation. Whatever a mother decides, she should be supported in her choice. • Assessments should be conducted locally to identify the range of feeding options that are acceptable, feasible, affordable, sustainable and safe in a particular context. • Information and education on mother-to-child transmission of HIV should be urgently directed to the general public, affected communities and families. • Adequate numbers of people who can counsel HIV-infected women on infant feeding should be trained, deployed, supervised and supported. Such support should include updated training as new information and recommendations emerge.
Breast health	• HIV-infected women who breastfeed should be assisted to ensure that they use a good breastfeeding technique to prevent mastitis, breast abscess and nipple fissures, which should be treated promptly if they occur.

Figure 2

Factors Associated with MTCT of HIV via Breastfeeding: A Summary

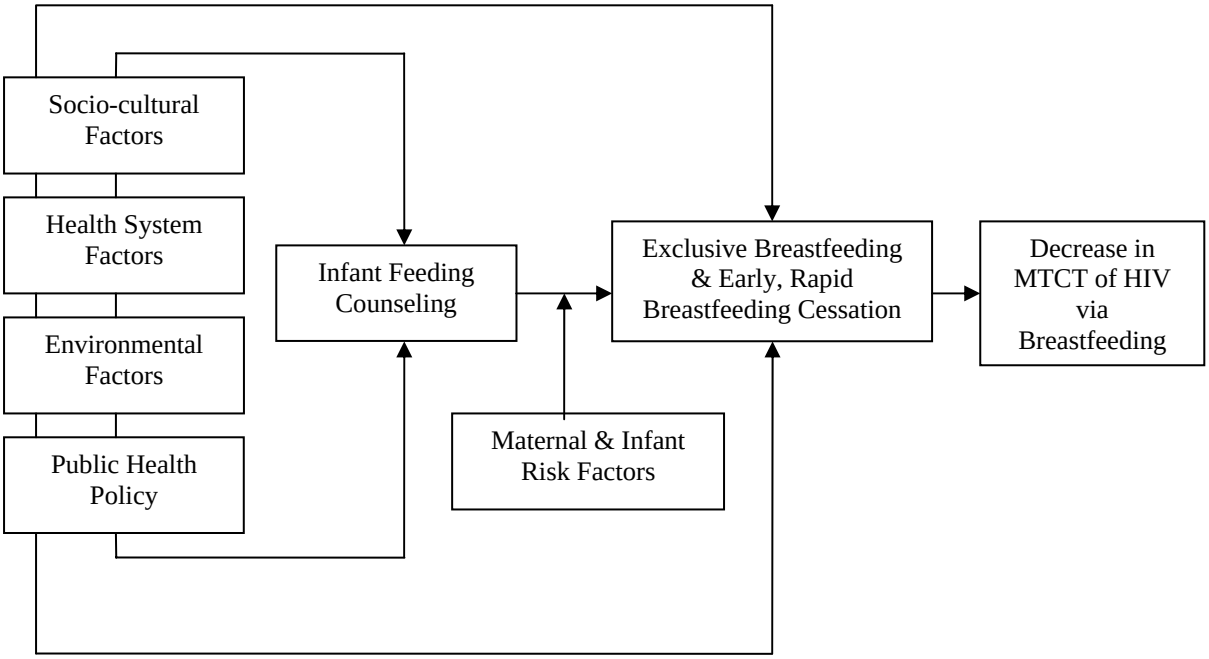


Table 2
Multi-Level Determinants of Infant Feeding Counseling Behavior among Malawian Nurses

Level	Determinants
Intrapersonal	• Lack of formal HIV and infant feeding counseling training • Lack of HIV and infant feeding knowledge and counseling skills • Not aware of WHO infant feeding recommendations for HIV-infected mothers • Negative attitudes in HIV-infected mothers' ability to follow WHO infant feeding recommendations
Interpersonal	• Trust patients have in nurses' recommendations • Nurses' traditional communication techniques of advice giving vs. counseling patients
Organizational	• Deterioration of health care system • Shortage of trained nurses • Lack of nursing standards • Poor working conditions • Long working hours • High patient to nurse ratios
Community	• Cultural beliefs that promote breastfeeding up to 2 years and mixed feeding at 3 months
Policy	• Government policies that influence health care system • Poor socio-economic conditions of country

CHAPTER III

THEORY, CONCEPTUAL MODELS & RESEARCH QUESTIONS

Overview

Theories help to guide process evaluation design, planning and implementation efforts (Glanz, Rimer & Lewis, 2002; Linnan & Steckler, 2002). To inform these efforts, researchers suggest that process evaluations be guided by the underlying theory of the intervention being delivered (Linnan & Steckler, 2002). With theory, process evaluators can plan what data to collect and from whom to collect it and why it should be collected (Helitzer & Yoon, 2002). Because theory is a useful first step in designing and implementing process evaluations (Baronowski & Stables, 2000; Forsetlund et al., 2003; Harachi et al., 1999; McGraw et al., 1994; Steckler & Linnan, 2002; Viadro, Earp, & Alpeter, 1997), this study used a social ecological perspective and theoretical concepts from the patient-provider communication literature to guide its process evaluation efforts. The following sections will describe the BAN Study infant feeding counseling protocol, its implicit theoretical framework and present a theoretically informed conceptual model of the multi-level determinants that influence nurses' infant feeding counseling behaviors and a conceptual model of the theorized patient-provider communication constructs and its influence on patient behavioral outcomes. This chapter concludes by stating the study's research questions.

BAN Study Infant Feeding Counseling Protocol

The aim of the BAN Study infant feeding counseling protocol was to guide BAN Study nurses on how to counsel HIV-infected mothers to practice exclusive breastfeeding

for their infant's first six months of life and early breastfeeding cessation between the infant's 21st and 24th week post partum (van der Horst, Jamieson, & Kazembe, 2005). The BAN Study infant feeding counseling protocol incorporated many of the information and concepts from the WHO HIV and Infant Feeding Counseling Training Course curriculum (WHO/UNICEF, 1993; WHO/UNAIDS/UNICEF 2000), which was based on years of field work and empirical evidence (H. Armstrong, personal communication, November 8, 2004). The course trained nurses to "counsel" versus "advise" mothers about infant feeding practices. WHO/UNICEF (1993) defines counseling as "a nurse helping a mother decide what is best for her and building a mother's confidence," while advising is defined as "a nurse telling a mother what they think they should do" (p.1). Every nurse on the BAN Study participated in a week-long infant feeding counseling training course conducted by a WHO-trained infant feeding counseling trainer (W. Msungama, personal communication, April 13, 2005). The training course included lectures, demonstrations, group work, role-play, clinical practice and class discussion sessions to help develop the BAN Study nurses' infant feeding clinical, support and counseling skills (WHO/UNICEF, 1993; WHO/UNAIDS/UNICEF, 2000).

Counseling Session Description

The BAN Study infant feeding protocol consisted of procedures to guide nurses on counseling HIV-infected mothers on exclusive breastfeeding, breast health, early breastfeeding cessation and complementary feeding (van der Horst, Jamieson, & Kazembe, 2005). These procedures were specific to the mother's pregnancy stage or infant's age and were posted as counseling aids in the counseling rooms (see Appendices A-D) (van der Horst, Jamieson, & Kazembe, 2005). The following is a description of the counseling sessions.

Each counseling session included both verbal and non-verbal counseling elements. The non-verbal elements remained the same for each counseling session, but the verbal elements changed depending on mother's pregnancy stage or infant's age. Non-verbal elements included the nurse establishing rapport with the mother, listening to the mother's infant feeding issues and displaying empathy. The verbal elements, which changed depending on the mother's visit type, included nurses counseling on exclusive breastfeeding for 6 months and stopping breastfeeding soon after, breast health issues, and complementary feeding. Table 3 displays the major verbal elements designed to be implemented during the counseling sessions by the mother's visit type. These counseling session visits were divided into four sequential time periods depending on the mother's pregnancy stage and infant's age. These time periods include the: (1) antenatal, (2) 1st to 18th week post partum, (3) 21st, 24th and 28th week post partum, and (4) 32nd to 48th week post partum visits.

Table 3
Major Verbal Counseling Elements Designed to be Implemented by Visit Type

Visit Type	Major Verbal Counseling Elements Designed to be Implemented
Antenatal	♦ Importance of exclusive breastfeeding for 6 months to prevent HIV transmission ♦ Risks of mixed feeding
1st to 18 week post partum	♦ Mother's demonstration of breastfeeding techniques ♦ Breast health issues-causes and treatments
21st, 24th and 28th week post partum	♦ Preparing mother and infant for stopping breastfeeding ♦ Stopping breastfeeding completely and introduction of other solids/liquids & Chiponde ♦ No breastfeeding and ensuring proper nutrition of baby via other solids/liquids & Chiponde
32nd to 48th week post partum	♦ Importance of giving infant other solids/liquids & Chiponde ♦ Assess if mother has stopped breastfeeding completely ♦ Advises mother about the importance of stopping breastfeeding to reduce risk of HIV infection to the infant

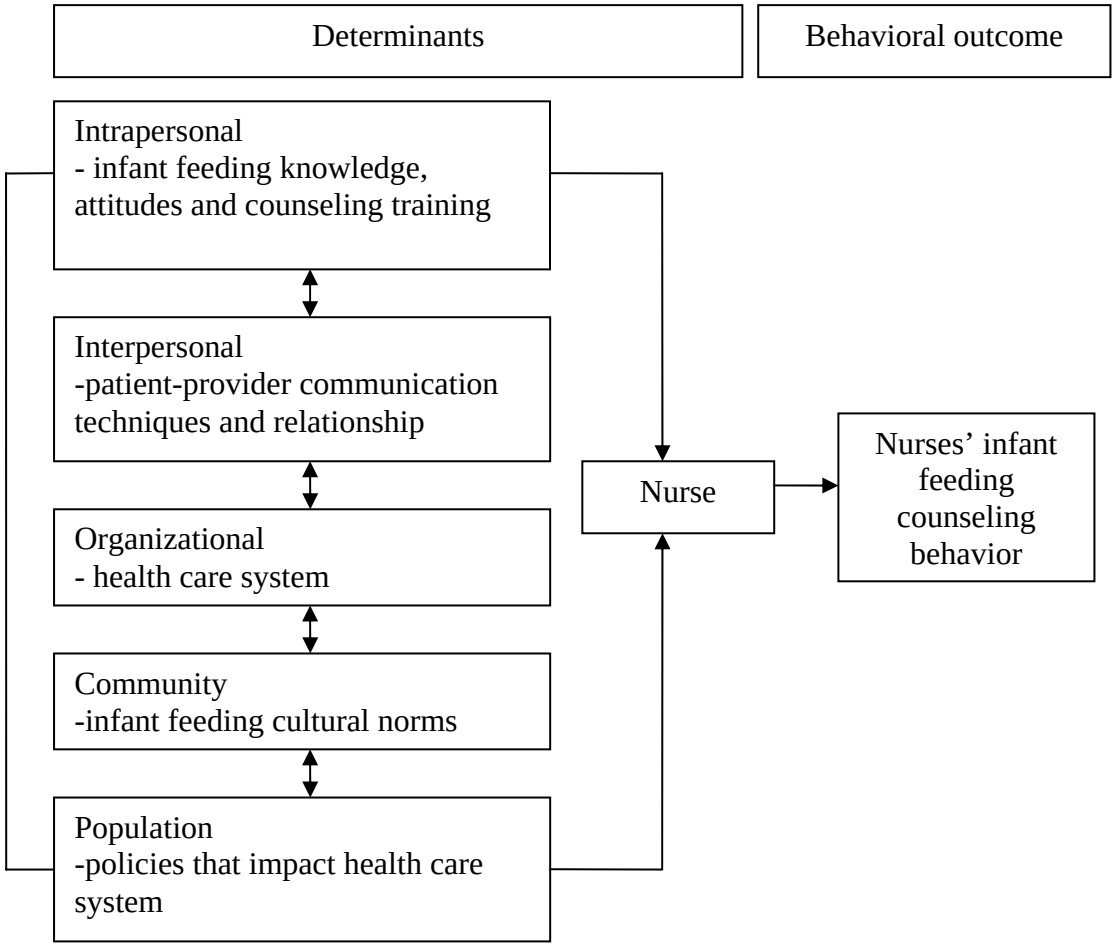
Conceptual Models

Although the BAN Study infant feeding counseling protocol and the WHO HIV and infant feeding counseling training curriculum lacked an explicit theoretical foundation (H. Armstrong, personal communication, November 8, 2004; van der Horst, Jamieson, & Kazembe, 2005), a theoretically informed conceptual model of what determinants influenced nurses' HIV and infant feeding counseling behavior and a conceptual model focusing on theoretically derived patient-provider relationship and communication concepts, provided an implicit theoretical framework for both the WHO HIV and infant feeding counseling training course curriculum (WHO/UNICEF, 1993; WHO/UNAIDS/UNICEF, 2000) and the BAN Study infant feeding counseling protocol (van der Horst, Jamieson, & Kazembe, 2005)

Determinants of nurses' counseling behavior. A conceptual framework for understanding the determinants that influence nurses' HIV and infant feeding counseling behavior was developed by using social ecological principles, which situate health behavior within the context of multiple levels of influence; from intrapersonal levels to population levels of influence (McLeroy, Bibeau, Steckler, & Glanz, 1988). Using a social ecological perspective to view and understand the factors that potentially influence nurses' HIV and infant feeding counseling behavior, in context to nurses' intrapersonal, interpersonal interactions and other social, cultural and environmental circumstances provided further insight into the study's investigation of how and why nurses implement the BAN Study infant feeding counseling protocol. For example, one of the research aims is to understand nurses' attitudes toward the BAN Study protocol. Using a social ecological perspective to organize the determinants of nurses' counseling behavior provided a view of how nurses' intrapersonal attitudes toward HIV and breastfeeding influenced their counseling behaviors.

As described in the review of the literature, nurses' HIV and infant feeding counseling behavior is influenced on: (1) an intrapersonal level by their lack of HIV and infant feeding knowledge, negative attitudes, cultural beliefs and lack of skills (2) an interpersonal level by the communication techniques they traditionally used with patients; (3) an organizational level by the deterioration of the Malawian health care system; (4) the community level by the local infant feeding cultural norms that promote early mixed feeding and breastfeeding up to two years; (5) and the population level by the government policies that effect the Malawian health care system (see Table 2). The following conceptual model presents these determinants, categorized by the social ecological perspective, and how they may influence nurses' HIV and infant feeding counseling behavior (see Figure 3).

Figure 3
Multi-Level Determinants that Influence Nurses' Infant Feeding Counseling Behavior



Viewing these multi-level determinants, from an ecological perspective, gave an understanding of the many factors that influence nurses' counseling behaviors. However, this dissertation study did not address all of these levels, but used process evaluation methods to focus on the interpersonal and intrapersonal level determinants. The following section describes the theorized interpersonal patient-provider constructs used in the WHO HIV and infant feeding counseling course curriculum (WHO/UNAIDS/UNICEF, 2000) and the BAN Study infant feeding counseling protocol (van der Horst, Jamieson, & Kazembe, 2005).

Patient-provider communication and relationship. Examining the dynamics involved in the interpersonal communication and relationship that occurs between the nurse and mother during the infant feeding counseling session, and how this influences HIV-infected mothers' infant feeding counseling practices, provided the study's theoretical foundation. Briefly, a review of the patient-provider communication literature concluded that patient-provider communication does influence patient outcomes (Roter & Hall, 1997), including HIV-infected mother's infant feeding practices (de Paoli, Manongi & Klepp, 2002; Piwoz et al., 2005; Seidel, Sewpaul & Dano, 2000).

In Malawi, community level cultural norms dictate the "blind faith" communities have for nurses and other health providers (Corneli et al., 2003). Traditional interpersonal patient-provider communication techniques may influence this cultural norm. For example, nurses in Malawi were trained to be directive and give strict instructions to their patients about recommended health behaviors, versus listening, supporting and working with their patients to understand their facilitators and barriers in carrying out recommended health behaviors (W. Msungama, personal communication, April 13, 2005). Based on the four patient-provider control prototypes outlined by Roter and Hall (1997), paternalism would best characterize the typical patient-provider relationship between nurses and HIV-infected mothers in Malawi. In this prototype, there is high health provider control and low patient control (Roter & Hall, 1997). Roter and Hall (1997) explained that for patients that are very sick and at their most vulnerable (e.g. being a pregnant or a breastfeeding HIV-infected mother), this relationship can be both nurturing and supportive because of its parent-child dynamic (Ende, Kazis, Ash & Moskowitz, 1989).

Although paternalism is the traditional form of communication and relationships between nurses and HIV-infected mothers in Malawi (W. Msungama, personal

communication, April 13, 2005), the WHO HIV and infant feeding counseling training course curriculum (WHO/UNAIDS/UNICEF, 2000) and the BAN Study infant feeding counseling protocol (van der Horst, Jamieson, & Kazembe, 2005) was developed from a mutuality prototype (Roter & Hall, 1997). In the mutuality prototype, the nurse and the patient recognize the strengths and resources each one brings to the counseling encounter, balancing out the power dynamic (Roter & Hall, 1997). Researchers note that influence and communication between patients and providers are most effective in changing health behavior if the relationship is characterized by mutual trust, respect, shared power and decision-making (Lewis, DeVellis & Sleath, 2002). These mutuality-type relationship characteristics were incorporated in the BAN Study infant feeding counseling protocol with the assumption that nurses' implementation of these mutuality counseling elements, versus the traditional paternalistic characteristics, would influence HIV-infected mothers' adherence to the BAN Study infant feeding recommendations (i.e. exclusively breastfeed for six months and early breastfeeding cessation between the infant's 21st and 24th week). Thus, within the BAN Study, nurses implementing this mutuality-type infant feeding counseling protocol, versus implementing the traditional paternalistic communication strategies, may influence HIV-infected mothers to follow the BAN Study infant feeding recommendations. Figure 4 shows how this mutuality patient-provider relationship, implicit in the BAN Study infant feeding counseling protocol, influences HIV-infected mothers' infant feeding counseling practices.

This change from a paternalistic to a mutuality-type relationship may be challenging for BAN Study nurses to consistently implement because traditionally, nurses in Malawi have been trained to establish a paternalistic-type relationship with their patients. Thus, this study investigated nurses' implementation consistency of mutuality-type counseling elements. Examples of mutuality-type counseling elements incorporated

in the BAN Study infant feeding counseling protocol and assessed in this study included nurses: (a) asking mothers about their infant feeding issues using open-ended questions, (b) not using commanding language during the counseling session , and (c) listening to mothers and showing active interest in understanding the mother's situation (i.e. empathy) (see Appendices E-H) (van der Horst, Jamieson & Kazembe, 2005; WHO/UNICEF, 1993; WHO/UNAIDS/UNICEF, 2000).

Provider behavior. Roter and Hall's (1997) proposed theoretical concepts examine the micro-level dynamics and behavioral consequences of patient and provider communication and their behaviors within the medical encounter. These theoretical concepts provided a framework for focusing on nurses' mutuality-oriented counseling behaviors that occurred during the infant feeding counseling session. Roter and Hall (1989, 1991 & 1997) characterized provider's mutuality-oriented behaviors as falling within the task or socio-emotional domain. In this study, specific task behaviors that nurses did and did not implement while counseling mothers on their infant feeding practices were assessed. Examples of task behaviors assessed included nurses: (a) explaining to mothers the advantages of giving only breast milk to her infant for 6 months to prevent HIV transmission, (b) advising mothers on the risks of mixed feeding, (c) asking mothers to demonstrate their breastfeeding techniques, and (d) asking mothers if they had experienced any breast health issues (see Appendices E-H) (van der Horst, Jamieson & Kazembe, 2005).

Based on the belief that all face-to-face behavior carries affective content, Roter and Hall (1989, 1991 & 1997) theorized that the socio-emotional domain and affective character of the patient-provider encounter could be seen on three levels: (1) intrinsic, (2) conveyed and (3) interpreted. Although the conveyed level, which describes the qualities of voice tone that carry emotional content, and the interpreted level, which reflects the

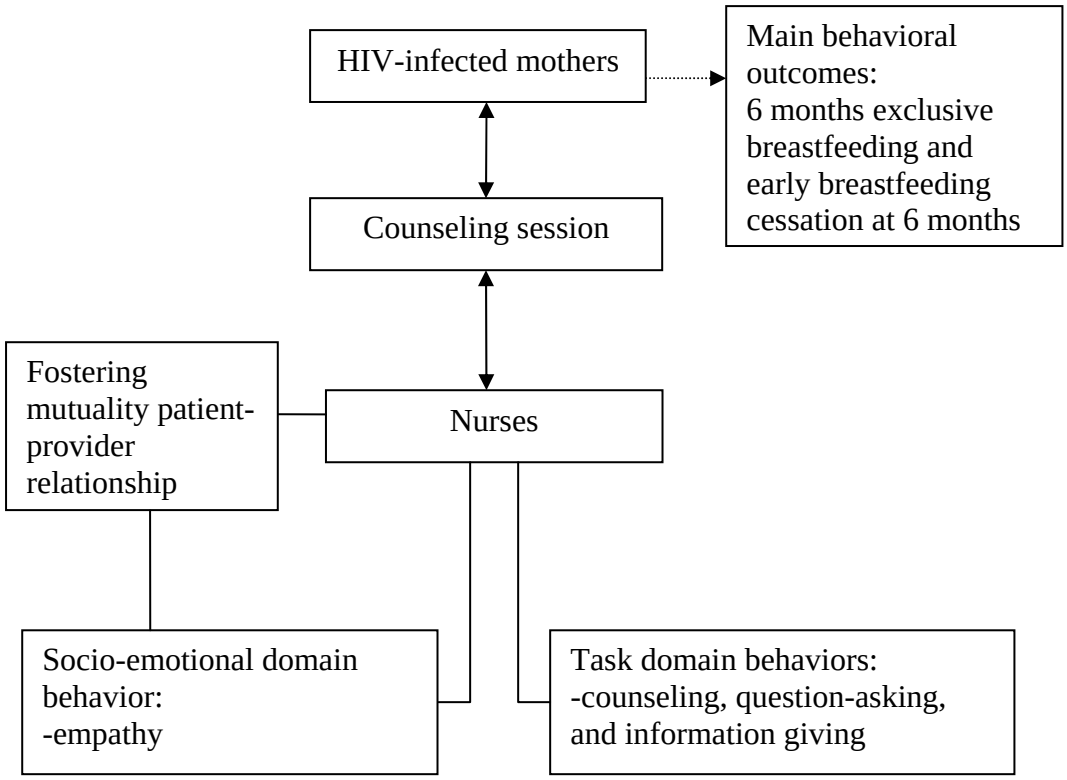
total impression created in the receiver of a communication were apparent during the counseling session, the intrinsic level was most relevant to this study (Roter & Hall, 1989, 1991 & 1997). The intrinsic level includes verbal exchanges with explicit socio-emotional content such as greetings, agreements, criticisms, statements of concern and empathy (Roter & Hall, 1989, 1991 & 1997). Empathy was the socio-emotional factor emphasized in the WHO HIV and infant feeding counseling course curriculum (WHO/UNICEF, 1993; WHO/UNAIDS/UNICEF, 2000) and the BAN Study infant feeding counseling protocol (van der Horst, Jamieson & Kazembe, 2005) and assessed in this study.

In this study, nurses' displayed empathy during the counseling session when they made an effort to understand the HIV-infected mother's perspective (Miller, Moyers, Ernst & Amrhein, 2003). Specifically, a nurse would display empathy when she showed an active interest in ensuring that she understood what the HIV-infected mother was saying by following the mother's statements, probing gently, and by using open-ended questions to gain clarity of the mother's infant feeding issues (Miller et al., 2003). In addition to asking open-ended questions, a nurse would also display empathy when she used reflective listening techniques, which included listening and repeating back (i.e. reflecting) what the mother had said in a slightly different way (WHO/UNICEF, 1993). Research suggests that nurses' skillful use of empathy techniques would facilitate the counseling session so that mothers felt comfortable saying what was important to them concerning infant feeding (Miller at al., 2003; WHO/UNICEF, 1993). This socio-emotional domain behavior is linked with nurses fostering a mutuality-type relationship with their patients. The BAN Study nurses were trained on how to implement these task and socio-emotional behaviors when counseling HIV-infected mothers enrolled in the BAN Study.

Figure 4 presents a conceptual model of the BAN Study infant feeding counseling protocol based on Roter and Hall's (1989, 1991, & 1997) patient-provider mutuality-type relationship concept and their socio-emotional and task domain behavior communication constructs for providers. This model shows how nurses fostering a mutuality type of relationship with their patients and implementing the task and socio-emotional domain behaviors in the protocol are theorized to influence HIV-infected mothers' infant feeding outcome behaviors recommended by the BAN Study.

Figure 4

Conceptual Model of How Nurses' Task and Socio-emotional Behaviors Influence HIV-infected Mothers' Behavioral Outcomes



Research Questions

To examine the mutuality-type relationship and task and socio-emotional domain behaviors of the BAN Study infant feeding protocol that nurses were trained to implement during their infant feeding counseling sessions with HIV-infected mothers, the following research questions guided this study:

1) What task and socio-emotional domain behaviors of the protocol were consistently implemented as designed?
2) What were nurses' patterns of adherence to the task and socio-emotional domain behaviors of the protocol?
3) What were nurses' attitudes toward the protocol?

Summary

While an overview of the BAN Study infant feeding counseling protocol provided details about the information nurses were trained to implement, viewing the many determinants from a social ecological perspective provided an understanding of the multi-levels in which nurses' counseling behavior may be influenced. This study used process evaluation approaches to examine how and why nurses implement the BAN Study infant feeding counseling protocol on two of the five social ecological levels presented, the intrapersonal and interpersonal levels.

Although, neither the WHO HIV and infant feeding counseling training course curriculum, nor the BAN Study infant feeding counseling protocol were based on an explicit theoretical foundation, Roter and Hall's (1989, 1991, & 1997) theorized constructs on patient-provider communication and relationships provided a conceptual framework for the protocol and this dissertation study. Roter and Hall's (1989, 1991, & 1997) provider focused task and socio-emotional theoretical concepts were used as a framework for the study to understand how the mutuality-type BAN Study infant feeding

counseling protocol, implemented by nurses, may influence the infant feeding behavior of HIV-infected mothers enrolled in the BAN Study. This framework served as a guide to identify appropriate methods and data collection techniques that should be used to answer the research questions.

CHAPTER IV

METHODS

Overview

This chapter will detail the methods used to answer the study's research questions: (1) what task and socio-emotional domain behaviors of the protocol were consistently implemented as designed; (2) what were nurses' patterns of adherence to the task and socio-emotional domain behaviors of the protocol; and (3) what were nurses' attitudes toward the BAN Study infant feeding counseling protocol.

Because of its emphasis on program implementation, a process evaluation approach, using observations and interviews and focusing on intervention fidelity and dose delivered, provided guidance to answer the research questions. In this chapter, how the dissertation author entered the field, process evaluation definitions and measures, a description of the research sample, data collection instruments and analysis techniques will be presented. The chapter concludes with the dissertation author's processes and decisions made to optimize the credibility of the study findings.

Entry into the Field

Many efforts were made by the dissertation author to facilitate the planning and coordination of conducting this study. As a member of the BAN Study nutrition team, the dissertation author made 3 trips to Lilongwe for 2 years prior to collecting data for this study. During these brief visits, the dissertation author met the Malawi-based BAN Study team, learned about the day-to-day operations of the study, established relationships and friendships with the nurses and other study staff, and learned more about Malawian culture. The dissertation author received technical assistance from the

Malawi-based BAN Study nutrition team staff, as well as the CDC and UNC co-investigators to coordinate the data collection process. The trips to Lilongwe and the coordination and communication with BAN Study team members led to this process evaluation study being successfully conducted within the context of an HIV/AIDS clinical trial. However, conducting this dissertation study was not without challenges. Difficulties ranged from the practical, such as having a space for the research team to work, to political. Although the BAN Study co-investigators and nursing supervisor welcomed the study concept, the nurses were initially very resistant and some believed that they would lose their job if their counseling performance was poor. After the dissertation author met with all of the nursing staff and explained in detail the research questions, confidentiality of the study data, and data collection process the nurses felt more at ease with the study and wanted to participate. Having gained the confidence and support from the BAN Study nurses, the dissertation author was able to begin the data collection process. In the following sections the methods used to collect the study data will be described.

Process Evaluation

Although much emphasis in the evaluation field is on impact and outcome evaluations (Israel et al., 1995), process evaluation is also important in advancing public health research and practice (Linnan & Steckler, 2002). The purpose of process evaluation is to document and analyze the way an intervention operates by assessing how intervention activities further shape objectives and providing data that can be used to interpret study impact and outcomes (Corbett et al., 1991; Dehar et al., 1993; Israel et al., 1995; McGraw et al., 1994). Researchers agree that conducting process evaluations are important toward advancing public health research and practice because they help to understand how and why interventions succeed or fail (Linnan & Steckler, 2002). Failure

to conduct process evaluations to inform study impact and outcomes may result in a Type III error, or program implementation failure (Basch et al., 1985).

Fidelity and dose delivered. This study focuses on assessing implementation fidelity and the implementation dose delivered by the BAN Study nurses. These process evaluation components were used to investigate: (1) what task and socio-emotional domain behaviors of the protocol were consistently implemented as designed and (2) what were nurses' patterns of adherence to the task and socio-emotional domain behaviors of the protocol. This study was guided by Linnan and Steckler's (2002) definitions of fidelity and dose delivered:

> Fidelity- The extent to which the intervention was delivered as planned. It represents the quality and integrity of the intervention as conceived by the developers. Fidelity is a function of the intervention providers (p.12).
>
> Dose delivered- The number or amount of intended units of each intervention or each component delivered or provided. Dose delivered is a function of the intervention providers (p.12).

Dose delivered and fidelity are distinct, but related components in assessing program implementation (Baranowski & Stables, 2000; Dane & Schneider, 1998; Dusenbury et al., 2003; Linnan & Steckler, 2002; Resnicow et al., 1998). Fidelity of implementation is difficult to measure with a standardized methodology or tool (Dunesbury et al., 2003; Linnan & Steckler, 2002). Thus, previous fidelity measurement tools have been specific to the program or intervention being assessed (Dunesbury et al., 2003) as was the case for this study. In terms of dose delivered, researchers note that intervention developers are more confident that the intended dose will be delivered within the context of a research environment with paid and trained research program implementers versus an environment where non-research program implementers are

involved (Dusenbury et al., 2003). This study involved paid research personnel (i.e., nurses), indicating high confidence that the intended dose would be delivered. Despite this high confidence, nurses may not have consistently delivered a number of key counseling elements because of socio-cultural, organizational, and other factors associated with infant feeding counseling behavior (see Figure 3 in Chapter III). Thus, dose delivered and fidelity data were collected to assess nurses' implementation adherence of the BAN Study infant feeding counseling protocol.

Sample

The study sample consisted of 6 nurses who were employed by the BAN Study. Analyzing these nurses' curricula vitae revealed that all of them were married, had an average age of 32 years (range, 28-46; median 30), had graduated from a nursing school in Malawi, had average of 6.8 years of nursing experience (range, 3-10; median 7), had participated in an infant feeding counseling training, and had been working for the BAN Study before enrollment of participants for the clinical trial began in April 2004. All nurses were fluent in both English and Chichewa. Study participants also included 123 HIV-infected mothers who reported to the BAN Study clinic for their regularly scheduled antenatal through 48th week post partum visits. The data collection period was November to December 2005.

Out of approximately 20 total nurses working on the BAN Study, 6 nurses were purposefully sampled and recruited for this study. This sample represented 30.0% of the total nurses working on the study. These 6 nurses were recruited by the BAN Study nurse supervisor and the nurse team leaders. Prior participation in the BAN Study HIV and infant feeding counseling training course was the only criteria necessary for inclusion in the study. All 6 nurses who were recruited to be in the study agreed to participate. These nurses were assigned by the nurse supervisor and the nurse team leaders to a two-week

counseling room rotation for this study, while the nurses not participating in this study were assigned to other BAN Study clinic duties.

A purposeful sample of mothers was also recruited for this study during the morning of their regularly scheduled visit in two stages. First, two members of the research team conducted a brief health education session on the purpose of the study every morning at 8:00 a.m., 9:00 a.m. and 10:00 a.m. while mothers waited in the clinic corridor to begin their BAN Study clinic visit. Second, mothers were recruited in the counseling room by a trained field investigator before the mother's routine counseling session began. Out of the 129 mother's recruited, 6 declined to participate and 123 accepted. The selection criteria for mothers' participation in this study was based on key variables identified as important from the BAN Study infant feeding counseling protocol. Specifically, selection of mothers for the study depended on their pregnancy stage or the age of their infant, which was categorized into four critical infant feeding counseling stages: (1) antenatal visits; (2) 1^{st} to 18^{th} week post partum visits; (3) 21^{st}, 24^{th} and 28^{th} week post partum visits; and (4) 32^{nd} to 48^{th} week post partum visits. These four stages were critical because the infant feeding counseling messages delivered at these stages differed depending on the mother's stage of pregnancy or their infant's age (van der Horst, Jamieson, & Kazembe, 2005). A description of the counseling messages nurses delivered during each of the four stages was presented in the third chapter of this dissertation.

Overall, each of the 6 nurses had at least 4 counseling sessions recorded at each of the 4 critical infant feeding counseling stages and at least 20 total counseling sessions were directly observed (see Table 4).

Data Collection Methods

Direct observations and interviews were the primary data collection methods used for this study. Direct observations of the counseling sessions were used to collect data on the fidelity and dose delivered-related research questions. (Bentley et al., 1994; Linnan & Steckler, 2002; McKenzie et al., 1994; Resnicow et al., 1988). Reports indicate that direct observation techniques are an effective approach to collect data on health behaviors (Bentley et al., 1994), verbal patient-provider interactions (Roter & Larson, 2002), and program implementation (Patton, 1990; Walsh et al., 2000). Interviews with nurses were conducted to ascertain their perspectives on the BAN Study infant feeding counseling protocol. Similar to direct observations, gathering information from program implementers via interviews is also an important component of evaluating programs (Patton, 1990).

Counseling session observations. An implementation checklist and field notes were used as tools to capture nurses' counseling behaviors observed during the counseling sessions. A trained field investigator audio-recorded, wrote field notes and completed an implementation checklist of each counseling session they directly observed. The audio-taped recordings were simultaneously transcribed and translated verbatim into English by a field investigator. Field notes captured the following aspects of the counseling session: (1) length of time; (2) any interruptions or disturbances that occurred; and (3) a description of the mother's non-verbal communication. Field investigators used a checklist tool to document nurses' implementation of key infant feeding counseling elements. The checklist items included verbal and non-verbal key counseling techniques that were derived from the WHO Breastfeeding Counseling Training Manual (WHO/UNICEF, 1993) and the BAN Study infant feeding counseling protocol (van der Horst, Jamieson, & Kazembe, 2005). The verbal checklist elements were tailored to the:

(1) antenatal visits; (2) 1st to 18th week post partum visits; (3) 21st, 24th and 28th week post partum visits; and (4) 32nd to 48th week post partum visits, while the non-verbal elements remained the same for all visits (see Appendices E-H).

Nurse interviews. Interviews with nurses were conducted after directly observing 20 of their counseling sessions. Using a pre-tested interview guide, a field investigator conducted an hour-long interview with each participating nurse in English. The field investigator who conducted the interview also transcribed the interview producing a verbatim transcript. The interview questions focused on nurses' attitudes toward the BAN Study infant feeding protocol, their implementation skills, and suggestions on how to improve their implementation (see Appendix I).

Data Collectors

All data were collected by four paid and trained Malawian field investigators who had educational and/or previous work experience in nutrition and or HIV/AIDS-related research. All field investigators were fluent in both Chichewa and English and were paid for working on this study. Prior to data collection, field investigators participated in a 3-week training. The training was conducted for 7 hours each week day by the field coordinator (author of this dissertation) and incorporated empowerment education approaches (Arnold et al., 1991; Vella, 1989, 1995). The first two weeks of training focused on research ethics, HIV/AIDS and infant feeding knowledge and attitudes, qualitative data collection techniques, observing counseling sessions, completing the implementation checklist, and team building. For the final week of training, the field investigators refined their transcribing and translation skills with an intensive exercise.

For this exercise, the field investigators, together, observed and audio-recorded a Chichewa mock counseling session, performed by two BAN Study nurses. Next, the field investigators individually transcribed the same audio-recording into Chichewa and then

translated the verbatim transcript into English. During the exercise, the field investigators recorded their transcription and translation times and discussed their Chichewa and English transcripts as a group. The average time it took for transcribing verbatim, the Chichewa audio-recording into Chichewa, was 7.5 hours and 8.5 hours for the translation of the transcript from Chichewa into English. Based on these results, the field coordinator decided that all Chichewa audio-recorded counseling sessions would be simultaneously transcribed and translated into English by the field investigators to decrease transcription/translation time. A benefit from this week-long exercise was that the field investigators developed a standard and group understanding of how they would transcribe/translate their English transcripts.

All field investigators were also trained on how and what to observe during the counseling sessions and complete the implementation checklist tool. To complete the implementation checklist, field investigators were trained to identify what items the nurse did and did not implement. During the 3-week training period, the field investigators' inter-rater reliability percentage was recorded to determine the degree to which they were in agreement with what they observed (DeVellis, 2002). To determine the inter-rater reliability percentage, the field investigators and the field coordinator observed an English mock counseling session performed by two BAN Study nurses, and completed the implementation checklist tool. The percent agreement was calculated by taking the number of items agreed upon and dividing that number by the total number of items and multiplying that number by 100. The inter-rater reliability was 84.6%, which was slightly below the preliminary criteria of achieving at least an 85.0% inter-rater reliability. Inter-rater reliability results of the Chichewa mock counseling session were also 84.6% among the field investigators.

Data Management

Transcripts. All audio-recorded counseling sessions and interviews were transcribed verbatim and translated (if necessary) into English by a field investigator to ensure accuracy of what was verbally said and how it was said during the counseling session and interviews (Sandelowski, 1994). With assistance from the field investigators, the field coordinator developed a standard of procedures document to guide field investigators in their transcription/translation process (see Appendix J). The database manager typed all hand-written transcripts into the study database and organized them by an assigned archival number. All transcripts were periodically reviewed by the field coordinator for clarity and completeness.

Implementation checklists. The database manager typed all completed implementation checklists into the study database and labeled it with an assigned archival number consistent with the archival number of the counseling session from which it was recorded. A record of the field investigator's name who recorded the implementation checklist, as well as the date and time of the counseling session was documented on each implementation checklist for organization and management purposes. For example, if there was a question about the items checked on a particular implementation checklist, the database manager or field coordinator could ask the field investigator who observed the session for clarification.

Field notes. The database manager also typed all field notes into the study database and labeled it with an assigned archival number consistent with the archival number of the counseling session and implementation checklist from which it was recorded.

Database organization. A complete record of a nurse's counseling session included a transcript, implementation checklist and field notes. These data were labeled

with the same archival number. The archival number assignment structure included the nurses' three-digit study identification, the mother's four-digit study visit number (e.g. visit 10.00) and the two-digit nurses' observation number out of 20 total observations. For example, for a nurse whose study identification number was 101, was counseling a mother during her 18th week post partum study visit and had completed seven of at least 20 counseling session observations, 101-13.00-07 would be the assigned archival number. The database manager documented and verbally communicated the progress of all completed records. This daily communication assisted the research team with achieving the study's sample size goals.

Validity

Many steps were taken to optimize the credibility of the study findings. Using Maxwell's (1992) typology of validity, as well as Rogers and Cowles (1993) audit trail documentation as a guide, the following section will describe how this study incorporated descriptive, interpretive, and theoretical validity steps, as well as an audit trail, to optimize the credibility of the study findings.

Audi-recordings and implementation checklists. Descriptive validity, or the descriptive accuracy and proper sequence of accounts (Maxwell, 1992), was established through various strategies. Having an audio-taped recording of all counseling sessions and interviews helped to provide a recorded account of participants' verbal communication. If a field investigator questioned any of the audio-recorded data, they requested other research team members to listen to the audio-recorded account until an agreement was made on the recorded data in question. The audio-taped recordings were relied upon as the most valid data collection tool.

As previously stated, the inter-rater reliability among the field investigators was 84.6%, which was slightly below the preliminary criteria of achieving at least an 85.0%

inter-rater reliability. Establishing an inter-rater reliability, that minimally met the preliminary criteria, helped to strengthen the credibility of the implementation checklist results, however, because the inter-rater reliability standard was minimally met, another strategy was employed to strengthen the descriptive validity of the implementation checklist.

During the data collection process, the audio-recorded counseling session transcript was assumed to capture the verbal communication more accurately than the field investigators' completion of the implementation checklist. Based on this assumption, each completed implementation checklist was cross-checked for accuracy with the counseling session transcript, which allowed the field investigator's implementation checklist assessment to be verified and corrected (if necessary). Through this validation process, it was discovered that 16 of the 123 completed implementation checklists (approximately 13.0%) were not marked correctly by the field investigator. Instituting this additional process strengthened descriptive validity of the implementation checklist findings.

Translation. Understanding the steps and methodological decisions made concerning translation of the recorded data was also important in establishing descriptive, as well as interpretive validity (Maxwell, 1992). Interpretive validity refers to the participants' account of a situation or issue, which is grounded in participants' language and relies, as much as possible, on their words and concepts (Maxwell, 1992). Inherent in any translation process is an interpretation of words, especially when there is an incompatibility between the languages in terms of sentence structure, which is the case with Chichewa and English (Birbili, 2000). When this incompatibility arises, Birbili (2000) suggests that the aim of the translation should be conceptual equivalence versus a literal translation. This research study involved collecting data in Chichewa (a native

Malawian language), and translating and presenting the study findings in English. There were many translation-related decisions made to maintain the descriptive and interpretive validity of the transcripts. First, because of the time-consuming process of transcribing verbatim Chichewa transcripts and then translating these transcripts into English, which took approximately 16 hours for field investigators to complete during the training period, the field coordinator decided to have the field investigators simultaneously translate and transcribe the Chichewa audio-recordings into English. This decreased the translation/transcription time to approximately 7 hours for a 25 minute counseling session. All field investigators had previous experience conducting this type of advanced translation process. Their similar backgrounds in HIV/AIDS, nutrition and qualitative research also influenced their transcription/translation speed and the terms they used to achieve conceptual equivalence in the English transcripts.

Back-translations were not conducted due to the limited time of the data collection phase and the decision to simultaneously transcribe and translate the counseling sessions. However, to strengthen the validity of the translated transcripts, the field investigators and field coordinator had daily discussions about the use and meaning of certain Chichewa words, utterances and non-verbal communication and made joint decisions about the most appropriate English terms or phrases to use to achieve conceptual equivalence (Birbili, 2000).

Another strategy employed to strengthen the validity of the data and how it was reported, was the U.S. field coordinator's (author of this dissertation) familiarity with Malawi and Malawian culture. The U.S. field coordinator had visited Malawi several times before beginning the data collection phase and spent a prolonged period of time working closely with the Malawian field investigators during the data collection phase to gain more knowledge and understanding of Malawian culture. Having these collaborative

discussions and spending time immersed in Malawian culture enabled the field coordinator to make translation-related decisions and account for translation-related challenges that occurred during the study (Birbili, 2000).

Dissertation committee. According to Maxwell (1992), theoretical validity, or how the researcher interprets and applies and concepts to characterize or explain the behaviors or accounts under study, is important when assessing the validity of a qualitative study. For this study, a committee of health sciences faculty and researchers was assembled to advise, guide and critique the dissertation author's use of terms to describe and explain nurses' implementation adherence and attitudes toward the BAN Study infant feeding counseling protocol. Theoretical validity was established by this committee agreeing on the author's use of theoretical concepts to describe and explain the relationships among the concepts (see Figure 4) and the terms used to explain and discuss the study findings (see Chapter VI Discussion).

Audit trail. An audit trail was maintained to document the steps, insights, interpretations and other factors during the data collection and analysis process (Rodgers & Cowles, 1993). A daily study diary was kept by the field coordinator to document the data collection process. Items included methodological decisions, sample size tracking, concerns or issues from the field investigators or nurse participants, field investigator daily responsibilities, data collection supply inventory tracking and pertinent conversations with BAN Study staff.

Field investigators recorded brief field notes of every counseling session, noting the counseling session's beginning and ending time, the non-verbal expressions and communication by the mother, interruptions that took place and their personal account of the counseling session. The field coordinator also documented analytic ideas and personal experiences throughout the study period. These documentation measures

established trustworthiness and rigor of the study process and strengthened the study findings (Rodgers & Cowles, 1993).

Data Analysis

Employing content analysis techniques, the counseling session transcripts, implementation checklists and interview transcripts were analyzed using a combination of case-oriented and variable-oriented approaches (Miles and Huberman, 1994). Counseling session transcripts and implementation checklist results were compared: (1) as a whole by nurse (i.e. case); (2) by mother's visit type (i.e. variable); and (3) by key counseling element (i.e. variable). Each nurse's total and individual interview responses were compared: (1) with other nurses' transcripts and (2) by comparing nurses' responses to individual interview questions. The following sections will detail the analysis process of the counseling session transcripts, implementation checklists and nurses' interviews.

Counseling session transcripts. Analysis of counseling session transcripts was guided by the implementation checklists and research questions concerning: (1) what task and socio-emotional domain behaviors of the protocol were consistently implemented as designed; (2) what were nurses' patterns of adherence to the task and socio-emotional domain behaviors of the protocol. Analysis of the counseling session transcripts began by reading and re-reading the transcripts to understand each transcript as a whole and writing a summary for each transcript, noting important features (Sandelowski, 1995, 1996). An example of a counseling session summary can be found in Appendix K. Next, using a systematic approach, each nurse's counseling session transcript summary was grouped by mothers' visit type for coding and further analysis.

The implementation checklist items were used to guide the coding of the counseling session transcripts. Using ATLAS.ti version 5.0 (Muhr, 2004), a qualitative software package, key counseling protocol elements (i.e. variables) listed in the

implementation checklist were used to code the counseling transcripts (see Appendices E-H). These codes varied by the mother's visit type. For example, the codes used for coding the 1st to 18th week post partum visits were different from the codes used for the 32nd to 48th week post partum visits because of the different counseling messages delivered during these visits. While coding the counseling transcripts recurring patterns appeared and warranted additional codes that were not captured by the implementation checklist items. For example, during many of the counseling session transcripts, mothers and/or nurses mentioned use or intended use of milk formula to feed their infant. Thus, a "milk formula" code was developed to account for this infant feeding element not captured in the implementation checklist. After each nurses' counseling session transcript was coded according to the mother' visit type, all coded data were read and re-read to ensure that the transcript data under each code was representative of that code. The coded transcript data were used to show examples of how nurses' implemented the counseling protocol. Operational definitions of each implementation checklist item used as a code, and codes developed during the coding process were developed collaboratively by the Malawian field investigators and U.S. field coordinator. A code book with these operational definitions, categorized by mothers' visit, can be found in the Appendices (see Appendix L).

After completing the coding process, the case-level data were organized using a visual display. In the visual display, each nurse's implementation adherence to the protocol was presented based on their implementation checklist results. The visual display was used to also organize the similarities and differences in each nurse's protocol delivery (see Appendix M). Next, this case-level display was used to conduct a cross-case analysis noting similarities, differences and patterns in implementation adherence between nurses. This case-oriented analysis lead to a variable-oriented analysis where the

variables were organized according to the mother's visit type and compared the nurses' overall average implementation adherence according to mothers' visit type and displayed summaries of key counseling elements not implemented by the nurses (Miles & Huberman, 1994) (see Appendix N). Results of the implementation checklists assisted the variable-oriented analysis in that it enabled the identification of key counseling elements not implemented by the nurses.

In presenting the findings, the implementation checklist results allowed for a quantitative assessment of elements implemented and not implemented by the nurses, while the counseling session transcripts presented examples of how and what key counseling elements nurses actually implemented.

The implementation checklists were used as a quantitative tool to assess nurses' implementation adherence to key counseling elements of the infant feeding counseling protocol and how consistent were nurses in their patterns of adherence to key counseling elements. Implementation adherence was measured by calculating a percent adherence. An implementation percent adherence was calculated by adding the "Y's" (i.e. "Yes" indicating that a specific counseling element was implemented) recorded by the field investigator during the counseling session, dividing that number by the total number of checklist items and multiplying this number by 100. Because nurses are implementing this protocol within the context of a clinical trial, which is highly monitored and supervised environment to ensure high quality care for the participants, implementing protocols at a high level is encouraged. Thus, 90% was determined as an acceptable implementation adherence level a priori. The percent adherence calculation was a weighted percentage, where verbal items on the implementation checklist contributed 80%, and non-verbal items contributed 20%. After a percent adherence was calculated for each implementation checklist, the implementation checklists were separated by nurse

and an average implementation percent adherence was calculated for each nurse. An average implementation percent adherence was also calculated for each nurse by the mother's visit (i.e. antenatal visit, 1st to 18th week post partum visit, 21st, 24th and 28th week post partum visit, and 32nd to 48th week post partum visit).

Nurses interviews. Analysis of the nurses' interview transcripts were guided by the research question concerning nurses' attitudes toward the BAN Study infant feeding counseling protocol. Similar to the counseling session transcripts, the nurses' interview transcripts were read and re-read to get a sense of the whole and a case profile was written on each nurse (Sandelowski, 1995, 1996). An example of a nurse's case profile can be found in Appendix O. Next, using ATLAS.ti version 5.0 (Muhr, 2004), the transcripts were analyzed with codes derived from the interview guide questions (see Appendix I). Codes developed during the coding process were also created based on ideas consistently mentioned by the nurses concerning their protocol implementation. After coding the interviews, a content analysis was conducted using within and cross-case analysis approaches (Miles & Huberman, 1994). Specifically, the coded data were analyzed first by describing the elements within each interview and then comparing these interview responses across nurses to discerned reoccurring patterns. These analysis techniques allowed for nurses' responses to be categorized by three main topic areas: (1) attitudes toward implementation; (2) barriers toward complete implementation; and (3) suggestions for implementation improvement, which are presented in the next chapter.

Human Subjects

The institutional review boards at the U.S. Centers for Disease Control and Prevention, the University of North Carolina at Chapel Hill, and the National Health Science Research Committee in Malawi approved this research study and each participant provided written informed consent (see Appendices P-R). Additionally, each member of

the research team signed a confidentiality agreement to protect the privacy of study participants.

Summary

In this chapter a description of how this study used process evaluation components, as well as primarily qualitative methods, to address the research questions was presented. Direct observations of counseling sessions and interviews with nurses served as the primary data sources. Recruitment efforts resulted in a sample of 6 nurses and 123 HIV-infected mothers. Each field investigator was trained on what and how to observe the counseling sessions, record the implementation checklists, take field notes, and refine their transcription/translation skills. The field coordinator made methodological decisions to reduce the transcription/translation time and incorporated strategies to strengthen the credibility of the study findings. A combination of a case and variable-oriented analysis of the counseling session transcripts, guided by the implementation checklists, resulted in a presentation of which key counseling elements of the BAN Study infant feeding protocol nurses adhered to and which were not adhered to and how consistent were nurses' patterns of adherence. A combination of within and cross-case analysis approaches were used to analyze the nurses' interviews. The next chapter will present these findings, along with nurses' insights about their protocol implementation adherence discerned from their interviews.

Table 4
Type and Number of Counseling Observations Recorded

Nurse	Antenatal	1st to 18th week post partum	21st, 24th, and 28th week post partum	32nd to 48th week post partum	Total
1	5	5	6	4	20
2	5	5	5	6	21
3	5	5	5	5	20
4	5	5	5	5	20
5	5	5	4	6	20
6	5	8	5	4	22
Total	30	33	30	30	123

CHAPTER V

FINDINGS

Overview

The findings concerning BAN Study nurses' implementation of the infant feeding counseling protocol focus on understanding: (1) what task and socio-emotional domain behaviors of the protocol were consistency implemented as designed; (2) what were nurses' patterns of adherence to the task and socio-emotional domains of the protocol; and (3) what were nurses' attitudes toward the protocol? This chapter is organized into four sections: (1) presents a description of the study setting to provide a context for the study findings, (2) presents the observation findings according to the mother's visit, (3) presents the observation findings according to individual nurses, and (4) presents the nurses' interview findings.

Study Setting

The BAN Study clinic is located at Bottom Hospital in Lilongwe, Malawi, where approximately 9,000 deliveries are done each year. Bottom Hospital is centrally located close to the city market, where Malawians in Lilongwe buy clothes, food and other household items. Mothers enrolled in the BAN Study receive a travel reimbursement of 500 Malawi Kwacha, approximately $3.85, for each clinic visit; however, many mothers walk many kilometers, starting in the early morning hours, to reach the BAN Study clinic before 7:30 a.m. Although Bottom Hospital is centrally located in town, most mothers live in the surrounding outskirt areas of Lilongwe. Travel reimbursements are sometimes spent to buy food for the family, versus transportation costs to and from the BAN Study clinic. Most mothers are already present in the morning to begin their clinic visit before

the nurses arrive, which is usually around 7:30 a.m. The BAN Study nurses' workday beings at 7:30 a.m. and it continues until the last mother has completed her study visit for the day, which is typically around 5:00 p.m., but can be as late as 6:30 p.m. Nurses work all day and get an hour lunch break; however, most nurses do not take the full hour because of the number of patients waiting for health services. Most nurses who work with the UNC Project and at Bottom Hospital end their workday at 5:00 p.m. The mothers check-in for their study visit with a reception nurse and then wait and sit on long wooden benches or chairs that line up on either side of the clinic corridor wall. Cries from infants, chatter from mothers and nurses loudly calling patients' into rooms, fill the clinic corridor.

On average, 31 mothers and 16 infants per day visit the study clinic and fill the clinic corridor waiting area to capacity. In addition to the many mothers and infants, there are approximately 20 nurses and three clinicians who interact directly with the mothers and infants daily. Other BAN Study team members who work in the clinic area are the pharmacy and laboratory technicians, data department staff and janitorial staff, resulting in much staff movement around the small clinic.

The length of the mothers' clinic visit depends on the type of study visit (e.g. antenatal, 1st week post partum, or 32nd week post partum visit). Mothers and infants are seen by a clinician and nurses for the following: (1) blood draws, (2) completing questionnaires, (3) counseling, (4) physical examinations and (5) distribution of medications, stipends, food coupons, maternal nutritional supplements and infant ready-to-use food. Among all of the study visit processes, the counseling room process usually takes the most time to complete because the material discussed depends on the mother's study visit. Counseling topics include, but are not limited to, domestic situations, HIV/AIDS-related stigma from the community, lack of household finances, maternal

nutrition, medication adherence, and infant feeding. During this study, the average counseling time recorded was 32 minutes. Specifically, the average time of the antenatal visits was 29 minutes (range 10-54 minutes), the average time of the 1st to 18th week post partum visits was 46 minutes (range 9-205 minutes), the average time of the 21st, 24th and 28th week post partum visits was 33 minutes (range 11-70 minutes), the average time of the 32nd to 48th week post partum visits was 22 minutes (range 10-42 minutes). Nurses were absent from the counseling room at least once during a counseling session to obtain medications from the pharmacy (located within the clinic) for the mother or infant, depending on what study arm the patient was randomized to and their study visit type. Nurses spent an average of 14 minutes out of the counseling room to obtain these items for their patients.

The counseling rooms had space for 3 people: the nurse, mother (with or without her infant) and the field investigator recording the observation. Since the study took place during the summer season, a fan was usually on to cool the people in the room and a window open slightly for air, but not open enough for other people to view who was in the counseling room. Items present in the room included a table against a wall, three chairs, the patient's folder, condoms, a wooden penis model to demonstrate condom use, medication bottles of study drugs to demonstrate how and when to take the prescribed medications, a baby doll for breastfeeding demonstrations, and a bottle of Chiponde cha mwana (Chichewa translation is "peanut butter for child"), a fortified energy-dense breast milk replacement food provided by the BAN Study to all infants (van der Horst, Jamieson, Kazembe, 2005). The wall in front of the nurse's table was posted with counseling aids on infant feeding and other counseling topics from the BAN Study protocol.

Observations by Mother's Visit

Results of the observations focus on answering: (1) what task and socio-emotional domain behaviors of the protocol were consistently implemented as designed; and (2) what were nurses' patterns of adherence to the task and socio-emotional domain behaviors of the protocol. These findings revealed that nurses implemented the protocol at a level of 90% average implementation adherence or above (see Table 5). Differences in nurses' average implementation adherence varied by the type of visit, with all of the nurses implementing 100% of the counseling elements during the antenatal visits, while the 32nd to 48th week post partum visits resulted in the lowest average percentage adherence of 92.7% (see Table 5).

For all the visits, nurses generally adhered to the non-verbal counseling elements, which included making eye contact with the mother and sitting with a posture that showed empathy (i.e. an active interest in the mother's perception, situation, meaning and feelings) and nodding and smiling during the session while the mother was discussing her infant feeding issues. The following sections will present data on which verbal key elements of the BAN Study infant feeding counseling protocol nurses adhered to and which were not adhered to according to the type of visit.

Antenatal Visit

The major counseling elements to be delivered at the antenatal visit were the (1) importance of exclusive breastfeeding for six months to prevent HIV transmission and (2) risks of mixed feeding (i.e., feeding the baby breast milk in addition to other liquids or solids). At the antenatal visits (28, 32 and 36 week gestation), nurses implemented 100% of the verbal key counseling elements listed in the implementation checklist tool. Before the mother had her baby, nurses counseled mothers on exclusive breastfeeding for six months by assessing the mothers' knowledge on the subject and either filling in gaps in

the mother's response, or reaffirming the mother's correct response. The following excerpt is a counseling session during a mother's 28th week of pregnancy and provides a typical example of how the nurses assessed a mother's knowledge of exclusive breastfeeding, actively listened to mothers and allowed mothers to complete their sentences before responding to mothers' response on exclusive breastfeeding:

Nurse: Before we start discussing much, I just want to remind you what is in the consent form which was read to you that we will need all the mothers to exclusively breastfeed their babies, is it?

Mother: Ummh [in agreement].

Nurse: I don't know? Now, when you hear the word exclusive breastfeeding what does it mean?

Mother: It means breastfeeding the baby exclusively for six months.

Nurse: Ummh [in agreement].

Mother: Then stop the baby breastfeeding.

Nurse: And stop the baby?

Mother: Yes.

Nurse: Thank you very much. That is very correct. I just want to add a little bit there. Exclusive breastfeeding means breastfeeding the baby frequently and it should only be breast milk without adding any other food or any drink but it should be only breast milk, is it?

Mother: Ummh [in agreement].

Nurse: Even water or traditional drugs or any other drug which the doctor has not yet prescribed for the baby, is it?

Mother: Ummh [in agreement].

Nurse: So you need to know that exclusive breastfeeding is giving the baby only breast milk and not other foods or any drink, is it?

This example was typical of the antenatal counseling sessions observed. Mothers were exposed to the concept of exclusive breastfeeding during the BAN Study consenting process, which took place before their first official BAN Study counseling session. In the

above example, the nurse used repeating/reflecting back counseling techniques and asked questions to assess the extent of the mother's exclusive breastfeeding knowledge and also waited for the mother to complete her sentences before responding verbally.

During the antenatal visit, nurses also implemented the protocol specific to advising mothers on the risks of mixed feeding (i.e., feeding infant other liquids and solids in addition to breastfeeding) and how it can increase the risk of HIV transmission to the infant. The following is an example of how nurses counseled mothers on the risks of mixed feeding and HIV transmission during the antenatal visits:

Nurse: Ok. And you don't need to give your baby food like gripe water [i.e. traditional medicine used to relieve an infant's gastrointestinal discomforts], formula milk, or magnesium or something to clear up the intestines. Those are not necessary to be given to your child. These foods make the baby's intestines to have wounds or get damaged, or get scratched because it is through those wounds where HIV can pass into the baby's body. And that means there is a great chance for the baby to get HIV when the baby is eating other foods in addition to breast milk.

Mother: Ummh [in agreement].

Nurse: Yes. Is there any question? Any question on this issue of mixed feeding?

Mother: No! It is well understood.

Nurse: Well understood?

Mother: Ummh [yes].

In this exchange, the nurse is explaining how adding other solids and liquids in addition breast milk (i.e. mixed feeding) can increase the risk of HIV transmission to the baby during the breastfeeding period. As described earlier, the practice of mixed feeding is common in Malawian culture. Thus, the nurse asks the mother if she understands and if she has any questions about this concept before moving on in the counseling session. Having the mothers understand the risks of mixed feeding is a major counseling element that all nurses did implement during the antenatal visit counseling sessions.

1st to 18th Week Post Partum Visit

In addition to the messages on exclusive breastfeeding for six months and the risks of mixed feeding to decrease the risk of HIV transmission from the mother to the infant, the major counseling elements to be implemented during the 1st to 18th week post partum visits were breastfeeding techniques and issues concerning breast health. The overall average implementation adherence percentage was slightly lower for nurses during the 1st to 18th week post partum visit (95.7%) than during the antenatal visits (100%). Nurses implemented the major counseling elements for these visits concerning breast health and breastfeeding techniques. The counseling elements on breastfeeding techniques were more often implemented than the elements concerning breast health. For example, asking the mother to demonstrate her breastfeeding techniques was implemented 93.9% of the time while a nurse asking the mother if she had experienced any breast health issues was implemented 66.6% of the time (see Table 6). The following exchange is an example of how nurses implemented the elements concerning a mother's breastfeeding techniques using open-ended questions:

Nurse: To make breastfeeding easy how should the baby be attached to the breast or rather how should you hold the baby?

Mother: One hand should have the baby's buttocks, its abdomen faces that of the mother, and the baby faces the breast. Four fingers below the breast and the thumb is on top.

Nurse: Where should the baby breastfeed then?

Mother: The nipple should be in the baby's mouth.

Nurse: What about the areola part of the breast?

Mother: The areola should as well be in the baby's mouth.

Nurse: It should as well be in the baby's mouth, the way you did when you were breastfeeding. I was just looking at what you were doing. Keep on breast feeding the way you did. When you hold your baby, be upright and the baby should be straight. You should relax. The baby's head should be on the inner side of the elbow

joint, the way you have done it. Your arm under the buttocks, the baby's abdomen and the mother's should touch each other. You both face each other. The nipple and greater part of the areola should be in the baby's mouth. Why did we say the areola should be in the baby's mouth?

Mother: So that the baby suckles nicely.

Nurse: Right. But also under the areola is where the milk ducts are situated and by suckling on this part the baby receives more milk.

The nurse in this exchange used open-ended questions to assess the mother's breastfeeding attachment technique knowledge, praised the mother for her correct breastfeeding attachment, and reiterated proper breastfeeding attachment by detailing the process and why proper attachment is important for the baby.

Breast health issues were not as consistently implemented compared the elements concerning breastfeeding techniques. Specifically, nurses asked mothers directly if they had experienced any breast health issues 66.6% of the time, but explained the causes and treatment of these breast health problems 91.0% of the time (see Table 6). The following is an example of how nurses implemented these key breast health-related counseling elements:

Nurse: Okay. Now, suppose you have cracked nipples. What are you supposed to do?

Mother: It's only that I have never heard about what to do but also have never seen such a case.

Nurse: You have never seen such a case? Have we not told you on what to do if you encounter such a problem during breastfeeding? Okay. So, today we are also going to discuss on that one [cracked nipples] because while you are breastfeeding your baby you are bound to encounter some of such problems. The nipple can crack if the baby is poorly attached to the breast. If you have cracked nipples, chances are very high that the baby can get infected with HIV because the baby could be suckling milk along with your blood. In addition to that, when the baby is not well attached to the breast, you could develop breast engorgement because the baby will be suckling less than expected. In which case, the baby will not be emptying all the milk from the breasts and then the milk does what?

Mother: It forms mastitis right in the breast.

Nurse: Mastitis. Then comes breast engorgement, not so?

Mother: Ummh [in agreement].

Nurse: This engorgement can also facilitate the transmission of HIV infection. It is recommended that whenever you have breast engorgement you express milk from that breast onto what?

Mother: A piece of cloth.

Nurse: A piece of cloth. This relieves the pain in a way. It is also advisable to keep breastfeeding from the healthy breast and seek medical attention. If the breast had developed an abscess, it's also good that you do what?

Mother: I report to the clinic.

Nurse: Yes. Do you have any question?

Mother: No.

During this exchange, the nurse described how poor attachment of the baby to the breast can lead to breast health problems and provided advice on how to treat this condition. Although nurses were more likely to describe the causes and treatment of breast health problems than ask mothers directly if they had experienced any breast health problems, their relatively low implementation adherence for these key counseling techniques (91.0% and 66.6%, respectively) resulted in some HIV-infected mothers not receiving this important information to help prevent the transmission of HIV to their infants during the breastfeeding period.

21st, 24th and 28th Week Post Partum Visit

The BAN Study protocol recommends early breastfeeding cessation when an infant is six months old. During the 21st, 24th and 28th week post partum counseling visits, the major counseling elements included counseling mothers on preparing their infants for early breastfeeding cessation before the infant reaches six months, stopping

breastfeeding at the sixth month and feeding the infant other liquids and solid foods including Chiponde cha mwana. The average implementation adherence of 97.8% during these visits was slightly more than the average implementation adherence of 95.7% during the 1st to 18th week post partum visits (see Table 5).

Specifically, during the 21st week post partum visit, counseling a mother on how to prepare herself and her baby for breastfeeding cessation was a key counseling element. Nurses counseled mothers on gradually stopping breastfeeding by expressing breast milk into a cup and cup feeding the infant over the course of four weeks versus abruptly stopping breastfeeding within a few days. The follow exchange is an example of how and what advice nurses typically gave to mothers to prepare them for early breastfeeding cessation:

> Nurse: Alright, thanks. I want then to discuss with you on stopping breastfeeding. In other words we would say preparing the baby to stop breastfeeding. It is not recommended to stop breastfeeding abruptly rather we need to prepare the baby before hand. From today on you need to teach your baby to take [breast] milk from the cup. You haven't yet introduced supplementary feeds to the baby but you maintain exclusive breastfeeding only that this time the baby is taking the breast milk from the cup. You express the breast milk into a cup and give it to your baby. Your baby has only been removed from the breast and is instead getting the same breast milk from a cup. This we are doing so that the baby gets used to taking the milk from the cup. Now, in the event that you stop your baby from breastfeeding you actually don't have problems because the baby is used to the cup, than if it was done abruptly. Sometimes you would be surprised that the baby might refuse to take the milk that you have expressed from your breasts if you happen to be the person giving this expressed milk. We advise that you should hand over the cup to your relative so that you transfer the feeding responsibility which has proven effective, hence, the baby can easily get used to the cup in that way. Your relatives should essentially help you in giving the expressed milk this time that supplementary feeds have not yet been introduced. This is also an opportune time to identify means of trying to calm down your baby in the event that it is crying. Initially, you might have been using your breast to calm it down. If you put your baby here [to the breast], it's easy for it to stop crying. If this approach is not effective, it is high time its father should as well assist in calming it down. Some babies can easily calm down in the hands of their

fathers not so?

Mother: Ummh [in agreement].

Nurse: The same should be followed if the baby wants to sleep. Initially, you might have been giving it the breast. But this time, try to put it on your back or whatever approaches that would help it to sleep. We want to make the baby to forget about the breast little by little. We don't need to do it abruptly, right?

Mother: Ummh [in agreement].

Nurse: This time you may try to put it on your back so that it sleeps or whatever approach you think can make the baby sleep. The bottom line is that the baby must be prevented from the breast as much as possible. This is preparing the baby to stop breastfeeding as opposed to an abrupt halt. A baby that has been prepared like this does not cause a lot of troubles. You may even let your relative sleep with the baby such that you only wake up at night to give expressed milk in a cup. Our aim is that we don't want the baby to be very close to the breast if anything the breast can only be offered occasionally. Do you have any question?

Mother: No, I don't have.

Nurse: Can you briefly explain what you have heard?

Mother: You are talking about preparing to stop breastfeeding a baby. You are saying that when a baby is crying we should give it expressed milk from a cup. If there is a relative nearby, she should take the responsibility to feed the baby by the cup. If the baby is still crying, we should try to calm it by putting it on the shoulder until the baby sleeps. If the father is near by he can as well take the responsibility of helping to calm down the baby, until it sleeps. If there is a relative, let her sleep together with the baby and help calm the baby.

Nurse: This is all done while you still keep on maintaining feeding through expressed breastfeeding using a cup. This is all exclusive breastfeeding because we haven't yet introduced supplementary feeding here. I should also thank you that you have explained well, an indication that you are attentive. Keep on breastfeeding exclusively but this time using expressed breast milk in a cup. We need a healthy baby by the end of the day.

During this exchange, the nurse provided the mother with many detailed instructions and advice on how to prepare the baby for breastfeeding cessation. Counseling on expressing breast milk for cup feeding, transferring feeding responsibilities to the father or relative

and getting the baby less dependent on the breast were all delivered and the nurse assessed how well the mother understood these messages by asking the mother to explain back what the nurse had just conveyed to her. Yet, with an overall implementation adherence of 90.0% for this element, there is evidence that providing specific advice to mothers on how to prepare their baby for breastfeeding cessation was not consistently implemented by nurses (see Table 6). Similarly, with an implementation adherence of 86.6%, some nurses also did not consistently provide advice to comfort the infant after stopping breastfeeding (see Table 6).

Typically, after counseling the mother on preparing the infant for breastfeeding cessation at the 21st week post partum visit, the nurse counsels the mother on completely stopping breastfeeding, the incorporation and preparation of complementary foods and how to administer Chiponde cha mwana during the 24th week post partum visit. Nurses implemented the key counseling element explaining to the mother that early breastfeeding cessation at 6 months reduces the risk of HIV transmission to the infant 93.3% of the time and the element explaining to the mother that she should stop breastfeeding starting at 21 weeks post partum and completely stop breastfeeding by 24 weeks 96.6% of the time (see Table 6). At an implementation adherence of 100.0%, nurses consistently implemented the key elements on introduction and preparation of complementary foods and administration of Chiponde cha mwana (see Table 6). The following counseling session exchange during a mother's 24th week post partum visit provides an example how nurses implemented the early breastfeeding cessation at 6 months to reduce the risk of HIV transmission to the infant:

Nurse: When do you think you are going to stop your baby from breastfeeding?

Mother: I have those thoughts of stopping my child breastfeeding. If things will be ok at the baby's father work, we are going to buy food for the baby so that when the baby stops breastfeeding, we should not

have problems.

Nurse: Thank you very much. What do you think are the preparation in terms of food and any other?

Mother: Milk, porridge, porridge flour and other things to add into the baby's porridge. That is what I am preparing.

Nurse: Do you have any question?

Mother: I just want to ask if I can stop my child breastfeeding today, or after six months.

Nurse: We are counting that your baby is six months old as of now. We count weeks and your baby is now 24 weeks old, thus six months. That is how we count here. When the baby is six months which is 24 weeks according to how we count here and we expect you to stop breastfeeding your baby. But what we want to avoid is mixing breast milk and other foods because we are trying to avoid or prevent our baby from getting the HIV. Sometimes you can force yourself to mix [breastfeeding] with other foods if you are not ready [to stop breastfeeding] and we want you to stop when you feel that you are ready. If you are ready, tomorrow you can stop your baby from breastfeeding and start giving your child other foods.

Mother: Ummh [in agreement].

Nurse: But we are really in need of the time when you will be ready. We can give you Chiponde today, yes. But we want first of all to get from you that you are ready to stop your baby from breastfeeding and ready to start giving your baby other foods. Whenever you will think that, "Today I don't want to breastfeed," then you start giving your baby other foods. Don't mix breast milk and other foods. That day you have made your decision to stop breastfeeding, start giving the baby other foods.

Mother: Yes I will stop her soon.

Nurse: Thank you very much. Today I am going to give you 10 chiponde jars. But please don't mix breast milk and other foods. When you will think to stop your baby, please do so. And also when you will be breastfeeding, you have to know why you will stop your baby from breastfeeding. When you prolong the baby from breastfeeding that means you will increase the chance for the baby to get HIV. And you have to ask yourself if you are really following the rules of HIV and breastfeeding cessation.

In this exchange, the nurse emphasized to the mother the importance of stopping

breastfeeding completely soon, emphasizing how this decision should be made by the mother and not the nurse. This nurse also ensured that the mother understood the dangers of mixed feeding and restated several times to the mother that she should stop breastfeeding completely before adding Chiponde cha mwana or other complementary foods to the baby's diet.

After the mother is counseled to stop breastfeeding completely during the 24th week visit, nurses at the 28th week post partum visit counseled mothers to assess if they had definitely stopped breastfeeding completely. Additional major counseling elements at the 28th week post partum visit included nurses discussing the preparation of a variety of nutritious complementary foods and assessing how mothers were administering Chiponde cha mwana to their infants during the 28th week post partum visit. The following is an example of how nurses counseled mothers on these key counseling elements using open-ended questions:

Nurse: Now after stopping breastfeeding, what foods are you giving to the baby?

Mother: I am feeding the baby with porridge and I am mixing it with Chiponde and a semi solid nsima [i.e. thick porridge which is a staple food in Malawi].

Nurse: You are also giving it nsima?

Mother: Yes, it is taking nsima.

Nurse: Okay! I have got your points but I want to ask you. You have said that you are giving Chiponde. Can you tell me how you are giving it? What did we say about the baby with Chiponde the last time we met?

Mother: It has to be mixed thoroughly and then put it here [sterile measuring cup provided by the BAN Study] from which you will be getting from to mix with porridge for the whole day.

Nurse: That is true. Now, how many times are you giving it to the baby?

Mother: I am giving it five times a day.

Nurse: It can eat like drinking water!

Mother: Even at night, I haven't yet bought milk [formula] because the father is away and I am afraid I might land myself in trouble [of not being able to afford to buy more milk formula]. So, I normally prepare porridge and put it in the food warmer. If we sleep at 7 p.m., we would wake up at 4 a.m. and I give the baby porridge. After eating, the baby will sleep again and wake up at 7 o'clock in the morning. I am trying very much on this because I have seen that with milk [formula] I cannot manage to buy.

Nurse: Okay, thank you very much. You are in fact doing what is expected of you because milk [formula] is now expensive to purchase, not so?

Mother: Yes, it's expensive.

Nurse: Thank you very much, we wish you all the best. Keep it up. Give other supplementary feeds along with Chiponde. Also make sure that the amount needed for Chiponde for that particular day has been finished by the baby.

Mother: I also do cook pumpkin leaves and give its broth to the baby.

Nurse: Broth from pumpkins leaves?

Mother: It's not good for the baby, not so?

Nurse: No, it's okay but the broth itself is not enough. Okay, so what other foods do you give?

Mother: Normally, if I feed my baby porridge at around 12 noon, I would thereafter give a broth of vegetables.

Nurse: Okay let me help you there. When you prepare relish, like whatever type of vegetables, know that your baby can as well eat some of the vegetables, not just the broth. Do you have a question? Is it clear?

Mother: Ummh [in agreement].

After listening to and assessing the mother's current complementary feeding practices, the nurse praised a few of the practices, while providing ways to improve other practices. The nurse focused her counseling on how and what types of foods the mother should be feeding her baby after stopping breastfeeding. Administering Chiponde cha mwana,

proper preparation of a variety of affordable and available foods were emphasized in the 28th week post partum infant feeding counseling session.

Milk formula. Feeding or intending to feed the baby milk formula was a consistent theme among the mothers after they reportedly stopped breastfeeding during the 24th and 28th week visits. As presented in the above exchange, after the nurse asked the mother about her complementary feeding practices, the mother told the nurse that she could not afford to buy milk formula. The nurse advised the mother that she should only be feeding her baby foods that were affordable and available in the household. Although not detailed in the BAN Study infant feeding counseling protocol, nurses counseled mothers who fed or intended to feed their infants milk formula. The following is an example of how nurses counseled, with much care, explanation and detail, mothers who intended to feed their baby milk formula:

Nurse: Thank you very much for all the preparations you are doing like buying milk [formula].

Mother: Ummh [in agreement].

Nurse: But what we can remind one another this time is the emphasis on milk [formula]. For one to stop breastfeeding the baby, it doesn't require that person to have milk [formula]. No! No! What you find at home, any food available at home can do, is it? Yes, you are preparing for that, but take note that we don't only need milk, but anything which you can find.

Mother: Ummh [in agreement].

Nurse: You can depend on porridge. It is not a command or requirement for your baby to be given milk [formula]. Porridge is enough.

Mother: Ummh [in agreement].

Nurse: Milk [formula] is expensive. At this age, the baby cannot get full with milk only….I just want to encourage you to give your baby different foods but frequently. You should not rely on milk only. Anything you can find is okay, is it? It is very necessary to give our baby different food, is it? So please don't just force yourself to have milk. You are free to give any kind of food available at home….And I am emphasizing on the baby's utensils. You were

talking about milk, is it?

Mother: Yes.

Nurse: Maybe when you find milk one day, you should not use a bottle for feeding milk to your baby. The bottle has got [measuring] marks remember?

Mother: Ummh [in agreement].

Nurse: We just want those bottles to assist you in measuring the milk. Have you ever given a baby formula milk?

Mother: Ummh [no].

Nurse: You have never?

Mother: No, I have not.

Nurse: When you will have money and buy formula milk, for example, Lactogen milk, it has been written that it is for children from six months upwards.

Mother: Ummh [in agreement].

Nurse: On the tin like this one [nurse showing example of Lactogen tin], there are a lot of instructions and many other things. They write the amount of water. For example, here it is written a bottle with 225 ml you have to read that you have to boil the water first, is it?

Mother: Yes.

Nurse: And the water should be left to cool and you can use the bottle, that clean bottle. Maybe the bottle was cooled too?

Mother: Ummh [in agreement].

Nurse: If the water should level at 225 ml you have to take nine spoons of milk [formula], because if you over dilute the milk the baby can get nothing from the milk that can help the baby to grow health, is it?

Mother: Ummh [in agreement].

Nurse: But also when you give your baby diluted milk, you are destroying the baby's health, is it? What is important is to have the exact milk and water contents. So may be you can have a chance of getting milk and because of ignorance you can just add a lot of water. There you cannot help your baby, is it?

Mother: Ummh [in agreement].

Nurse: And also I told you to measure nine spoons. Let me show you the spoon which is found in Lactogen and may other milk. It looks like this [nurse showing the mother the measuring spoon]. You have to read what has been written on the tin. You will not fill the spoon to the capacity but at least try to level the spoon. If you will over fill that means the milk can finish up very fast. But this is the good measure. With the measure I told you and the level of water in the bottle you put nine spoons of milk [formula]. And take note that the measurements differ according to the type of Lactogen milk you have bought.

Mother: Ummh [in agreement].

Nurse: Other types of Lactogen milk have instructions of taking 10 spoons of milk [formula] into 250 ml of water.

Mother: Ummh [in agreement].

Nurse: These are the difficulties of formula milk because it requires one to know how much to put in and follow the instructions. And also if you don't have any idea of what to do, it is very dangerous for the baby. Do you have any question on what I have said?

Mother: No.

In this exchange, the nurse took time to explain to the mother in detail how to properly prepare milk formula so the mother would understand the steps involved in the process and how improper preparation could increase the infant's risks of morbidity and/or mortality.

Unlike the example above, some nurses did not counsel mothers on proper milk formula preparation prior to the mother deciding to feed their infants this way. After understanding that the mother was feeding their infant with milk formula, nurses would often probe the mothers on how they prepared these feeds and have to advise them on proper preparation. The following is an example of how a nurse typically counseled mothers to assess and correct their current milk formula preparation techniques:

Nurse: I remember when we were talking of foods; you said that you give your child milk [formula]. What kind of milk are you giving your child?

Mother: Lactogen [type of infant milk formula].

Nurse: Lactogen?

Mother: Yes.

Nurse: You are giving your child Lactogen number what?

Mother: One.

Nurse: Number one? How old is your baby?

Mother: My baby is seven months and Lactogen number two is scarce. I have been looking for it, but it is nowhere to be found.

Nurse: Ok. But the most important regarding to the age of the baby, from six months upwards is number two. Lactogen number two is found in the Burundi's shops in area 47 sector two. Maybe it is very far with you but if you have time please go and buy. That is very true. Lactogen number two is scarce nowadays. I remember one day, we walked around the town we didn't find one. Fortunately my friend told me to check with those shops in area 47 sector two. You have to check at the bottom of the tin, there is expiry date so you have to do that. For example, this tin of Lactogen [nurse showing the nurse one tin of Lactogen], its expiration date is 2004 and it is not supposed to be given to the child, is it?

Mother: Yes.

Nurse: When you pick that tin, make sure to check the expiration date at the bottom. Maybe it can happen that Lactogen number two is still available at those shops because they have stayed there long. But the most important milk for our baby at this age is Lactogen number two, is it? So what are the measurements you are using?

Mother: I measure two spoons.

Nurse: Using which spoons?

Mother: The inside tin spoon.

Nurse: The spoon which is found in the Lactogen tin?

Mother: Ummh [yes].

Nurse: When you look very careful, there are procedures to follow written on this tin. The instructions say in 225 ml water and put in nine spoons of milk [formula]. When we take this bottle [infant's bottle], which is 120 ml, we can take it as half of 225 ml, is it? So we need to put these spoons of milk [formula] at four times or 4 ½

times. Sometimes the problem is how we measure a level of spoon, because this spoon inside the tin is very big.

Mother: Ummh [in agreement].

Nurse: Maybe you are telling me that you put two spoons of milk [powder] and yet it is full to capacity, like this [nurse demonstrating milk formula powder filling spoon and not being leveled across the spoon]. We are not supposed to fill the spoon like that because nine spoons of milk [formula] for 225 ml of water is what is needed. Now, we need to boil water first. After the water is cooled, we need to pour the water into the measured bottle like this [nurse demonstrating how water should be poured into bottle for measuring]. But if you use this 120 ml cup, we can put in 4 ½ spoons, is it?

Mother: Yes.

Nurse: But if we are using a big bottle which can hold water of 225 ml we need to measure nine spoonfuls of milk [formula]. When we do 4 ½ spoons of milk [formula] that means we are not measuring or giving the baby all the required nutrients in the milk. That happens when you over dilute the milk and it can end up in the baby having diarrhea. That is because the measurements are not per recommended, is it?

Mother: Ummh [in agreement].

Nurse: I have seen you using this bottle to feed the baby. We want you to use a cup for feeding the baby. This bottle is very difficult to clean, is it? This bottle should be used for storage only or for preparing the milk.

In this exchange, the nurse asked the mother questions to assess her milk formula preparation and the mother's responses indicated that she was not properly preparing the milk formula as instructed on the Lactogen tin, nor following the BAN Study infant feeding guidelines to cup feed, versus bottle feed her baby (see Appendix B). Intentions to use and actual use of milk formula was consistently reported by the mothers during the counseling sessions. Although the BAN Study infant feeding counseling protocol provides minimal information on how to counsel mothers on use and proper preparation

of milk formula, the examples above provide evidence that some nurses counseled mothers on how to properly prepare and use milk formula for their infants.

32nd to 48th Week Post Partum Visits

Similar to the 21st, 24th and 28th week post partum visits, the major counseling elements implemented during the 32nd to 48th week post partum visits concerned the importance of stopping breastfeeding completely to reduce the risk of HIV infection to the infant and the importance of giving the infant complementary foods in addition to Chiponde cha mwana. Although the key counseling elements designed to be implemented were similar to the elements counseled in previous visits, the 32nd to 48th week post partum visits resulted in an average implementation adherence of 92.7%, the lowest average implementation adherence of all visit types (see Table 5).

Although nurses did consistently implement counseling on how the mother was administering the Chiponde cha mwana in addition to other complementary foods, with a 100.0% implementation adherence, nurses were not as consistent when counseling on stopping breastfeeding completely. Among the counseling sessions recorded, nurses asked mothers if they had stopped breastfeeding completely in 73.3% of the sessions and advised mothers about the importance of stopping breastfeeding to reduce the risk of HIV infection to the infant in 50.0% of the session resulting in the lowest implementation adherence of all of the major counseling elements assessed by the implementation checklist (see Table 6).

In Malawian culture, mixed feeding after three months and breastfeeding for up to two years is a common practice (National Statistical Office [Malawi] & ORC Macro, 2001). Thus, ensuring that mothers had completely stopped breastfeeding and emphasizing the importance of stopping breastfeeding to reduce the risk of HIV

transmission to the infant were important counseling elements for all nurses to consistently implement during the 32nd to 48th week post partum visits.

Summary

With an average implementation adherence percentage above 90% for all visit types, results from the observations indicated that nurses were implementing the BAN Study infant feeding counseling protocol as designed (see Table 5). During their counseling sessions, nurses displayed their verbal and non-verbal counseling techniques, as well as their flexibility in counseling mothers on the proper preparation of milk formula, an important subject not detailed in the BAN Study infant feeding counseling protocol. Although nurses generally implemented the verbal counseling elements as intended, some elements, such as asking a mother directly if she had experiences any breast health problems during the 1st to 18th week post partum visit, providing mothers with specific advice to prepare the infant for breastfeeding cessation during the 21st, 24th and 28th week visits and advising mothers about the importance of stopping breastfeeding to reduce the risk of HIV transmission to the infant during the 32nd to 48th week post partum visit were not as consistently implemented as other key counseling elements (see Table 6). To provide further insight on the study findings, the next section will present a more detailed account of nurses' implementation adherence patterns.

Observations by Nurse

Similar to the observations categorized by visit above, the observations by nurse will also focus on answering the following research questions: (1) what task and socio-emotional domain behaviors of the protocol were consistently implemented as designed and (2) what were nurses' patterns of adherence to the task and socio-emotional domain behaviors of the protocol. Although findings from the nurses' observations revealed that, overall, nurses implemented the protocol at an acceptable level of 90% total average

implementation adherence or above, implementation adherence varied by visit (see Table 7). For example, although their total average implementation adherence across all visit types was above 90%, there were two nurses whose implementation adherence percentages were below 90% for specific visit types (see Table 7). To provide specificity to the general observation findings by mother's visit presented in the first section, the following section will present the observation findings according to each nurse.

Nurse 1

Compared to the other nurses, this nurse's total average implementation adherence was the highest at 98.9% (see Table 7). With an average implementation adherence of 100.0%, the nurse consistently implemented all of the key counseling elements during the antenatal, 21st, 24th and 28th week post partum and 32nd to 48th week post partum visits (see Table 7). However, during the 1st to 18th week visit, the nurse's average implementation adherence decreased to 95.8% due to not consistently implementing issues concerning breast health. Specifically, the nurse did not ask the mother if she had experienced any breast health issues during two of the five recorded observations and did not explain the causes and treatment of breast health issues to the mother in one of the five recorded observations (see Table 8).

Nurse 2

Although her implementation adherence was not as high as Nurse 1, this nurse's total average implementation adherence of 97.9% was higher than the remaining nurses (see Table 7). Similar to Nurse 1, she had an average implementation score of 100.0% for three of the four visit types: antenatal, 1st to 18th week post partum, and 21st, 24th and 28th week post partum visits. However, the 32nd to 48th week post partum visit resulted in the nurses' lowest average implementation adherence of 91.6% (see Table 7). During the 32nd to 48th week post partum visit, this nurse consistently did not advise mothers about

the importance of stopping breastfeeding to reduce the risk of HIV transmission to the infant in five of the six recorded observations (see Table 8).

Nurse 3

With a total average implementation adherence of 95.4%, this nurse's implementation adherence was the second lowest percentage (see Table 7). Similar to the other nurses, this nurse consistently implemented the key counseling elements during the antenatal visit. However, the 1st to 18th week post partum visit resulted in a 95.6% average implementation adherence, the 21st to 24th and 28th week post partum resulted in a 96.2% and the 32nd to 48th week post partum visit resulted in the nurse's lowest average implementation adherence of 90.0%. Specifically, during the 1st to 18th week post partum visit, the nurse did not ask mothers if they had experienced any breast health issues during two of the five recorded observations and did not ask the mother to demonstrate her breastfeeding techniques during one of the five recorded observations (see Table 8). For the 21st, 24th and 28th week post partum visits, during one of the five recorded observations, the nurse did not explain to the mother that early breastfeeding cessation at six months may help to reduce the risk of HIV transmission to the infant, nor did this nurse provide the mother with specific advice to comfort the infant after stopping breastfeeding (see Table 8). Similar to Nurse 2, this nurse also consistently did not advise mothers about the importance of stopping breastfeeding completely to reduce the risk of HIV infection to the infant. Not implementing this key element occurred in all of the five recorded observations during the 32nd to 48th week post partum visit (see Table 8).

Nurse 4

This nurse's total average implementation adherence of 95.7% was the third lowest percentage among the participating nurses. As with all of the nurses, this nurse's average implementation adherence was 100.0% during the antenatal visits. However,

similar to Nurse 1, this nurse's lowest average implementation adherence occurred during the 1st to 18th week post partum visit where she had an average implementation adherence of 89.6%, resulting in one of two instances where a nurse's average implementation adherence was below 90% (see Table 7). Her average implementation adherence was 95.4% during the 21st, 24th and 28th week post partum visits and 98.0% during the 32nd to 48th week post partum visits (see Table 7).

Key counseling elements not implemented during the 1st to 18th week post partum visit included breast health-related issues. Nurse 4 did not address mothers' breast health issues by explaining the causes and treatment of breast health problems during two of the five recorded observations and consistently did not ask mothers directly if they had experienced any breast health issues in four of the five recorded observations (see Table 8). Similar to Nurse 3, this nurse also did not ask the mother to demonstrate her breastfeeding techniques during one of her five recorded observations (see Table 8). For one of the five recorded observations, this nurse did not explain to the mother that early breastfeeding cessation at six months reduces the risk of HIV transmission to the infant and did not explain to the mother that she should stop breastfeeding starting at the infant's 21st week of life and stop completely by week 24 during the 21st, 24th and 28th week post partum visits (see Table 8). Similar to other nurses, this nurse also did not advise the mother about the importance of stopping breastfeeding completely to reduce the risk of HIV transmission to the infant in one of the five recorded observations during the 32nd to 48th week post partum visit (see Table 8).

Nurse 5

Compared to the other nurses, this nurse's total average implementation adherence of 93.3% was the lowest (see Table 7). Again, similar to other nurses, she had an average implementation adherence of 100.0% during the antenatal visits, but with each visit type

her average implementation adherence percentage decreased. Her average implementation adherence was 96.2% during the 1st to 18th week post partum visit, 95.2% during the 21st, 24th and 28th week post partum visits and 82.0% during the 32nd to 48th week post partum visits, the lowest average implementation adherence among all nurses for any visit type (see Table 7). For one of the five recorded observations during the 1st to 18th week post partum visit the nurse did not advise the mother on the risk of mixed feeding and how it may increase the risk of HIV transmission to the infant, did not engage the mother in dialogue to assess how well she understood the importance of giving only breast milk to the infant for six months and did seem rushed or showed impatience toward the mother during the counseling session (see Table 8). All of these key elements were not implemented during the same counseling observation. Consistently, for three of the four recorded observations during the 21st, 24th and 28th week post partum visits the nurse did not provide mothers with specific advice to prepare their babies for breastfeeding cessation and did not provide mothers with specific advice to comfort infants after stopping breastfeeding (see Table 8). Also, in a consistent manner, the nurse did not ask mothers if they had stopped breastfeeding completely in six of the six recorded observations and, similar to other nurses, did not advise mothers about the importance of stopping breastfeeding to reduce the risk of HIV transmission to their infants in four of the six recorded observations during the 32nd to 48th week post partum visits (see Table 8).

Nurse 6

With a total average implementation adherence of 97.8%, this nurse's adherence was the third highest among the nurses (see Table 7). Similar to the other nurses, this nurse also had a 100.0% average implementation percentage during her antenatal visits and also, similar to Nurses 1 and 2, had an average implementation percentage of 100.0%

during the 21st, 24th and 28th week post partum visits (see Table 7). However, her average implementation adherence during the 1st to 18th week post partum visits was 96.5% and 95.0% during the 32nd to 48th week post partum visit (see Table 7). These adherence percentages resulted from the nurse not advising the mother on the risks of mixed feeding and how it may increase the risk of HIV transmission to the infant in one of the eight recorded observations and, similar to other nurses, not asking mothers directly if they had experienced any breast health issues in three of the eight observations recorded during the 1st to 18th week post partum visits (see Table 8). In line with most of the nurses, this nurse also did not ask mothers directly if they had stopped breastfeeding completely in two of the four recorded observations during the 32nd to 48th week post partum visits (see Table 8).

Summary

Nurses' total average implementation adherence was above 90.0% across all visit types. However, nurses' consistency in implementation adherence varied by visit type. Although all nurses had an average implementation adherence during the antenatal visits, nurses differed in their implementation of key counseling elements during other visit types. During the 1st to 18th week post partum visits, four of the six nurses did not consistently implement breast health-related issues (see Table 8). Although average implementation adherence was relatively higher among each nurse during the 21st, 24, and 28th week post partum visit compared to the other visit types (excluding the antenatal visit), three of the six nurses who did not have an average implementation adherence 100.0% (see Table 7), did not implement key counseling elements related to breastfeeding cessation (see Table 8). Finally, five of the six nurses did not consistently ask mothers directly if they had stopped breastfeeding completely during the 32nd to 48th week post partum visits.

While these observation findings by nurse presented nurses' implementation patterns across each visit type, the findings from the interviews with each nurse will reveal further insight on their inconsistent implementation patterns of key counseling elements and also their attitudes toward the infant feeding protocol.

Nurses Interviews

The interviews with the six nurses focused on investigating two of the three research questions. Specifically, findings from the nurses' interviews answer: (1) how consistent are nurses in their patterns of adherence to key elements of the protocol when counseling HIV-infected mothers; and (2) what are nurse attitudes toward the BAN Study infant feeding counseling protocol. The interviews revealed many characteristics specific to what, how and why nurses implement most, but not all, of the key elements of the BAN Study infant feeding counseling protocol. In the following section, nurses reported on: (1) their general attitudes toward implementation; (2) barriers toward complete implementation; and (3) suggestions for improving their implementation.

General Attitudes toward Implementation

Counseling feelings. To assess various aspects of nurses' attitudes toward the BAN Study infant feeding counseling protocol, nurses were asked how they feel when counseling the HIV-infected mothers. In addition to describing their emotional states, nurses also responded with examples of their counseling techniques. For example, one nurse with over 10 years of nursing experience confidently said, "I don't have any problems when I'm counseling the mothers. I just feel relaxed." She continued by saying:

> I just want to make the mothers understand what the recommendations for infant feeding are when I'm counseling them. If they don't really understand, then that is when problems come. So, when counseling we have to repeat, explain properly, take our time and let them ask questions to make sure the client has really understood what you were talking about.…I feel good because I'm used to counseling these mothers. I know where to go in my counseling. Like when a mother gets bored, I know I have to go this way or that way and then I might say, "Oh! This one, I think where she is now, she can't understand anymore

> information." So, I stop there and next time I will start there again...I feel good because I want them to understand about HIV. In this way, we are helping our infants not to get infected with HIV.

Similarly, another nurse with three years of nursing experience said that she feels good about her counseling because she is helping to prevent the transmission of HIV to the infant. She responded, "I'm really helping that their children should be HIV negative, so I really feel good."

Overall, the nurses reported having positive emotions when counseling the mothers because they believed that their counseling was preventing the transmission of HIV from the mothers to the infants during the breastfeeding period. Nurses' responses were accompanied with a description of some of the techniques they use during a counseling session, such as repeating back and allowing the mother to ask questions, to ensure that mothers understand the BAN Study infant feeding recommendations.

When asked about their strongest counseling skills, nurses often mentioned additional counseling techniques they employ. Most of the nurses identified non-verbal counseling techniques as their strongest counseling skills. These techniques included: active listening, eye contact with the mothers, rapport building, empathy and having a positive attitude while counseling the mothers. As one nurse with over 10 years nursing experience explained, "When you receive a client [into the counseling room], first of all, you have to start with joyness and you have to build a rapport so that the mother will feel comfortable talking." Another nurse with eight years of nursing experience shared that her strongest counseling skill was empathy when she said, "I think my strongest counseling skill is that I put myself in the shoes of the client." Active listening was also identified as the strongest counseling skill among nurses. One nurse with three years of nursing experience said, "I listen first to the client. I do listen so that I can probe more to understand what resources they have for feeding their baby." Another nurse with six

years of experience described several of her non-verbal counseling strengths when she stated, “I’m supportive and caring to the mothers spiritually and physically.” Nurses consistently identified non-verbal counseling techniques as their strength versus verbal counseling techniques and messages.

Implementation importance. Most of the nurses identified exclusive breastfeeding for six months and early breastfeeding cessation as the two most important counseling elements to implement. Although the prioritization of the elements varied by nurse, exclusive breastfeeding and early breastfeeding cessation were identified by nurses as the two most important elements of the protocol to implement. For example, one nurse with nine years of nursing experience said, “Exclusive breastfeeding for six months is the most important element. The second one, early breastfeeding cessation, is another important element.” Another nurse with eight years of nursing experience stated, “Early breastfeeding cessation is a very important element of this protocol…I think that’s the most important [element].”

Although the nurses identified exclusive breastfeeding for six months and early breastfeeding cessation as the two most important counseling elements, they reported that early breastfeeding cessation counseling was the most difficult element for them to implement. This was identified as the most difficult to implement because some mothers were not willing to stop breastfeeding at six months, which made their counseling sessions more difficult than others in terms of getting mothers to understand the importance of changing their behavior. One nurse with five years of nursing experience expressed her difficulty with implementing the counseling elements on early breastfeeding cessation when she said, “When a mother refuses to stop breastfeeding, it’s difficult. Because they have made a decision that they will not stop breastfeeding it is

difficult to convince them to stop." One nurse with over 10 years of nursing experience shared an example of why early breastfeeding cessation is difficult for her to implement:

> Cessation is difficult for me because we tell them [mothers] they should start expressing their breast milk for cup feeding at 21 weeks post partum, but you may find that at 24 weeks post partum, when they come back to the clinic, they only did cup feeding for two days and then continued to breastfeed. So it's a challenge for me to counsel mothers on the importance of cessation.

Another nurse with eight years of nursing experience articulated why implementation of the breastfeeding cessation elements, specifically on preparation for cessation, was difficult for her when she said:

> Our women [mothers in the BAN Study] are not used to stopping their infants from breastfeeding at six months. So to prepare these infants and mothers to stop breastfeeding at six months is not easy. I think it has to take more time, more skills and a lot of knowledge to deliver this [information on breastfeeding cessation].

Nurses associated a mother's lack of knowledge, negative attitudes and cultural practices of not stopping breastfeeding at six months with their difficulty in implementing this major counseling element in a way that influences mothers to change their current infant feeding behavior and stop breastfeeding their infant at six months.

In contrast, the other major counseling element, exclusive breastfeeding for six months, and complementary feeding (i.e. the addition of solid foods and liquids to an infant's diet after stopping breastfeeding) were identified as the easiest counseling elements for nurses to implement. One nurse with six years of nursing experience simply stated, "It's exclusive breastfeeding and complementary feeding." Another nurse with three years of nursing experience shared, "When I give counseling on exclusive breastfeeding, it is so easy." She went on to explain why she believed that complementary feeding counseling elements were easy for her to implement:

> I think the complementary feeding is easy for me. I like it so much because these mothers think that maybe feeding an infant is very difficult and to me I think it is not that difficult. Since we [Malawians] start giving our children food early [before 3 months of life], they understand what to give and how to prepare it. You

> don't have to do a lot of counseling or explaining because they understand…complementary feeding is not a new thing for them.

Although the nurses identified exclusive breastfeeding for six months and complementary feeding as the easiest counseling elements for them to implement, and breastfeeding cessation as the most difficult, they recognized that these counseling elements, as well as others, were important when counseling the HIV-infected mothers in the BAN Study.

During their interview, nurses were asked to review the implementation checklist tool (see Appendices E-H) used to assess and record their implementation of specific counseling elements. After their review of the implementation checklist tool, they were asked to identify the five most important counseling elements on the checklist. All of the nurses interviewed said that all of the counseling elements, verbal and non-verbal were equally important to implement. For example, one nurse with eight years of nursing experience said, "Everything is important here. All is important so I cannot leave anything out. I cannot just say one thing is important here because in counseling they are all important." Similarly, another nurse with three years of nursing experience also thought that all of the implementation checklist tools were important when she said, "I feel all these points are very important and I cannot say that five out of these are important because we really need to implement all of these skills for the counseling to work."

Although all of the nurses believed that all of the counseling elements listed in the implementation checklist tool were important to implement, one nurse with over 10 years of nursing experience did acknowledge that all of the elements may not be covered during a counseling session. She said:

> I think all these areas are important because in counseling we have to use all these because if you skip one, that means you have also skipped a very important issue for the client. Of course, sometimes you can skip accidentally, but not intentionally.

This tendency to not implement all of the key protocol elements during a counseling session, either accidentally or otherwise was evident by the nurses when they self-rated their counseling implementation. When asked how they would rate their implementation of the BAN study infant feeding counseling protocol, all of the nurses were hesitant to rate their implementation skills. For example, one nurse with nine years of nursing experienced shared that she could not judge her counseling implementation skills when she said, "I give the information that is needed and I think I try my best, but I can't judge myself. It's another person who can judge me." This nurse went on to say that she does not implement all of the infant feeding counseling elements provided in the protocol, but does her best: "The information [I give] is not enough, but I try to give all the information that is supposed to be given when I'm counseling." Other nurses shared these sentiments of implementing most, but not all of the protocol elements. A few nurses estimated that they implemented at least 90% of the infant feeding counseling protocol during a session. For example, one nurse with eight years of nursing experience said, "In general, I try as much as possible to implement everything, but if there were 100 messages to be delivered I try as much as possible to give these women 90% of the messages." Another nurse with three years of nursing experience said, "I feel I implement what is in the protocol. I feel 90% of the information I really deliver to the mother. Because I am a human being, I can always forget some of the things."

These responses revealed various attitudes nurses have toward counseling and implementing the protocol. Emotionally, the nurses feel good about their counseling because they feel they are helping to prevent the transmission of HIV from the mother to the infant. However, when commenting on the importance of the counseling elements, their ease and difficulty in implementing some of the key counseling elements and rating their implementation adherence to the protocol, they identified gaps in their

implementation of the BAN Study counseling protocol. The next section will discuss some of the barriers nurses' face when implementing the protocol.

Barriers toward Complete Implementation

Patient to nurse ratio. Nurses consistently identified high patient to nurse ratio as the key reason why they were not able to implement 100% of the infant feeding counseling elements during a counseling session. On a typical work day, there are two nurses counseling patients and an average of 31 mothers and 16 infants waiting for counseling and other BAN Study health care services (data not shown), accounting for approximately 15 mothers to counsel for every nurse per day. Half of the nurses interviewed mentioned that the high number of patients waiting in the clinic corridor to be counseled sometimes overwhelms them, resulting in them skipping important counseling elements during a counseling session. For example, one nurse with eight years of nursing experience directly associated poor counseling conducted by nurses in general, to the high patient to nurse ratio when she said, "poor counseling also comes due to pressure of work because this patient to nurse ratio is just too high. Sometimes maybe you counsel a client too quickly thinking that you have left a lot of people waiting outside for you to counsel." Another nurse with six years of nursing experience also stated that she sometimes incorporates shortcuts when counseling mothers because of the pressure of her work and not wanting mothers to wait all day in the clinic for services:

> Nurse: I feel sometimes it's difficult for each and everybody to maintain the [counseling] process due to the pressure of work. Sometimes we have a lot of clients that need to complete all the [study] procedures within a day and sometimes you can even do shortcuts just to feel that everybody should be attended to. But it's not good for our clients. If you think "I should maintain the way it [counseling] is supposed to be done," sometimes you find that some clients stay here a long time. I think some of our clients complain and say, "Today, I have stayed too long!" And when I think about the breastfeeding mothers who stay here so long with only a bottle of Fanta [soda] and a bun to eat, to me, I feel

somehow it [waiting for long periods] is an inconvenience to our clients.

Interviewer: So sometimes you try to do some shortcuts in your counseling in order to accommodate all the mothers so that they shouldn't stay at the clinic for so long? Is that what you are saying?

Nurse: Yes.

Nurses associated working in an environment with a high patient to nurse ratio as a barrier toward implementing the BAN Study infant feeding counseling protocol as designed. Another barrier identified was the minimal training nurses received to prepare them for counseling the mothers enrolled in the BAN Study.

Training. Nurses identified a need for additional training as another reason for why they may not implement all of the protocol elements in a counseling session. One nurse with eight years of nursing experience simply stated, "I really really need more training on counseling." She goes on to talk about why more training is important to her:

> It's important that we need to be trained more on this infant feeding because it's so crucial. The way you deliver the message matters most because if we don't deliver the message properly it will not work. Yes, it will kill our infants.

When describing their counseling training needs, nurses identified two types of nurses working on the BAN Study; those that had participated in a formal, two or more week-long infant feeding counseling training course and those that participated in a week-long HIV and infant feeding counseling training course as part of their orientation to the overall BAN Study. The nurses that mentioned that they needed additional training all indicated that they had not participated in a formal infant feeding counseling course. One nurse with six years of nursing experience said, "We nurses need to have a formal course training in counseling." Another nurse with five years of nursing experience described the differences between her training and that of a formal counseling training:

Nurse: From what I have observed, most nurses here in the BAN study have only done orientation counseling, not the full counseling training. So at least I think we can learn a lot from the full training

where we can be trained on more [counseling] skills because we have not been briefed on these skills.

Interviewer: What's the full training for infant feeding counseling?

Nurse: It's about four-six weeks

Interviewer: BAN-study orientation in infant feeding counseling is for how long?

Nurse: One week only.

Interviewer: So you feel that if there was a full training counseling course for counselors that could be an advantage?

Nurse: Yes.

Nurses described the high patient to nurse ratio and lack of additional infant feeding counseling training as two key factors hindering their ability to implement all of the protocol elements during a counseling session. Despite these two factors negatively influencing their implementation adherence, the nurses provided suggestions on how to improve their implementation of the counseling protocol.

Suggestions for Implementation Improvement

More nursing staff. In addition to suggesting their enrollment in a formal infant feeding counseling training (as mentioned in the section above), the most common suggestion of the nurses was to increase the number of nursing staff. Nurses believed that having more nurses on the BAN Study would decrease the workload and the high patient to nurse ratio. One nurse with five years of nursing experience commented, "We do have a lot of clients to attend to, so it's difficult to have enough time to counsel a client. So, I think they should increase the number of nurses." Similarly, another nurse with three years of nursing experience suggested, "First, we have a shortage of staff. If we can improve on the shortage of staff and be many, we can be able to implement whatever is in the protocol." Another nurse with eight years of nursing experience simply said, "We need more staff to improve this nurse patient ratio, we need more staff!"

Counseling guidance. In addition to more staff, other suggestions included the addition of counseling guidance on when and how to probe for milk formula usage or intentions by the mother and a list of local recipes for complementary feeding ideas. Based on the many women she has counseled who have fed or intended to feed their infants milk formula, one nurse with nine years of nursing experience explained why nurses needed additional guidance on how to counsel mothers on their use of milk formula. She explained:

> On infant feeding, I feel that the information [in the protocol] is not enough because some ladies who have enough food, but are not giving it to the baby correctly. For example, she might have formula milk and after probing her, you know that she is dissolving it [the powder formula] wrong. So, I think from visit 16.00 [28th week post partum visit], I think there should be some information that should be added to it [infant feeding protocol] especially to give us a guide to remind us that we should probe for formula milk use. For example, she can tell you that, "I took two scoops of Lactogen [type of formula milk] for my baby and dissolved it in 250 ml of water." So, this baby is taking in only water, not milk and this baby may end up having diarrhea.

This nurse also suggested having recipes as guidance while counseling on complementary feeding: "There are some foods, which need some recipes. There is need for some recipes. If you have enough recipes, you can tell her [the mother] 'mix four plates of maize with beans and that porridge will be nutritious to the baby.'"

Monitoring. In addition to having more guidance on how to counsel on milk formula and complementary feeding, one nurse with five years of nursing experience also suggested that the nurses have a monitor observe their counseling sessions. She stated, "I think the first thing to improve the way the nurses are counseling the clients is to maybe have somebody observe the sessions, just like you [the research team] have done. This would help us improve on implementation."

Nurses' suggestions for how to improve their implementation of the BAN Study infant feeding protocol included: additional infant feeding counseling training, increase in

nursing staff, guidance on infant milk formula and complementary feeding counseling, and monitoring of counseling sessions.

Summary

The description of the study setting provided context to study findings, which revealed that nurse adhered to the infant feeding counseling protocol at an acceptable level, but consistency of their adherence varied by mothers' visit type and by nurse. Issues related to breast health, during the 1st to 18th week visit and breastfeeding cessation, during the 32nd to 48th week visit, were not implemented consistently. Nurses counseled mothers on infant feeding issues outside the scope of the protocol when counseling mothers who were feeding, or intended to feed their infants milk formula after stopping breastfeeding. Nurses' interviews provided insight as to their attitudes toward the protocol, which was primarily positive. Nurses' barriers toward complete implementation of the protocol included the high patient to nurse ratio and the need for additional training. Overall, findings from the nurses' interviews, as well as the observations, provided evidence to answer the study's research questions. The final chapter will discuss these findings, the study's strengths and limitations and implications for public health research, policy and practice.

Table 5
Percent Adherence of Major Counseling Elements Implemented by Visit Type

Visit	Major counseling elements	Avg. implementation adherence
Antenatal	Counseling on importance of giving only breast milk and nothing else to baby for 6 months to prevent HIV transmission to infant.	100%
	Counseling mother on the risks of mixed feeding and how it may increase the risk of HIV transmission to infant.	
1st to 18th week post partum	Counseling mother on the importance of giving only breast milk and nothing else to baby for 6 months to prevent HIV transmission to infant.	95.7%
	Counseling mother on the risks of mixed feeding and how it may increase the risk of HIV transmission to infant.	
	Counseling mother on breast health issues	
	Counseling mother on her breastfeeding demonstration techniques	
21st, 24th and 28th week post partum	Counseling mother on importance of early breastfeeding cessation at 6 months to reduce the risk of HIV transmission to infant.	97.8%
	Counseling mother with specific advice on how to prepare the mother for early breastfeeding cessation.	
	Counseling mother on the importance of introducing complementary foods and liquids to the infant at 24 weeks of age.	
	Counseling mother on administration of Chiponde cha mwana at 24 weeks of age.	
32nd to 48th week post partum visit	Counseling mother to assess if she has stopped breastfeeding completely reduce risk of HIV infection to infant.	92.7%
	Counseling mother on administration of Chiponde cha mwana at 24 weeks of age.	
	Counseling mother on importance of giving infant complementary foods in addition to Chiponde cha mwana.	

Table 6
Percent Adherence of Key Counseling Elements Implemented by Visit Type

Visit (total number of observations)	Key counseling element	How often implemented	
		N	%
Antenatal (n=30)	Nurse advised mother to give only breast milk and nothing else to baby for 6 months.	30	100.0
	Nurse advised mother on the advantages of giving only breast milk to her infant for 6 months to prevent HIV transmission to infant.	30	100.0
	Nurse advised mother on the risks of mixed feeding and how it may increase the risk of HIV transmission to infant.	30	100.0
1st to 18th week post partum (n=33)	Nurse engaged mother in dialogue to assess how well she understood the importance of giving only breast milk to her infant for 6 months	32	97.0
	Nurse advised mother on the advantages of giving only breast milk to her infant for 6 months to prevent HIV transmission to infant.	33	100.0
	Nurse advised mother on the risks of mixed feeding and how it may increase the risk of HIV transmission to infant.	31	94.0
	Nurse asked mother if she had experienced any breast health issues	22	66.6
	Nurse addressed mother's breast health issues by explaining the cause of breast health problems and how they should be treated	30	91.0
	Nurse asked mother to demonstrate her breastfeeding techniques	31	93.9
21st, 24th and 28th week post partum (n=30)	Nurse explained to mother that early breastfeeding cessation at 6 months reduces the risk of HIV transmission to infant.	28	93.3
	Nurse explained to mother that she should stop breastfeeding starting at week 21 and completely stop by week 24.	29	96.6
	Nurse provided mother with specific advice to prepare the baby for breastfeeding cessation.	27	90.0
	Nurse provided mother with specific advice to comfort infant after weaning.	26	86.6
	Nurse advised mother on the importance of introducing complementary foods to infant at 24 weeks of age.	30	100.0
	Nurse advised mother on how to prepare complementary foods at the 24th week visit.	30	100.0
	Nurse advised mother to give spoonful of Chiponde cha mwana 3 times per day at the 24th week visit.	30	100.0

32nd to 48th week post partum visit (n=30)	Nurse asked mother about infant feeding status and if she has stopped breastfeeding completely.	22	73.3
	Nurse advised mother about the importance of stopping breastfeeding to reduce risk of HIV infection to infant.	15	50.0
	Nurse advised mother on importance of giving infant complementary foods in addition to Chiponde cha mwana.	30	100.0

Table 7
Nurses' Average Implementation Adherence by Visit Type (%)

Nurse	Antenatal	1st to 18th week post partum	21st, 24th, and 28th week post partum	32nd to 48th week post partum	Total
1	100.0	95.8	100.0	100.0	98.9
2	100.0	100.0	100.0	91.6	97.9
3	100.0	95.6	96.2	90.0	95.4
4	100.0	89.6	95.4	98.0	95.7
5	100.0	96.2	95.2	82.0	93.3
6	100.0	96.5	100.0	95.0	97.8

Table 8
Key Counseling Elements Not Implemented by Nurse

Nurse	Key counseling element	Visit	Number of times element not implemented by total observations recorded
1	Ask mother if she had experienced any breast health issues	1st to 18th week post partum	2 of 5 observations
	Address mother's breast health issues by explaining the causes of breast health problems and how they should be treated	1st to 18th week post partum	1 of 5 observations
2	Advise mother about the importance of stopping breastfeeding to reduce risk of HIV infection to the infant	32nd to 48th week post partum	5 of 6 observations
3	Ask mother to demonstrate her breastfeeding techniques	1st to 18th week post partum	1 of 5 observations
	Ask mother if she had experienced any breast health issues	1st to 18th week post partum	2 of 5 observations
	Explain to mother that early breastfeeding cessation at 6 months reduces the risk of HIV transmission to the infant	21st, 24th and 28th week post partum	1 of 5 observations
	Provide mother with specific advice to comfort the infant after weaning	21st, 24th and 28th week post partum	1 of 5 observations
	Advise mother about the importance of stopping breastfeeding to reduce risk of HIV infection to the infant	32nd to 48th week post partum	5 of 5 observations
4	Address mother's breast health issues by explaining the causes of breast health problems and how they should be treated	1st to 18th week post partum	2 of 5 observations
	Ask mother if she had experienced any breast health issues	1st to 18th week post partum	4 of 5 observations
	Ask mother to demonstrate her breastfeeding techniques	1st to 18th week post partum	1 of 5 observations
	Explain to mother that early breastfeeding cessation at 6 months reduces the risk of HIV transmission to the infant	21st, 24th and 28th week post partum	1 of 5 observations

Table 8 (cont).
Key Counseling Elements Not Implemented by Nurse

Nurse	Key counseling element	Visit	Number of times element not implemented by total observations recorded
4 (cont)	Explain to mother that she should stop breastfeeding starting at week 21 and completely stop by week 24	21st, 24th and 28th week post partum	1 of 5 observations
	Advise mother about the importance of stopping breastfeeding to reduce the risk of HIV infection to the infant.	32nd to 48th week post partum	1 of 5 observations
5	Advise mother on the risks of mixed feeding and how it may increase the risk of HIV transmission to the infant.	1st to 18th week post partum	1 of 5 observations
	Engage mother in dialogue to assess how well she understood the importance of giving only breast milk to her infant for 6 months.	1st to 18th week post partum	1 of 5 observations
	Seem rushed or showed impatience toward mother during the counseling session	1st to 18th week post partum	1 of 5 observations
	Provide mother with specific advice to prepare the baby for breastfeeding cessation	21st, 24th and 28th week post partum	3 of 4 observations
	Provide mother with specific advice to comfort the infant after weaning	21st, 24th and 28th week post partum	3 of 4 observations
	Ask mother about infant feeding status and if she had stopped breastfeeding completely	32nd to 48th week post partum	6 of 6 observations
	Advise mother about the importance of stopping breastfeeding to reduce risk of HIV infection to infant	32nd to 48th week post partum	4 of 6 observations
6	Advise mother on the risks of mixed feeding and how it may increase the risk of HIV transmission to the infant	1st to 18th week post partum	1 of 8 observations
	Ask mother if she had experienced any breast health issues	1st to 18th week post partum	3 of 8 observations
	Ask mother about infant feeding status and if she had stopped breastfeeding completely	32nd to 48th week post partum	2 of 4 observations

CHAPTER VI

DISCUSSION

Summary of Key Findings

Nurses implemented the protocol at an acceptable level of 90% average implementation adherence or above. However, nurses' implementation adherence varied by the visit type and by nurse. Specifically, the 32nd to 48th week post partum visit resulted in the lowest average implementation adherence of 92.7% and Nurse 5 had the lowest total average implementation adherence of 93.3%. Inconsistent implementation of key counseling elements occurred during the 1st to 18th week post partum visit where nurses asked mothers directly if they had experienced any breast health issues in 66.6% of the counseling sessions observed and during the 32nd to 48th week post partum visit where nurses asked mothers if they had stopped breastfeeding completely 73.3% of the time and advised them about the importance of stopping breastfeeding to reduce the risk of HIV infection to the infant in only 50.0% of the counseling sessions observed. Although not detailed in the current infant feeding counseling protocol, nurses demonstrated their knowledge and flexibility when counseling mothers on their use of, or intended use of, milk formula. Perceived barriers toward nurses implementing the infant feeding protocol consistently included: (1) high patient to nurse ratio and (2) minimal HIV and infant feeding counseling training.

Overall implementation adherence. Nurses' overall average implementation of 90% or above among all visit types was contrary to what was expected based on previous studies. Prevention of mother to child transmission (PMTCT) programs that have observed how trained health providers counsel mothers on infant feeding issues have

reported poor infant feeding counseling among counselors in South Africa (Chopra et al., 2002; Chopra et al., 2005) and Botswana (Programme Review Team et al., 2002) and "satisfactory" in Zambia (Horizons Program, 2002). Also, results of the BAN Study formative data on health providers not trained on HIV and infant feeding counseling suggested that nurses' negative attitude towards HIV-infected mothers' ability to exclusive breastfeed for six months, and stop breastfeeding at six months, would result in an average implementation adherence below 90% (Piwoz et al., 2006). Reasons for BAN Study nurses' high implementation adherence could be a result of the study context. As previously detailed, the BAN Study is a clinical trial that takes place at one site in a controlled experimental study environment (van der Horst, Jamieson & Kazembe, 2005), whereas the other studies featured health workers providing infant feeding counseling in the context of country-wide pilot PMTCT programs (Chopra et al., 2005; Horizons Program, 2002; Programme Review Team et al., 2002). Another reason for nurses' high implementation may be the nursing education and research experience of the nurses' themselves. Compared to nurses working in the government sector, BAN Study nurse have more research experience, research-oriented training and receive a higher salary. Thus, these characteristics may have contributed to their high implementation adherence. Nurses' participation in an infant feeding counseling training, organized by the BAN Study co-investigators, may have also contributed to this high implementation adherence percentage among the nurses. Based on the BAN Study formative research results (Piwoz et al., 2006), the training sought to educate nurses about the risks and benefits of infant feeding options of HIV-infected women in Malawi, challenge existing negative attitudes toward HIV-infected mother's ability to exclusive breastfeed for six months and stop breastfeeding at six months to prevent HIV transmission to the infant and examine infant feeding cultural norms that were not supportive of the BAN Study infant feeding

counseling recommendations.

Implementation adherence by visit type. Although the nurses' average implementation adherence was above 90%, these results found that their implementation was inconsistent depending on the visit type. The lowest average implementation adherence occurred during the 32nd to 48th week post partum visits, where nurses did not consistently ask mothers if they had stopped breastfeeding completely or advise them about the importance of stopping breastfeeding to reduce the risk of HIV infection to the infant. Per the protocol, mothers are counseled to stop breastfeeding and give the infant other complementary foods during the 24th week post partum visit and the 28th week post partum visit, if they have not stopped breastfeeding completely. During the 32nd to 48th week post partum visits, nurses may have assumed that mothers had stopped breastfeeding completely since they had started giving their infant other solid foods. However, the infant feeding culture in Malawi supports giving infants solid foods while breastfeeding (National Statistical Office [Malawi] & ORC Macro, 2001). Thus, asking the mother at every visit after 24 weeks if she has stopped breastfeeding her infant completely and re-iterating the importance of stopping breastfeeding are important counseling elements for nurses to consistently implement, but were not consistently implemented in this study.

Nurses also did not consistently implement asking the mothers if they had experienced any breast health issues during the 1st to 18th week post partum visits. Although nurses did consistently explain to mothers the cause and treatment of breast health problems and observed their breastfeeding technique, they did not directly ask the mothers if they had experienced any breast health issues. Although not asked, nurses may have closely observed the physical appearance of the mother's breasts during her breastfeeding demonstration. However, by not asking the mother directly if she had

experienced any breast health issues, nurses may have missed opportunities to counsel and treat breast health problems, which have been linked to an increased risk of MTCT of HIV via breastfeeding (Ekpini et al., 1997; John-Stewart et al., 2004; John et al., 2001; Ogundele & Coulter, 2003; Semba et al., 1999; WHO, 2004b).

Implementation adherence by nurse. Although each nurses' overall average implementation adherence for all visit types was above 90%, Nurse 5 had the lowest total average implementation adherence of 93.3%. Based on the data collected, it is difficult to conclude if this percentage was associated with this nurse's level of HIV and infant feeding counseling training. As stated previously, all nurses did participate in a week-long HIV and infant feeding counseling training course. However, the interviews with nurses revealed that there were some BAN Study nurses who participated in a two or more week-long HIV and infant feeding counseling training course. It is not clear if any of the nurses who participated in this longer training were in this study sample. Therefore, it cannot be determined if the low implementation adherence of Nurse 5 was associated with her level of infant feeding counseling training or other factors.

Counseling on milk formula. Nurses counseling mothers on proper preparation of milk formula was an unexpected finding because counseling on the use and proper preparation of milk formula was not detailed in the BAN Study infant feeding counseling protocol. However, nurses demonstrated their knowledge and skills when they properly counseled mothers who intended to use, or were already using milk formula after stopping breastfeeding at six months. Using the WHO (2001) recommendations regarding infant feeding for HIV-infected mothers to guide an analysis of the BAN formative results, Piwoz and colleagues (2003) reported that milk formula was not acceptable, feasible, affordable, sustainable or safe for Malawian mothers to use as a replacement food after stopping breastfeeding. Based on these findings, the BAN Study

infant feeding counseling protocol did not emphasize giving milk formula to infants after stopping breastfeeding at six months, but Chiponde cha mwana, a locally produced and nutritious ready-to-use therapeutic food (van der Horst, Jamieson & Kazembe, 2005). Although the nurses in this study provided appropriate advice and techniques while counseling mothers on milk formula use and preparation, BAN Study co-investigators along with the nursing staff, should develop a training session and an additional counseling aid, to guide all nurses on how to counsel mothers who intend to feed, or who are already feeding, milk formula to their infants.

Addressing barriers toward complete implementation. Interviews with nurses revealed nurses' reasons for why their implementation of key counseling elements was not consistent. First, nurses associated their lack of complete implementation adherence with the high patient to nurse ratio present within the BAN Study clinic. Although the BAN Study average of 15 patients per 1 nurse counselor per day is not high compared to generally higher patient to nurse ratios in the Malawi government-run hospitals for all health care services, including counseling, (up to 50:1 or more) (Atiken & Kemp, 2003), the patient to nurse ratio may increase as the BAN Study enrollment increases. For example, as of April 23, 2006, there have been approximately 656 HIV-infected mothers randomly assigned to an intervention group (I. Mdala, personal communication, April 29, 2006) and the total sample size goal is 2,418 HIV-infected mothers (van der Horst, Jamieson, & Kazembe, 2005). As the BAN Study enrollment increases and the number of nurse counselors stays the same, the clinic may reach a capacity where the patient to nurse counselor ratio is higher than 15:1 per day. With the current 15:1 patient to nurse ratio and each counseling session lasting an average of 32 minutes, nurses are currently counseling for approximately 8 hours per day. To maintain the nurses' present level of implementation adherence to the infant feeding counseling protocol, strategic planning by

the BAN Study co-investigators and study coordinators should include a plan for how to address this high patient to nurse ratio now before the study reaches its peak enrollment capacity.

Nurses also indicated that more HIV and infant feeding counseling training would also improve their implementation adherence of key counseling elements. As indicated previously, all nurses in this study were trained on HIV and infant feeding counseling before the BAN Study began enrolling patients in April 2004. However, nurses indicated that they needed additional counseling training. Currently, the UNC Project holds continuing education trainings and workshops over the weekends for targeted support and clinical staff. Although nurses indicated that they desired a full or formal HIV and infant feeding counseling training course, which typically last for two weeks or more, conducting several weekend counseling trainings that target elements with low implementation adherence, such as breast health during the 1st to 18th week post partum visits, may be a more practical alternative that meets the training needs of the nursing staff as well as the weekday personnel needs of the BAN Study.

Study Strengths

Direct observation method. A strength of this study was having trained field investigators to directly observe the counseling sessions. Although direct observation methods are an effective approach to assess program implementation (Patton, 1990; Walsh et al., 2000) only two previous study reported using this method to observe health provider's infant feeding counseling behaviors (Chopra et al., 2005; Horizon Program, 2002). By using direct observation methods this study was able to observe the actual infant feeding counseling behavior of the BAN Study nurses versus relying on their self-reported infant feeding counseling behavior as did previous studies (Bradley & Meme, 1992; Davies-Adetugbo, 1996: Owoaje, Oyemade & Kolude, 2002).

Triangulation of data. Having more than one data collection method to answer the research questions allowed for an assessment of expected and unexpected occurrences and situations nurses encountered during their counseling sessions. Thus, having transcripts of the counseling sessions, the implementation checklists and interviews with nurses and triangulating these data sources to assess nurses' implementation of the BAN infant feeding protocol was also a strength of this study (Miles & Huberman, 1994).

Theory-informed inquiry. This study was guided by Roter and Hall's (1997) patient-provider communication and relationship theoretical concepts. Applying Roter and Hall's patient-provider communication and provider related behavioral domains to this process evaluation supported the theoretical basis of the BAN infant feeding protocol that nurses' adherence to the protocol may influence mother's infant feeding behaviors. Having this theoretical framework to guide the inquiry and assessment of the process evaluation was another strength.

Empowerment training. Using an empowerment education approach to conduct the 2-week training with field investigators was also a strength of this study (Arnold et al., 1991; Vella, 1989, 1995). The training incorporated a participatory and empowering environment for the field investigators and the field coordinator (author of this dissertation) to build rapport, understand each other's working style, foster a communicative environment and work as a team. Thus, using an empowerment approach for the training helped to facilitate the data collection process.

Study Limitations

Back-translations. A limitation of this study was the inability to conduct back-translations of the English transcripts. Back-translations were not conducted because of the field coordinator's decision to have the audio-recordings simultaneously transcribed and translated into English, thus skipping the step of producing a verbatim Chichewa

transcript. Although back-translations were not conducted, the field coordinator and field investigators used group consensus to decide on the appropriate English translations for certain Chichewa words or phrases to achieve conceptual equivalency (Birbili, 2000)

Nurse interview questions. Although the interviews with the nurses helped to shed light on explaining nurses' general patterns of implementation adherence, the interview questions were not tailored for each nurse to inquire about the specific counseling behavior observed. With tailored questions, nurses may have provided more detailed information to help inform their specific implementation adherence patterns, versus the general responses on implementation adherence received.

Focus on nurses. This research was designed to focus on nurses, the implementers of the infant feeding counseling protocol, rather than the mothers who received the protocol. Although not collecting data from the mothers to assess their comprehension and actual implementation of the counseling elements received is a limitation, the BAN Study impact evaluation is collecting data from the mothers on their actual infant feeding practices (van der Horst, Jamieson & Kazembe 2005). By limiting the study focus to the nurses and assessing if they implemented the BAN Study infant feeding protocol as intended, the study findings make it possible for BAN Study co-investigators to rule out Type III error, or failure to adequately implement the protocol (Basch et al., 1985; Resnicow et al., 1998).

Sampling of nurses. The method used to sample the nurses may have limited the transferability and applicability of these findings to other nursing populations. Instead of selecting the nurses randomly, the BAN Study nursing supervisor and nurse team leaders recruited and purposefully sampled the nurses who participated in this study. Because the 6 participating nurses were not selected randomly from the 20 BAN Study nurses, selection bias may have occurred.

Nurses' characteristics. The study findings indicate that the participating BAN Study nurses implemented the protocol at an acceptable level of 90% or above. The specialized training and clinical trial experience of the nurses may have contributed to this high implementation adherence. Most of the BAN Study nurses had previous clinical trial work experience and training in research ethics and all aspects of the BAN Study. The BAN Study nurses' specialized background and training surpass that of nurses who work for Malawi government-run health care facilities, who generally get paid less and receive minimal additional training. Thus, the BAN Study nurses' characteristics may have contributed to their high implementation adherence limiting the transferability of these results to nurses' who do not have these background characteristics.

Direct observation method. Although direct observation is a strength of this study, its primary limitation is the potential for reactivity, where the field investigator's presence may have affected the nurse's counseling behavior (Bentley et al., 1994; Curtis et al., 1993; Patton, 1990; Redman et al., 1989; Walsh et al., 2000). Recognizing that reactivity would occur, the research design included observing many (at least 20) counseling sessions for each nurse to give the nurse and field investigator time to get used to each other's presence in the room and for the nurse to return to her habitual counseling behaviors (Patton, 1990). When comparing the first five observations with the last 15 for each nurse, reactivity was only evident for one nurse during the first of her 20 observations.

Public Health Implications of Study Findings

Theoretical. Theoretically, these study findings supported Roter and Hall's (1989, 1991 & 1997) patient-provider communication and relationship concepts of providers displaying mutuality-oriented behavior, which were categorized into task and socio-emotional domains. Nurses demonstrated mutuality-oriented behavior when they used

open-ended questions to ask mothers about their infant feeding practices, did not use commanding language, and showed empathy during the counseling sessions. Nurses' implementation of mutuality-oriented behavior included both task and socio-emotional domains. Nurses did implement specific task behaviors which included advising mothers on the BAN Study infant feeding counseling recommendations. Nurses also implemented socio-emotional content when they displayed empathy, which was demonstrated when they used reflective/repeating back techniques and open-ended questions to facilitate the counseling sessions so mothers felt comfortable saying what was important to them about infant feeding. Nurses' implementation of these theoretical patient-provider communication and relationship concepts (Roter & Hall, 1997) should influence mothers' infant feeding practices to comply with the BAN Study infant feeding recommendations to exclusively breastfeed for six months and early breastfeeding cessation at six months (de Paoli, Manongi & Klepp, 2002; Piwoz et al., 2005; Seidel, Sewpaul & Dano, 2000).

Research, policy and practice. The research findings have important implications for public health research, policy and practice. First, although this study meets the call for the integration of behavioral science research into HIV/AIDS clinical trials (Tolley & Severy, 2006), process evaluation studies, focusing on the intervention providers in Africa, are not frequently reported in the literature. In fact, a search of literature on the topic resulted in reports of process evaluation studies conducted in the context of community-based HIV/AIDS education interventions in Uganda (Kinsman et al., 2002; Mitchell et al., 2001), but not in the context of an HIV/AIDS clinical trial. The incorporation of this process evaluation study into the BAN Study clinical trial guarded against the implementation failure of the study's infant feeding counseling protocol and will assist the co-investigators with the interpretation of the BAN study's impact and outcome evaluation results concerning the BAN Study aim to assess the feasibility of

mothers exclusively breastfeeding for six months and then stopping breastfeeding at six months (Israel et al., 1995; Linnan & Steckler, 2002).

Second, these study findings have policy implications in that they shed light on nurses' adherence toward implementing WHO (2001) infant feeding recommendations for HIV-infected women in resource-poor areas. Although this study took place within the context of a clinical trial, the results can provide policymakers with an indication of how applicable these policy recommendations are for nurses to implement in resource-poor areas.

Third, and potentially most important, the findings suggest that even with a brief, week-long intensive training in infant feeding counseling, nurses counseled HIV-infected mothers on the BAN Study infant feeding recommendations of exclusive breastfeeding for six months and early breastfeeding cessation at six months. This finding is important for public health practice in resource-poor areas because it suggests that nurses, who are critical health service providers in HIV/AIDS care and treatment, do not necessarily have to attend a two or more week long infant feeding counseling training course to properly counsel HIV-infected mothers on infant feeding in resource-poor areas, like Malawi.

Conclusion

Although these study findings indicated that nurses were implementing the infant feeding protocol at an acceptable level, results also shed light on protocol items (i.e., breastfeeding cessation and breast health) that were not being consistently implemented and additional items that should be added to the existing protocol (e.g., milk formula preparation and use). As a result of these findings, the dissertation author made recommendations to the BAN Study nutrition team to develop a counseling aid on milk formula use and preparation and to organize a one-day training session for all BAN Study nurse on protocol the items that were not consistently implemented and the new milk

formula counseling aid. Overall, implementation of these recommendations may improve all nurses' implementation of the protocol and subsequently strengthen the interpretation of the BAN Study's impact and health outcome evaluation findings.

Appendix A

36th Week Antenatal to 18th Week Post Partum
Exclusive Breastfeeding Counseling Aid

Introduction:
The purpose of this counseling script is to provide guiding information to breastfeeding counselors for counseling before delivery during the week 36 antenatal visit counseling session.

Find out from the client what she remembers about exclusive breastfeeding from previous counseling sessions:

> "*Could you tell me what you remember about benefits of exclusive breastfeeding?"*

Benefits of exclusive breastfeeding

Initiate breastfeeding immediately after birth

- Breastfeeding immediately after birth helps to bring your milk in more quickly.
- Your baby will benefit from the antibodies in your first milk (colostrum). They are your baby's first immunization.
- You will also benefit from early breastfeeding initiation. The baby's sucking action will help to return your womb to normal size and reduce bleeding.
- Immediate breastfeeding helps to establish an emotional bond between you and your baby.
- Breast milk alone is enough food and drink for your baby from birth to six months.
- Breast milk alone is all that the baby needs to quench its thirst and to grow strong.
- Never give anything to your baby to cleanse its gut or settle its stomach.
- Giving other foods and liquids to young babies increases the risks of diarrhea and malnutrition.
- **Do not** give gripe water, artificial milk, or other foods to your newborn baby. These may damage the gut, causing diarrhea and may also increase the risk that you will give HIV to your baby during breastfeeding.

- Giving other foods and liquids too early will also cause you to produce less breast milk.

- Breastfeeding your baby exclusively will reduce the risk that you will give HIV to your baby during breastfeeding.

Ensuring adequate exclusive breastfeeding

Breastfeed frequently and on-demand

- The amount of milk you produce is determined by how often you breastfeed. The more often the baby feeds, the more milk you will produce.

- Feed your baby on demand to ensure it is getting enough milk during exclusive breastfeeding.

- Give enough time to breastfeeding – emptying each breast – to ensure that the baby gets the hind milk, which is very nourishing and helps you to produce more milk.

- The hind milk will make your baby feel full and help it to grow strong.

- Do not allow the baby to "monkey around" (start and stop feeding, and changing breasts quickly) and don't let it be distracted by noise or other people.

- Burp your baby (break wind) after each feed to remove excess air and comfort your baby.

- If you have to be away from your baby, express your milk in a clean cup. Ask someone you trust to cup-feed your baby while you are away. Expressed milk can be stored at room temperature for up to 8-10 hours.

Ensure that your baby is well-positioned and attached to the breast

- Proper positioning and attachment will help your baby suckle efficiently, will increase your milk supply, and will prevent sore and cracked nipples.

- Signs of proper positioning and attachment are:
  - ✓ *The baby is held close, facing you*
  - ✓ *The baby's ear, shoulder and hip are in a straight line*
  - ✓ *The baby's mouth is wide open (his lips are rolled outward)*
  - ✓ *The baby's chin is touching the breast*
  - ✓ *The baby's cheek is flattened against the breast*
  - ✓ *A lot of the darkened area (areola) is in the baby's mouth*
  - ✓ *You will see his jaw move*
  - ✓ *You will hear slow deep sucks while the baby is feeding*

Emphasize need for immediate medical care for breast or other problems

Seek immediate medical care for breast or other problems

- Breastfeeding from cracked nipples, breasts with sores, or from breasts that are inflamed or engorged may increase the risk of passing HIV to your baby.

- If you experience any of these problems, express the milk from the affected breast into a cloth and continuing feeding from the healthy breast.

- Seek immediate medical care if you have any problems.

- Seek immediate medical care if your baby has mouth sores.

Ask about family support for exclusive breast feeding

Appendix B

From 21st Week Post Partum Visit
Breastfeeding Cessation Counseling Aid

Introduction

The purpose of this counselling script is to provide guiding information to counsellors for counselling mothers on early breastfeeding cessation. Start early breastfeeding cessation counselling at week 21 visit schedule

Remind the mother about and the reasons for early breastfeeding cessation

"Tell me, why mothers in this study should stop breast feeding early?"

Risk of HIV transmission continues after 6 months if breastfeeding continues

- You reduce the risk of HIV transmission to your baby if you stop breastfeeding early at 6 months. The longer the child breast feeds, the higher the chances of getting HIV.
- The risk that you can transmit HIV to your baby increases if you start giving your baby other foods or drinks in the first 6 months while still breastfeeding
- At six months the child is old enough to start eating other foods.
- Early cessation of breast feeding reduces the chances of mother to child transmission of HIV.

"Can you tell me what you know on how to stop breast feeding ***(here the nurse should probe more and if the mother has other children find out how she stopped breastfeeding the other children).*** *Tell me, how will you stop breast-feeding this baby at this early age?*

To prepare your baby for cessation:

Teach your baby to drink from a cup

- Express your milk to a cup that has been thoroughly cleaned in boiling water.
- Make sure that your baby is awake. Hold your baby sitting upright or semi-upright on your lap. Put a cloth underneath the baby's chin to catch any dribble.

- Hold the cup to the baby's lips and tilt it just enough so that the milk touches the lips. The cup rests lightly on the baby's lower lip, and the edges of the cup touch the outer part of the baby's upper lip.

- Keep the cup tilted so that he/she can take the milk. Do not pour the milk or push on the baby's lower lip. Let the baby take the milk at its own speed.

- A low-birth-weight baby starts to take the milk into its mouth with its tongue. A full term or older baby sucks the milk, spilling some of it.

- You will know the baby has had enough when it closes its mouth and does not take any more.

- If the baby does not drink very much, offer it more at the next feeding or feed it earlier than usual.

Practice cup-feeding slowly and patiently

- Cup-feeding practice should be done when the baby is rested and calm – not fussy.

- Talk to the baby and look into its eyes to show your love.

- Allow other family members to cup-feed the baby.

- Always cup-feed your expressed milk if you must be separated from your baby.

- If baby refuses expressed breast milk in a cup, let another caregiver try to feed the baby.

- If the baby still refuses the expressed breast milk, wait until the baby is very hungry and try again.

Gradually reduce breastfeeding frequency at around 5 months

- Beginning at 5 months, start to cup-feed your baby with expressed breast milk.

- Lengthen the time interval between breastfeeds to once every 4-6 hours.

- Cup-feed with expressed milk in-between feeds.

Monitor the infant's urine output during the transition process

- Your baby should urinate at least 6 times per day.

Feeding at night

If baby causes problems at night or has difficulty sleeping at night:

Breastfeed your baby late

- Accustom your baby to a late night feeding**.**
- Reduce the number of night feedings gradually so that by 6 months it is not waking often to feed.
- When it is near the time to stop breastfeeding, carry or rock the baby to sleep if it wakes in the night.

Try not to breastfeed the baby in order to sleep.

- Instead, lay the baby down and pat it back gently and rhythmically to calm it and to ease the baby into sleep.
- Helping your baby fall asleep on its own will make it easier for you to stop breastfeeding early because the baby will not rely only on breastfeeding to fall asleep.

Help your baby learn the difference between day and night.

- Follow a night time ritual of bathing, cuddling, and feeding each night to accustom the baby to bedtime.
- Do not over-stimulate with your baby with loud noise or play before bedtime.
- Allow other family members to help the baby to fall asleep.
- This may help your baby sleep longer through the night, minimizing the disturbance to other family members.
- If the baby wakes, determine if it is cold or uncomfortable first, and take care of these needs, before feeding it.
- Comfort the baby when it wakens by singing, carrying, or practicing baby massage not by offering the breast or milk.
- If comforting alone is insufficient to soothe the baby, have the mother or another caregiver feed the baby with expressed milk in a cup during the night.

Assess if the mother has any concerns on cessation of breast-feeding

"Can you tell me any concerns that you may have on cessation of breast feeding?" Probe more

"What do you think will be the reaction of your family members and community when you stop breast-feeding early?"

Here counsel the mother accordingly

- Ensure that the mother has adequate support and care to avoid complications of early rapid breast feeding cessation.
- Prevent and treat breast engorgement.
- Provide supportive counseling and education on how to feed and care for non-breastfed infant.
- Provide information on family planning services.

Appendix C

From Week 24 Post Partum Visit
Complementary Feeding Counseling Script

Introduction:

Use this counseling aid for reference information on complementary feeding. Start using this aid for counseling beginning at week 24 postnatal visit schedule.

> *Find out from the mother the foods that are available in her home. If she has other children, ask how she fed them after weaning. Counsel her on how she can prepare these to make food for the baby.*

Age of introduction

- Start complementary feeding when your baby is six months old. Your baby can grow well on breast milk alone up to six months as long as it is fed frequently, both breasts are emptied completely at each feeding, and you are taking care of your health.

- At six months your baby cannot get enough nutrients from breast milk alone, so the baby has to be fed other foods. If you introduce complementary foods late, your baby may lose weight because your baby is not getting adequate nutrients from breast milk alone.

- It is easier to feed babies as they like to put things in their mouths and try new tastes.

- When your baby turns six months old you will start feeding your child Chiponde Cha Mwana instead of your breast milk.

Feeding with Chiponde Cha Mwana

Give small amounts of *Chiponde cha Mwana* ***75g- 1 sterile container per day (show the mother the sterile container)***

- Feed one sterile container full of Chiponde cha Mwana to your baby per day. If your baby does not tolerate the Chiponde cha Mwana feed small quantities but frequently spread through the day.

- Let your baby suck the *Chiponde cha Mwana* from a clean spoon.

- Do not mix the *Chiponde cha Mwana* with other foods. If your baby refuses to eat *Chiponde cha Mwana* from a spoon, try mixing it with a little porridge and make sure the baby has finished the mixed portion.

- Give the baby boiled water to drink after each feed.

- Keep *Chiponde cha Mwana* in a safe place, stored with the lid on tightly. Finish one sterile container in a day before filling another.
- Finish one jar before opening another. Do not use the opened jar for more than 2 weeks; the opened jar should be used within 2 weeks.

Food amounts, nutrient density and variety

- Once your baby is used to *Chiponde cha Mwana*, also begin feeding enriched porridge at least 2 times per day.

- Feed your child frequently to increase amount of food eaten in a day.

- If you have milk feeds, give your baby milk feeds before other feeds.

- Give child enriched porridge to ensure giving nutrient dense food. Enriched porridge is porridge mixed with energy-rich or protein rich or both foods. These foods include cooking oil, groundnut flour, sugar, honey, groundnuts, milk, soybeans, meat, and fish.

- Enriched porridge can be made from ingredients that you have at home.

- Enrich your baby's porridge by adding milk, oil, and sugar.

- Prepare one cup/bowl (about 200 ml) of porridge every time. The porridge should be soft and easily fed with a spoon (it should not be thin porridge).

- Feed your baby lovingly and patiently so that he or she eats the whole portion that you prepared.

- Give energy-rich and protein rich foods on their own or use them to enrich porridge.

- Use Likuni Phala (special kind of enriched complementary porridge flour).

- Feed infant from own plate and encourage it to eat as much as possible. Sometimes children have to be coaxed into eating.

- You can ensure that the child eats enough by feeding the baby yourself or encouraging the baby to eat; feeding the baby from separate plate; and feeding the baby before the rest of the family members.

- Give child a variety of foods to prevent micronutrient deficiencies such as vitamin A deficiency. Some of the foods include carrots, mangoes, paw paws and dark green vegetables such as Amaranthus, black jack leaves, pumpkin leaves, mustard, and rape.

- Provide vitamin A supplementation from the age of 6-59 months with the frequency of every 6 months.

- High nutrient density foods include
  - Porridge from maize and Soya flour in the ratio of 4:1 or cassava and Soya flour in the ratio of 7:3.
  - Mashed bananas + milk.
  - Mashed sweet potatoes + groundnuts (Futali).
  - Porridge + vegetable gravy.
  - Porridge + cooked legumes (mashed flour).
  - Porridge + groundnut flour.
  - Porridge + milk, margarine.

- Adding oil to porridge increases energy and not other nutrients.

- Give snacks at least 2-3 times a day, in addition to family meals and porridge, to ensure variety, for example, cooked maize and beans, avocado, mangoes, sweet potatoes.

- Avoid giving children sweets, soft drinks such as Fanta as these cause loss of appetite and the child may not eat adequate food.

Guidelines on frequency, quantity and quality of complementary foods

Age	**No. of feeds per day**	**Quantity**	**Quality/Type**
6 - 8 months	2 to 3 times per day	50 – 100 ml per feed	Enriched porridge with sugar, oil, pounded groundnuts in addition to Chiponde cha Mwana
9 - 11 months	3 to 4 times per day	100 to 150 ml per feed	Enriched, pounded, mashed or strained foods e.g. powder meats, vegetables and fruit juice or mashed fruit in addition to Chiponde cha Mwana
12 - 24 months	4 to 5 times per day	200 to 300 ml per feed	Enriched, chopped/mashed foods and snacks

Feeding frequency

- Babies need to be fed frequently because they have small stomachs (200ml) so they cannot eat much at one feeding—about a teacup of food. They also need more energy and nutrients as they grow and become active.

- Give small frequent and easily digestible meals, at least 3 times in addition to milk and 5 times per day for those that are not getting any form of milk. Easily digestible meals include soft foods.

- Vary servings with age; gradually increase the quantity and frequency of feed.

- Give snacks in season as one way to increase frequency of feeding. Snacks include mangoes, mashed bananas, pumpkins, cooked maize and beans.

Food safety

- Complementary foods and drinks fed to your baby must be clean to prevent infections such as diarrhea.

- You can ensure food safety by:
  - Thoroughly washing hands with *soap* and *clean* water before preparing feeds.
  - Washing feeding and mixing utensils thoroughly with soap and water or boil them to sterilize before preparation of feed and after feeding the baby.
  - Use open cup to feed baby instead of a bottle.
  - Not using unfinished milk for next feed. Unfinished milk can be discarded or used for baking.
  - Washing cup or bowl for infant's food with soap and water immediately after feeding. This prevents bacteria from breeding on feeding utensils.
  - Storing food and drinking water in clean covered containers and protecting contamination from rodents, insects and other animals.
  - Keeping food preparation surfaces clean.
  - Putting all feces in a latrine/toilet.

Feeding during illness

- Sick children need more food and drink to fight infection.

- AIDS-related illnesses which affect nutrition most include diarrhea, measles, malaria, sore mouth and throat.

- Diseases cause weight loss because sick children do not eat enough due to loss of appetite; Sore mouth or throat or stomach so eating is difficult; and lack of proper persuasion for the baby to eat. They absorb less nutrients– their gut may be damaged by infection; use nutrients faster than usual to rebuild immune system.

- Sick children need more food to recover faster and lose less weight.

- You can encourage child to eat enough if you feed Chiponde cha Mwana three times per day and other foods more often (every 1-2 hours) because sick children eat very little each time.

- Give drinks and soft foods which the child likes such as porridge, milk, soup, mashed bananas –could be enriched with energy-rich foods.

- You can encourage the child to eat enough if you feed when the child is washed, comfortable and not when tired, and when temperature is low.

- In case of vomiting, give smaller amounts of food and drink but more frequently.

- Recovering children need extra food for catch up growth. Give recovering children more at each meal.

Practice responsive feeding

- Refers to the interaction between you and your child that leads to positive feeding experience, adequate dietary intake and enhanced development opportunities.

- Responsive feeding behaviors include active physical help and verbalization during eating, role playing and persistence but not forcing. The behaviors encourage baby to eat more.

Assess if the mother has any concerns on complementary feeding:

"Can you tell me any concerns that you may have on Complementary feeding? Probe more

Tell me, how is your family supporting you on how you are feeding your baby?

- Provide supportive counseling and education on how to feed and care for non-breastfed infant.

- Ensure that the mother has adequate support and care to avoid complications of malnutrition of non breastfed babies.

- Provide information on family planning services.

Appendix D

Breast Health and Care Information Counseling Aid

Keeping your breasts healthy is important to reduce the risk of HIV transmission.

- When breasts are unhealthy – with sore or cracked nipples, infections, and abscesses they are more likely to cause the baby to become infected with HIV.
- Never feed your baby from a breast that is infected or sore, including cracked or bloody nipples.
- In these cases, carefully express the milk onto a cloth, discard it, and seek immediate medical attention.
- You may continue breastfeeding from the other breast if it is healthy and not affected by the problem.

Preventing and treating engorgement

- Engorgement (a swollen, tight, painful breast) occurs when breast milk is not fully drained from the breast. This is most often the result of poor positioning or attachment to the breast, and insufficient feeding frequency.
- This problem may be solved by breastfeeding more often and/or for longer periods, applying moist heat compresses to the affected breast(s), and expressing the breast milk by hand to relieve the pressure and pain. Improving infant positioning and attachment will also help relieve the problem.
- Engorgement may also occur immediately after breastfeeding cessation, especially if it is very rapid. If this occurs, you must take care to regularly express your milk onto a cloth and discard it.

Preventing and treating mastitis

- Mastitis is caused by insufficient removal of milk from the breast.
- It may be due to poor breastfeeding technique, such as infrequent feeding or improper attachment to the breast, or due to an infection.
- Mastitis usually occurs in one breast only. Signs of mastitis are painful, red, swollen, or hard breasts accompanied by maternal fever and body ache.
- If mastitis is caused by poor breastfeeding technique, the solution is to breastfeed more frequently.
- Moist heat compresses can be applied for several minutes before each feeding.

- If mastitis is caused by rapid breastfeeding cessation, express your milk onto a cloth, and take appropriate medicines for fever and pain. Cold compresses can be used to reduce inflammation.

- Mothers should rest and drink additional fluids.

Cracked and sore nipples

- These are caused by poor positioning of the infant on the breast, or the use of harsh soaps on the nipple.

- These can be prevented by proper infant positioning and attachment.

- Do not breastfeed from cracked or bloody nipples but express and discard the milk.

- To facilitate healing, apply some breast milk to the sore nipple and let it air dry. Avoid using ointments (except in the case of candidiasis).

- Once the breast has healed, resume feeding by positioning the baby so that his mouth covers as much as possible of the areola.

Abscesses

- Abscesses are severely painful swollen lumps, or local areas on the breast which are red, hot, and swollen. Mothers with breast abscesses may or may not have fever.

- If untreated, skin discoloration and tissue damage occurs.

- Abscesses contain pus that should be drained through incision or drainage. Seek medical attention immediately for this care.

- Mothers will be given appropriate antibiotics and anti-inflammatory drugs to treat breast abscesses.

- Mothers should express and discard milk from affected breasts until treatment is concluded. Breastfeeding may resume after the abscess is healed.

Appendix E

Antenatal Implementation Checklist

ANTENATAL VISIT
(Only Visit Codes: 03.00, 04.00, 05.00)

Nurse ID ☐☐☐ **Participant ID** ☐☐☐☐☐-☐-☐

Visit Code ☐☐.☐☐ **Observation Date:** ☐☐/☐☐/☐☐

Observer's Name: _____

Session Start Time: _____ **Session End Time: _____**

Communication Mode	Item	Yes (Y), No (N), N/A
VERBAL	Nurse asked mother about infant feeding issues using open-ended questions	
	Nurse advised mother to give only breast milk and nothing else to baby for 6 months.	
	Nurse advised mother on the advantages of giving only breast milk to her infant for 6 months to prevent HIV transmission to infant.	
	Nurse advised mother on the risks of mixed feeding and how it may increase the risk of HIV transmission to infant.	
	Nurse engaged mother in dialogue to assess how well she understood the importance of giving only breast milk to her infant for 6 months.	
	Nurse allowed mother to complete her sentences before responding to the mother's infant feeding issues.	
	Nurse used reflecting back/repeating techniques to show an active interest in understanding the mother's perception, situation, meaning and feelings (i.e. empathy).	
	Nurse did not use commanding language/imperatives during infant feeding counseling session.	
NON-VERBAL		
	Nurse nodded and/or smiled during session when mother discussed infant feeding issues.	
	Nurse made eye contact with mother to show her active interest in the mother's perception, situation, meaning and feelings (i.e. empathy).	
	Nurse sat with posture that showed her active interest in mother's perception, situation, meaning and feelings (i.e. empathy).	
	Nurse did not seem rushed or show impatience toward mother during the counseling session.	
	Nurse touched mother in a socially appropriate way during the counseling session that showed her active interest in mother's perception, situation, meaning and feelings (i.e. empathy).	

Appendix F

1st to 18th Week Post Partum Visit Implementation Checklist

1st to 18th WEEK POST PARTUM VISIT
(Only Visit Codes: 07.00 to 13.00)

Nurse ID ☐☐☐ **Participant ID** ☐☐☐☐☐-☐-☐

Visit Code ☐☐.☐☐ **Observation Date:** ☐☐/☐☐/☐☐

Observer's Name: _____

Session Start Time: _____ **Session End Time: _____**

Communication Mode	Item	Yes (Y), No (N), N/A
VERBAL	Nurse asked mother about infant feeding issues using open-ended questions	
	Nurse advised mother on the advantages of giving only breast milk to her infant for 6 months to prevent HIV transmission to infant	
	Nurse advised mother on the risks of mixed feeding and how it may increase the risk of HIV transmission to infant	
	Nurse engaged mother in dialogue to assess how well she understood the importance of giving only breast milk to her infant for 6 months	
	Nurse asked mother if she had experienced any breast health issues	
	Nurse addressed mother's breast health issues by explaining the cause of breast health problems and how they should be treated.	
	Nurse asked mother to demonstrate her breastfeeding techniques.	
	Nurse corrected mother who demonstrated incorrect breastfeeding techniques.	
	Nurse praised mother who demonstrated proper breastfeeding techniques.	
	Nurse allowed mother to complete her sentences before responding to the mother's infant feeding issues.	
	Nurse used reflecting back/repeating techniques to show an active interest in understanding the mother's perception, situation, meaning and feelings (i.e. empathy).	
	Nurse did not use commanding language/imperatives during infant feeding counseling session.	
NON-VERBAL		
	Nurse nodded and/or smiled during session when mother discussed infant feeding issues.	
	Nurse made eye contact with mother to show her active interest in the mother's perception, situation, meaning and feelings (i.e. empathy).	
	Nurse sat with posture that showed her active interest in mother's perception, situation, meaning and feelings (i.e. empathy).	
	Nurse did not seem rushed or show impatience toward mother during the counseling session.	
	Nurse touched mother in a socially appropriate way during the counseling session that showed her active interest in mother's perception, situation, meaning and feelings (i.e. empathy).	

Appendix G

21st, 24th and 28th Week Post Partum Visit Implementation Checklist

21st 24th and 28th WEEK POST PARTUM VISIT (Only Visit Codes: 14.00, 15.00, 16.00)

Nurse ID ☐☐☐ **Participant ID** ☐☐☐☐☐-☐-☐

Visit Code ☐☐.☐☐ **Observation Date:** ☐☐/☐☐/☐☐

Observer's Name: _____

Session Start Time: _____ **Session End Time: _____**

Communication Mode	Item	Yes (Y), No (N), N/A
VERBAL	Nurse asked mother about infant feeding issues using open-ended questions.	
	Nurse explained to mother that early breastfeeding cessation at 6 months reduces the risk of HIV transmission to infant.	
	Nurse explained to mother that she should stop breastfeeding starting at week 21 and completely stop by week 24.	
	Nurse provided mother with specific advice to prepare the baby for breastfeeding cessation.	
	Nurse provided mother with specific advice to comfort infant after weaning.	
	Nurse advised mother on the importance of introducing complementary foods to infant at 24 weeks of age.	
	Nurse advised mother on how to prepare complementary foods at the 24th week visit (**15.00 visit code only).**	
	Nurse advised mother to give spoonful of Chiponde cha mwana 3 times per day at the 24th week visit (**15.00 visit code only).**	
	Nurse allowed mother to complete her sentences before responding to the mother's infant feeding issues.	
	Nurse used reflecting back/repeating techniques to show an active interest in understanding the mother's perception, situation, meaning and feelings (i.e. empathy).	
	Nurse did not use commanding language/imperatives during infant feeding counseling session.	
NON-VERBAL		
	Nurse nodded and/or smiled during session when mother discussed infant feeding issues.	
	Nurse made eye contact with mother to show her active interest in the mother's perception, situation, meaning and feelings (i.e. empathy).	
	Nurse sat with posture that showed her active interest in mother's perception, situation, meaning and feelings (i.e. empathy).	
	Nurse did not seem rushed or show impatience toward mother during the counseling session.	
	Nurse touched mother in a socially appropriate way during the counseling session that showed her active interest in mother's perception, situation, meaning and feelings (i.e. empathy).	

Appendix H

32nd to 48th Week Post Partum Visit Implementation Checklist

32nd to 48th WEEK POST PARTUM VISIT (Only Visit Codes: 17.00 to 20.00)

Nurse ID ☐☐☐ **Participant ID** ☐☐☐☐☐-☐-☐

Visit Code ☐☐.☐☐ **Observation Date:** ☐☐/☐☐/☐☐

Observer's Name: _____

Session Start Time: _____ **Session End Time: _____**

Communication Mode	Item	Yes (Y), No (N), N/A
VERBAL	Nurse asked mother about infant feeding issues using open-ended questions.	
	Nurse asked mother about infant feeding status and if she has stopped breastfeeding completely.	
	Nurse advised mother about the importance of stopping breastfeeding to reduce risk of HIV infection to infant.	
	Nurse asked mother about nature of Chiponde cha mwana use.	
	Nurse advised mother on importance of giving infant complementary foods in addition to Chiponde cha mwana.	
	Nurse allowed mother to complete her sentences before responding to the mother's infant feeding issues.	
	Nurse used reflecting back/repeating techniques to show an active interest in understanding the mother's perception, situation, meaning and feelings (i.e. empathy).	
	Nurse did not use commanding language/imperatives during infant feeding counseling session.	
NON-VERBAL		
	Nurse nodded and/or smiled during session when mother discussed infant feeding issues.	
	Nurse made eye contact with mother to show her active interest in the mother's perception, situation, meaning and feelings (i.e. empathy).	
	Nurse sat with posture that showed her active interest in mother's perception, situation, meaning and feelings (i.e. empathy).	
	Nurse did not seem rushed or show impatience toward mother during the counseling session.	
	Nurse touched mother in a socially appropriate way during the counseling session that showed her active interest in mother's perception, situation, meaning and feelings (i.e. empathy).	

Appendix I

Post-Observation Nurse Interview Guide

Introduction:
Thank you again for participating in this study. I want to remind you that this interview will be approximately 1-hour and the questions will be related to the counseling content specific to infant feeding taking place in the BAN Study. The purpose of this interview is to get your insight about the current infant feeding counseling recommendations, the current protocol and how this protocol is implemented. Your insight may help the BAN Study Nutrition team improve the procedures and protocol related to infant feeding counseling.

I want to remind you that this interview will be audio-recorded. As stated in the informed consent, if at any time you feel uncomfortable or would not like to be recorded, I will stop audio-recording immediately.

Are you ready to being the interview?

1. Overall, what do you think about the BAN Study infant feeding recommendations for HIV-infected mothers to breastfeed exclusively for the first 6 months of the baby's life and stop breastfeeding at 6 months?

2. How have mothers responded to the recommendation to breastfeed exclusively for the first 6 months of the baby's life? (probe on mother's understanding of this recommendation, initial reaction to this recommendation).

3. How have mothers responded to the recommendation to stop breastfeeding their baby at 6 months? (probe on mother's understanding of this recommendation, initial reaction to this recommendation).

4. What would you say are the factors that help mothers follow these recommendations?

5. What would you say are the factors that prevent mothers from following these recommendations?

6. How do you feel when you are counseling the HIV-infected mothers about infant feeding? (probe for good or bad feelings such as helpful, saddened, conflicted, and tired. After they respond with their initial feelings, probe with "Could you tell me more about why you feel this way?")

7. Now, let's talk about implementation of the BAN Study counseling protocol. Overall, what do you think about your implementation of the BAN Study infant feeding counseling protocol?

8. What would you identify as your strongest counseling skill?

9. What would you identify as the counseling skill that could use improvement?

10. What would you say is the easiest part of the infant feeding counseling protocol for you to implement?

11. What would you say is the most difficult part of the infant feeding counseling protocol for you to implement?

12. What suggestions do you have for improving the implementation of the current BAN Study infant feeding counseling protocol? (NOTE: Take a few moments for nurse to think about any suggestions she may have. If she says there is nothing she would change, probe with, "Are you sure there is nothing you would change?)

13. What would you identify as the most important elements of the BAN Study infant feeding counseling protocol?

14. Now, here is a copy of the checklist we have been using in our observations. I'd like to give you a few minutes to read over the checklist items. The checklist items were taken from the BAN Study infant feeding counseling protocol and the WHO breastfeeding counseling training manual. The items are specific to the mother's visit code because we know that you counsel the mother based on her visit code. So, just take a few minutes to look over the checklist. (NOTE: Wait a few minutes and answer any of the nurse's questions she has about the checklist). Now, based on your brief review of the checklist, I'd like you to put an "X" by the 5 verbal or non-verbal counseling items that you believe are the most important to implement. (NOTE: get copy of checklist back from nurse at end of interview after she answers this question).

15. Now, let's talk about the clients that you have counseled on infant feeding. Tell me a story about a counseling session with a BAN Study client when you discussed the recommendation to exclusively breastfeed her baby for 6 months (story could be good or bad, whatever the nurse chooses to share).

16. Tell me a story about a counseling session with a BAN Study client when you discussed the recommendation of early breastfeeding cessation (story could be good or bad, whatever the nurse chooses to share).

Appendix J

Transcription/Translation Standard of Procedures

Version Date: 14 November 2005

Purpose: To clarify the procedures involved in transcribing and translating the tape-recorded infant feeding counseling session observations between nurses and clients in this study.

1. Transcribers/Translators use headphones when transcribing and translating the tape-recorded observation.

2. Transcribers/Translators record translation/translation "start" and "stop" times on their written transcript during the transcription/translation process.

3. Transcribers/Translators record who is speaking on the tape-recorded observation (i.e. Mother or Nurse) and when they are speaking in their written transcript.

4. If Transcriber/Translator is not sure if it was the mother or the nurse who was speaking on the tape-recorded observation, the Transcriber/Translator listens to another tape recording of that nurse's counseling session to differentiate the nurse's voice from the mother's voice.

5. If after hearing another tape recording for that specific nurse and the Transcriber/Translator is still not able to differentiate the nurse's voice from the mother's voice, the Transcriber/Translator has the person who observed the counseling session, listen to the tape-recorded observation to differentiate between the two voices (NOTE: procedure only applicable if the Transcriber/Translator was not the person who observed the counseling session).

6. When there are sections of the recording that are inaudible, the Transcriber/Translator records the word, "inaudible", on their written transcript and asks the field supervisor to also listen to that section of the tape to confirm that it is inaudible.

7. If there are Chichewa words and/or phrases that are difficult to translate into English, the Transcriber/Translator writes the word or phrase in Chichewa and consults with the field supervisor or other members of the research team to assess how this word and/or phrase might translate into English. If after these consultations the Transcriber/Translator is still not sure about how to translate the word or phrase into English, they consult with the project coordinator.

8. With each "Ehh", "Ah", "Ummm" or other sounds that imply agreement, disagreement, emotions or other expressions, the Transcriber/Translator adds context to these sounds by recording on their written transcript (a) what these sounds mean and (b) the tone in which these sounds were said. For example, "Ohhh" (surprised tone), or "Ehh" (in agreement).

9. If a sentence or section translated into English does not make sense to the Transcriber/Translator or is difficult for them to understand, revise it to make sense in English and use parentheses to add context to the translated sentence or section when needed.

10. After the Transcriber/Translator completely transcribes the tape-recorded session, the Transcriber/Translator takes 10-15 more minutes to read over the final transcription. With this final read, the Transcriber/Translator adds context in parentheses where needed and corrects any major grammatical errors.

11. Transcriber/Translator delivers completed transcript to the field supervisor.

12. If there are questions or concerns that the other research team members have about the translated and transcribed transcript, the Transcriber/Translator is available for clarification for the duration of the data collection phase (until February 2006).

Appendix K

Example of Counseling Session Summary

Archival Number:	000-04.00-04 (week 32 antenatal visit)
Implementation checklist:	100% (20% non-verbal, 80% verbal)
Observation Time:	42 minutes
Field notes:	Mother seems like she listened attentively. Mother responded to nurses' questions by nodding in agreement. Mother smiles and laughs when mixed feeding was mentioned. Mother shook head back and forth when answering "no" to a question.

Observation:
Nurse reminds mother what they had discussed during last visit and mentions that although she was not her specific counselor last time it was okay because the counselors know what was discussed in previous visits. Nurse asks mother what Exclusive Breast Feeding (EBF) is and why is it important. Mother answers the questions correctly. Nurse fills in missing gaps in mother's response so mother has more comprehensive picture of EBF. Mother knew why EBF was important and when to start breastfeeding, which she said was immediately after the baby is born. Nurse provides more comprehensive explanation of benefits of breastfeeding immediately after birth (contracting of uterus, milk comes in quicker, colostrum). Nurse discusses risks of mixed feeding. Mother understands that it could lead to HIV transmission to baby. Nurse explains process in which mixed feeding can lead to HIV transmission. Nurse addresses risk of giving the baby traditional medicines to close the fontenella (or soft spot in the baby's head) which is not advised. Nurse also advised against giving gripe water for stomach upsets and taught mother how to belch baby after feedings.

Nurse summarizes what has been covered in counseling session before moving on to next topic area. Nurse discusses importance of draining milk from one breast during a feeding before going to the other. Mother demonstrates breastfeeding with a doll. Mother had previous child so knew about proper breastfeeding attachment and answered nurses' questions correctly.

Nurse summarizes topics covered today and tells mother what to expect next in her visit today. Mother will be receiving medicine today. Mother forgets to bring Nevirapine back with her to BAN study and forgets what the medicine was for. I think it is the medicine they were given in CTA clinic. Nurse reminds mother to bring the medicine back next visit and says that she will talk with mother as if she had not received the medicine. Instructs mother on when to take medicines (when labor pains begin) and asks mother if she has any questions about why she is taking the medicine and when to take them. Nurse quickly tells mother what will happen next visit and what drugs she will receive next visit while admitting that she forgot to tell the mother about it earlier in the counseling session.

Appendix L

Code Book

(1) Antenatal Visit

(1, 1) Assessment of mother's EBF knowledge (d). This includes any references made by the nurse to assess whether or not the mother understands the benefits of giving her baby only breast milk for the baby's first 6 months of life.

(1, 2) Commanding language use (d). This includes any references made by the nurse to the mother that suggests a direct order, suggestion or command. Examples include the following: "You should…Don't …You shouldn't"

(1, 3) Do you understand (i)? This includes any references to techniques or questions asked by the nurse to ensure that the mother understands what is being said during the session.

(1, 4) EBF advantages and HIV transmission (d). This includes any references made by the nurse to the mother about the benefits of giving the baby only breast milk for the first 6 months of life to prevent HIV transmission to the baby.

(1, 5) EBF for 6 months (d). This includes any references made by the nurse to the mother on giving only breast milk and nothing else to the baby for the first 6 months of life.

(1, 6) Milk formula feeding (i). This includes any references made by the nurse or mother about formula or bottle feeding.

(1, 7) Mixed feeding risk and HIV transmission (d). This includes any references made by the nurse to the mother about the HIV transmission risks of feeding other liquids (i.e. gripe water, teas, formula, and minerals) and solids (i.e. phala, nsima, cereal and yogurt) to the baby in addition to breastfeeding.

(1, 8) Mother completes sentences (d). This includes any silences or pauses the nurse takes to allow the mother to complete her sentences before the nurse responds to the mother's infant feeding issues.

(1, 9) Open-ended questions (d). This includes any references made by the nurse to the mother about infant feeding issues using open-ended questions. Open-ended questions usually start with "How? What? When? Where? Why?"

(1, 10) Reflecting back/repeating (d). This includes any references made by the nurse to repeat back what the mother has told the nurse regarding her infant feeding issues.

(2) 1st to 18th Week Post Partum Visit

(2, 1) Asking mother for demo of breastfeeding (d). This includes any references made by the nurse asking the mother to breastfeed her baby during the counseling session.

(2, 2) Assessment of mother's EBF knowledge (d). This includes any references made by the nurse to assess whether or not the mother understands the benefits of giving her baby only breast milk for the baby's first 6 months of life.

(2, 3) Breast health asking (d). This includes any references made by the nurse asking the mother if she had any breast conditions that may influence her breastfeeding process.

(2, 4) Causes and treatment of breast health issues (d). This includes any references made by the nurse to the mother about the causes of breast conditions and how they can be treated.

(2, 5) Commanding language use (d). This includes any references made by the nurse to the mother that suggests a direct order, suggestion or command. Examples include the following: "You should…Don't …You shouldn't"

(2, 6) Correcting incorrect BF techniques (d). This includes any references made by the nurse to correct the mother if the mother demonstrates poor breastfeeding techniques during the session. Correct breastfeeding techniques include: The baby having most of the areola into its mouth, the baby's tongue being over the bottom gums and the baby's chin is touching the mother's breast.

(2, 7) Do you understand (d)? This includes any references to techniques or questions asked by the nurse to ensure that the mother understands what is being said during the session.

(2, 8) EBF advantages and HIV transmission (d). This includes any references made by the nurse to the mother about the benefits of giving the baby only breast milk for the first 6 months of life to prevent HIV transmission to the baby.

(2, 9) Mixed feeding risk and HIV transmission (d). This includes any references made by the nurse to the mother about the HIV transmission risks of feeding other liquids (i.e. gripe water, teas, formula) and solids (i.e. phala, porridge) to the baby in addition to breastfeeding.

(2, 10) Mother completes sentences (d). This includes any silences or pauses the nurse takes to allow the mother to complete her sentences before the nurse responds to the mother's infant feeding issues.

(2, 11) Open-ended questions (d). This includes any references made by the nurse to the mother about infant feeding issues using open-ended questions. Open-ended questions usually start with "How? What? When? Where? Why?"

(2, 12) Praised mother for correct BF technique (d). This includes any references made by the nurse praising the mother for demonstrating proper breastfeeding techniques during the counseling session.

(2, 13) Reflecting back/repeating (d). This includes any references made by the nurse to repeat back what the mother has told the nurse regarding her infant feeding issues.

(3) 21st, 24th and 28th Week Post Partum Visit

(3, 1) Asking mother if she is ready to stop breastfeeding (i). This includes any reference made by the nurse to ask the mother if she is ready to stop breastfeeding her baby.

(3, 2) Comforting baby after weaning (d). This includes any reference made by the nurse to the mother about how to comfort the baby after weaning is complete. Examples of specific advice include: massaging the baby, spending time with the baby and cradling the baby during feedings.

(3, 3) Commanding language use (d). This includes any references made by the nurse to the mother that suggests a direct order, suggestion or command. Examples include the following: "You should…Don't …You shouldn't"

(3, 4) Do you understand (d)? This includes any references to techniques or questions asked by the nurse to ensure that the mother understands what is being said during the session.

(3, 5) Explained why early BF cessation (d). This includes any reference made by the nurse explaining to the mother the benefit of reducing the risk of HIV transmission to the baby if she stops breastfeeding her baby at 6 months.

(3, 6) Intro of complementary foods at 24 wks (d). This includes any reference made by the nurse to the mother about the importance of feeding the baby other solids and liquids during the weaning process at 24 weeks.

(3, 7) Milk formula feeding (i). This includes any references made by the nurse or mother about formula or bottle feeding.

(3, 8) Mixed feeding risk and HIV transmission (d). This includes any references made by the nurse to the mother about the HIV transmission

risks of feeding other liquids (i.e. gripe water, teas, formula) and solids (i.e. phala, porridge) to the baby in addition to breastfeeding.

(3, 9) Mother completes sentences (d). This includes any silences or pauses the nurse takes to allow the mother to complete her sentences before the nurse responds to the mother's infant feeding issues.

(3, 10) Open-ended questions (d). This includes any references made by the nurse to the mother about infant feeding issues using open-ended questions. Open-ended questions usually start with "How? What? When? Where? Why?"

(3, 11) Preparing baby for BF cessation (d). This includes any reference made by the nurse to the mother about how to prepare for stopping breastfeeding. Examples of specific advice include: teaching your baby to drink from a cup, gradually reducing breastfeeding frequency at around 5 months, and not nursing the baby to sleep.

(3, 12) Reflecting back/repeating (d). This includes any references made by the nurse to repeat back what the mother has told the nurse regarding her infant feeding issues.

(3, 13) Stop BF starting at wk 24 and stop by wk 28 (d). This includes any reference made by the nurse explaining to the mother that she should start weaning her baby at 24 weeks and completely stop breastfeeding by the 28th week.

(3, 14) Visit 15.00 (24th wk) Chiponde administration (d). This includes any reference made by the nurse giving specific instructions to the mother on how to feed the baby Chiponde cha Mwana. Mother should give one spoonful of Chiponde to the baby 3 times a day.

(3, 15) Visit 15.00 (24th wk) preparation of complementary foods at 24th wk (d). This includes any reference made by the nurse to the mother on how to properly prepare other foods for the baby at 24 weeks of age. This advice is only given to the mother at the 24th week visit.

(4) 32nd to 48th Week Post Partum Visit

(4, 1) Asked mother if she stopped breastfeeding completely (d). This includes any reference made by the nurse asking her directly if she has stopped breastfeeding the baby completely.

(4, 2) Commanding language use (d). This includes any references made by the nurse to the mother that suggests a direct order, suggestion or command. Examples include the following: "You should…Don't …You shouldn't"

(4, 3) Importance of complementary foods in addition to Chiponde (d). This includes any reference made by the nurse to the mother regarding the mother feeding the baby Chiponde cha mwana in addition to other foods.

(4, 4) Importance of stopping BF to reduce HIV transmission risk (d). This includes any reference made by the nurse explaining to the mother the importance of stopping breastfeeding to reducing the risk of HIV transmission to the baby.

(4, 5) Milk formula feeding (i). This includes any references made by the nurse or mother about formula or bottle feeding.

(4, 6) Mother completes sentences (d). This includes any silences or pauses the nurse takes to allow the mother to complete her sentences before the nurse responds to the mother's infant feeding issues.

(4, 7) Nature of Chiponde use (d). This includes any reference made by the nurse to the mother regarding the mother's use of Chiponde cha mwana.

(4, 8) Open-ended questions (d). This includes any references made by the nurse to the mother about infant feeding issues using open-ended questions. Open-ended questions usually start with "How? What? When? Where? Why?"

(4, 9) Reflecting back/repeating (d). This includes any references made by the nurse to repeat back what the mother has told the nurse regarding her infant feeding issues.

(d) Denotes deductive code
(i) Denotes inductive code

Appendix M

Case-Level Display of Nurses' Counseling Protocol Implementation by Nurse

Nurse/Visit category	Implementation adherence	Key counseling elements implemented	How nurse's implementation was similar or different from other nurses.
Nurse 1			
Antenatal visit	100%	Yes	Ends session re-asking mother the first question about the meaning of EBF. Her method of assessing mother's understanding of EBF Nurse has pattern of summarizing topic area before moving onto next topic Uses reflecting/repeating back techniques more often than other nurses.
1st to 18th week post partum	95.8%	No Did not ask mother if she had experience any breast health issues& did not address mother's breast health issues by explaining the causes of breast health problems and how they should be treated	
21st, 24th and 28th week post partum	100.0%	Yes	
32nd to 48th week post partum	100.0%	Yes	
Nurse 2			
Antenatal visit	100.0%	Yes	Nurse would confirm with mother the number study visit she was on at the beginning of each visit counseling session. Nurse would remind mothers that they are enrolled in a research study and emphasized the importance of complying with what they are counseled to do in terms of infant feeding and drug compliance.
1st to 18th week post partum	100.0%	Yes	
21st, 24th and 28th week post partum	100.0%	Yes	
32nd to 48th week post partum	91.6%	No Nurse did not advise mother about the important of stopping breastfeeding to reduce risk of HIV infection to the infant	
Nurse 3			
Antenatal visit	100.0%	Yes	Nurse would confirm with mother the number study visit she was on at the beginning of each visit counseling session.
1st to 18th week post	95.6%	No Nurses did not ask	

Nurse/Visit category	Implementation adherence	Key counseling elements implemented	How nurse's implementation was similar or different from other nurses.
partum		mother to demonstrate her breastfeeding technique & Nurse did not ask mother if she had experienced any breast health issues	Nurse did not counsel mother specifically on what the mother had just said to the nurse about her infant feeding practices, but instead, counseled the mother on protocol information. Reflected lack of flexibility in counseling compare to other nurses. Compared to other nurses, does not ask open-ended questions of the mother to assess whether the mother understood the information she was just counseled on. Nurse gives mother large amounts of infant feeding information before asking mother if she has questions about the information compared to other nurses.
21st, 24th and 28th week post partum	96.2%	No Nurse did not explain to mother that early breastfeeding cessation at 6 months reduces the risk of HIV transmission to the infant & nurse did not provide mother with specific advice to comfort the infant after weaning	
32nd to 48th week post partum	90.0%	No Nurse did not advise mother about the importance of stopping breastfeeding to reduce risk of HIV infection to the infant	
Nurse 4			
Antenatal visit	100.0%	Yes	Nurse asks mother many open-ended questions about the infant feeding topics covered during the session at the end of each counseling session to assess mother's understanding of the topics covered more often than other nurses. If mother does not understand, nurse counsels on these topics and asks mother again, using open-ended questions, about her understanding of the main topics covered.
1st to 18th week post partum	89.6%	No Nurse did not address mother's breast health issues by explaining the causes of breast health problems and how they should be treated & nurse did not ask mother if she had experienced any breast health issues & nurse did not ask mother to demonstrate her breastfeeding technique	
21st, 24th and 28th week post partum	95.4%	No Nurse did not explain to mother that early breastfeeding cessation at 6 months reduces the	

Nurse/Visit category	Implementation adherence	Key counseling elements implemented	How nurse's implementation was similar or different from other nurses.
		risk of HIV transmission to the infant & nurse did not explain to mother that she should stop breastfeeding starting at week 21 and completely stop by week 24	
32nd to 48th week post partum	98.0%	No Nurse did not advise mother about the importance of stopping breastfeeding to reduce the risk of HIV infection to the infant.	
Nurse 5			
Antenatal visit	100.0%	Yes	Nurse did not implement as many key counseling elements during the 32nd to 48th week post partum visit compare to other nurses.
1st to 18th week post partum	96.2%	No Nurse did not advise mother on the risks of mixed feeding and how it may increase the risk of HIV transmission to the infant & nurse did not engage mother in dialogue to assess how well she understood the importance of giving only breast milk to her infant for 6 months & nurse did seem rushed or showed impatience toward the mother during the counseling session	
21st, 24th and 28th week post partum	95.2%	No Nurse did not provide mother with specific advice to prepare the baby for breastfeeding cessation & Nurse did not provide mother with specific advice to comfort the infant after weaning	

Nurse/Visit category	Implementation adherence	Key counseling elements implemented	How nurse's implementation was similar or different from other nurses.
32nd to 48th week post partum	82.0%	No Nurse did not ask mother about infant feeding status and if she had stopped breastfeeding completely & nurse did not advise mother about the importance of stopping breastfeeding to reduce risk of HIV infection to the infant	
Nurse 6			
Antenatal visit	100.0%	Yes	Nurse missed opportunities to counsel mothers on the risks of milk formula and proper preparation of milk formula when mothers mentioned their use, or intention to use it after they stopped breastfeeding compared to other nurses.
1st to 18th week post partum	96.5%	No Nurse did not advise mother on the risks of mixed feeding and how it may increase the risk of HIV transmission to the infant & nurse did not ask mother if she had experienced any breast health issues	
21st, 24th and 28th week post partum	100.0%	Yes	
32nd to 48th week post partum	95.0%	No Nurse did not ask mother about infant feeding status and if she had stopped breastfeeding completely	

Appendix N

Variable-Level Display of Nurses' Counseling Protocol Implementation by Mother's Visit Type

Visit	Overall average implementation adherence	Key counseling elements implemented	Summary of key counseling elements not implemented
Antenatal visit	100%	Yes	
1st to 18th week post partum	95.7%	No	Did not ask mother if she had experience any breast health issues Did not address mother's breast health issues by explaining the causes of breast health problems and how they should be treated Did not ask mother to demonstrate her breastfeeding technique Did not advise mother on the risks of mixed feeding and how it may increase the risk of HIV transmission to the infant Did not engage mother in dialogue to assess how well she understood the importance of giving only breast milk to her infant for 6 months Did seem rushed or showed impatience toward the mother during the counseling session
21st, 24th and 28th week post partum	97.8%	Yes	Did not explain to mother that early breastfeeding cessation at 6 months reduces the risk of HIV transmission to the infant Did not provide mother with specific advice to comfort the infant after weaning Did not explain to mother that she should stop breastfeeding starting at week 21 and completely stop by week 24

Visit	Overall average implementation adherence	Key counseling elements implemented	Summary of key counseling elements not implemented
21st, 24th and 28th week post partum (cont.)			Did not provide mother with specific advice to prepare the baby for breastfeeding cessation
32nd to 48th week post partum	92.7%	Yes	Did not advise mother about the important of stopping breastfeeding to reduce risk of HIV infection to the infant Did not ask mother about infant feeding status and if she had stopped breastfeeding completely

Appendix O

Example of Nurse Case Profile

Notes for Nurse 001 Age: 46 Marital status: Married Years of nursing experience: 10 yrs. Attended HIV and IF Training: Yes Employee of BAN Study before April 2004: Yes
Community-level norms: Mothers don't really understand what EBF is. Cases where mothers come in with baby having diarrhea at 3 months. Nurse associates that with mixed feeding. Associates poverty and illiteracy with mothers not following recommendations to EBF for 6 months. Nurse sees mothers BF outside, but they say they have stopped. Cannot act as BF police. Mothers don't want to stop BF because they don't see the harm in it if they are feeling well. Poverty, fear of husband and relatives knowing their HIV status also prevent mothers from stopping at 6 months. Believe that ½ mothers understand the recommendations to EBF for 6 months and then stop, other1/2 do not understand recommendations resulting in them not following them. Some mothers think automatically that if they stop BF at 6 months that they need to buy milk for the baby. Most women don't have any food or money to buy it, especially if they live in the village. Protocol attitudes: Nurse believes in recommendations and thinks they are fine, but mothers are not able to following them because of cultural reasons (i.e. stigma in the community about HIV, infant feeding culture to mix feed). Some mothers understand and follow and some don't understand no matter how many times you counsel them about why they need to follow the recommendations. Implementation issues: Initial reaction when telling them to prepare for stopping breastfeeding is "no" and some act like their child is not near 6 months yet because culturally, they want to BF for 2 years. Told story of mother pretending that child was not 6 months so she would not have to stop breastfeeding. Some believe that Chiponde is not enough, so they have fathers buy formula, but they are not preparing it correctly so baby has diarrhea resulting in low birth weight. Protocol attitudes: Nurse believes that mothers who know and understand their status are more likely to follow recommendations of EBF and stopping at 6 months. Those randomized to ARVs for either mother or child may understand the significance of stopping BF at 6 months than mothers/infants who are not on ARVs. Since their meds are over at 6 months, they understand that breastfeeding past this time my increase risk of HIV for the baby. Implementation improvement: Tell mothers that they don't have to buy expensive milk for baby, but have the baby eat what the family eats in addition to the Chiponde. Those that understand counseling recommendations share the information with husband and relatives. Sometimes husbands want to stop breastfeeding earlier than 6 months to reduce HIV transmission (just a story). But telling the family helps support their efforts to EBF and stop breastfeeding at 6 months.

Notes for Nurse 001
Age: 46
Marital status: Married
Years of nursing experience: 10 yrs.
Attended HIV and IF Training: Yes
Employee of BAN Study before April 2004: Yes

Implementation quality: When asked how she felt while counseling, she responded that they felt "open" and really wants the mothers to understand the infant feeding recommendations to prevent HIV to the baby. She in her counseling sessions she repeats points over (reflecting back technique) to ensure that mother understands the recommendations. I take time and allow them to ask questions to ensure they understand the recommendations.

Implementation quality: Nurse says she feels good when counseling (with confidence) because she is used to counseling. She knows what to do and where to go when counseling if a mothers is bored or tired during the session. She feels good because her aim is to prevent HIV transmission from the mother to the infant and any other people.

Protocol attitudes: When asked what she thought about the BAN protocol on infant feeding, she said that is it good. The problem is the state of the Malawians being in poverty and illiteracy and influence of relatives and community about infant feeding norms. Nurses have no problems implementing the protocol it is how the mothers are receiving it that brings problems.

Implementation quality: When asked what counseling skill is her best, she becomes shy and at first does not understand the question. In my observations, Malawians are humble about their skill set. They don't like to say, "I'm good at this or that" I don't know what to call it, but that is their culture. Modesty. When asked about skills, then she says that her skills depend on the client. She talks about first you need to build a rapport. She also mentions that because of the audio-taping the clients have not been willing to open up as much during the counseling sessions. Identified "rapport" as her strongest counseling skill and said that once rapport is established with a client, it is easier for the nurse to counseling her about anything. The nurse mentions that they have counseled some mothers on domestic violence and child abuse because the mother feels comfortable sharing that they of personal information with the nurse because they know it will remain confidential. Trust Nurse.

Implementation improvement: Counseling skill that could be improved upon by all the nurse working on the study is establishing rapport with the client. She said that all nurses are 1. So, if one nurse is talking down to a client during another part of the patient flow (i.e. examination, specimen collection, interview room, etc.) then the mother will not be open with her in the counseling room because of her experience with other nurses.

Implementation quality: Easiest part of protocol to implement is right after delivery. Tell story of mothers using local medicine to give to baby to clean the baby's gastrointestinal tract. Have to explain to them about EBF, not mix feeding and good attachment. Counseling after delivery allows for the counseling message during the

Notes for Nurse 001
Age: 46
Marital status: Married
Years of nursing experience: 10 yrs.
Attended HIV and IF Training: Yes
Employee of BAN Study before April 2004: Yes

antenatal period to come together. Most difficult part to implement is at 6 months, the cessation because mothers don't follow it sometimes. She tells a story about a mother who cup feeds for 2 days at her 21st visit and then goes back to breastfeeding, so the baby has not practiced cup feeding and it makes it more difficult to stop breastfeeding at that 6th month (24 weeks)

Implementation improvement: Thoughts about improving the overall protocol-none offered. Thoughts about improving the BAN study for mothers. Nurse concerned about what will happen to the baby's nutrition after 6 months and that they current supplement is not enough. Told story of doing a mother's dietary recall and all the mother had to eat or drink in the last 24 hours was water at 2pm. Suggests increasing the maize flour and extending it for up to 1 year versus the 6 months.

Important elements: Most important elements of BAN protocol for nurse was advice on EBF and risk reduction from mother to husband or other partners. After looking at our implementation checklist, she says that all of these elements are important. Also pointed out that sometimes counselors can skip some the implementation element accidentally.

Appendix P

Malawi Institutional Review Board Approvals

Telephone: +265 789 400
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All Communications should be addressed to:
The Secretary for Health and Population

In reply please quote No. MED/4/36o
MINISTRY OF HEALTH AND POPULATION
P.O. BOX 30377
LILONGWE 3
MALAWI

4th July, 2005

Dr. F. Martinson
Field Director
UNC Project
Private Bag A -106
Lilongwe

Dear Dr. Martinson

Re: Protocol # 353: Breastfeeding, Antiretroviral and Nutrition Sub-study on infant feeding and counseling process

Thank you very much for your letter dated 10 June, 2005 and the attached application for the above sub-study that you submitted to the NHSRC for scientific and ethical approval.

I am pleased to inform you that the National Health Sciences Research Committee during a meeting held on 24th June, 2005 approved the above study. The committee however suggested the following: -

- rather than give gifts participants should be given re – imbursement for transport
- Giving gifts to nurses who are already participating in the study may interfere with counseling. If the nurses are being offered something as participants, then it doesn't have to be different from everyone else.

As you proceed with implementation of your study please ensure that all requirements of the NHSRC are followed as per attachment.

Yours faithfully

W M Kazembe
For: **SECRETARY FOR HEALTH**

Telephone: +265 789 400
Facsimile: +265 789 431

All Communications should be addressed to:
The Secretary for Health and Population

In reply please quote No. MED/4/33e
MINISTRY OF HEALTH AND POPULATION
P.O. BOX 30377
LILONGWE 3
MALAWI

The Field Director,

UNC Project,

Private Bag A-104,

Lilongwe

Dear Sir,

BAN Protocol. 368 breast feeding antiretroviral and nutrition sub study on infant feeding counseling process.

Amendment requesting Oct 5th 2005, 10 in number.

All are accepted and the study may proceed.

PP
Prof E M Molyneux

Head of Pediatrics' Department

Appendix Q

CDC Institution Review Board Approval Letter

Ahmed, Yusuf

From: Peterson, Felecia
Sent: Tuesday, October 04, 2005 4:31 PM
To: Jamieson, Denise
Cc: Redmond-Leonard, Joan A; Ahmed, Yusuf; Lawton, Kay E.
Subject: 4672: IRB Approval of New Protocol , (Expedited)

DATE: 10/4/2005

FROM: IRB Administrator
Human Research Protection Office
Office of the Chief Science Officer, OD/CDC

SUBJECT: IRB Approval of New Protocol #4672, ""BAN Substudy on Infant Feeding Counseling Process"" (Expedited)

TO: Denise Jamieson, MD, MPH [DJJ0]
NCCDPHP/DRH

New protocol #4672 has been approved by CDC IRB "G" for the maximum allowable period of one year and it will expire on 8/16/2006. The protocol was reviewed in accordance with the expedited review process outlined in 45 CFR 46.110(b)(1), categories (6) & (7).

If other institutions involved in this protocol are being awarded CDC funds through the CDC Procurement and Grants Office (PGO), you are required to send a copy of this IRB approval to the CDC PGO award specialist handling the award. You are also required to verify with the award specialist that the awardee has provided PGO with the required documentation and has approval to begin or continue research involving human subjects as described in this protocol.

As a reminder, the IRB must review and approve all human subjects research protocols at intervals appropriate to the degree of risk, but not less than once per year. There is no grace period beyond one year from the last IRB approval date. It is ultimately your responsibility to submit your research protocol for continuation review and approval by the IRB. Please keep this approval in your protocol file as proof of IRB approval and as a reminder of the expiration date. To avoid lapses in approval of your research and the possible suspension of subject enrollment and/or termination of the protocol, please submit your continuation request at least six weeks before the protocol's expiration date of 8/16/2006.

Any problems of a serious nature should be brought to the immediate attention of the IRB, and any proposed changes to the protocol should be submitted as an amendment to the protocol for IRB approval before they are implemented.

If you have any questions, please contact the Human Research Protection Office at (404) 371-5980 or e-mail: huma@cdc.gov.

Felecia Peterson

cc:
Joan Redmond-Leonard
Yusuf Ahmed
Kay Lawton

Appendix R

UNC Institutional Review Board Approval Letters

THE UNIVERSITY
of NORTH CAROLINA
at CHAPEL HILL

OFFICE OF HUMAN
RESEARCH ETHICS

BIOMEDICAL INSTITUTIONAL
REVIEW BOARD (IRB)

MEDICAL SCHOOL BUILDING 52
CAMPUS BOX 7097
CHAPEL HILL, NC 27599-7097

T 919-966-3544
F 919-966-9879
http://ohre.unc.edu

TO: Charles M. Van der Horst, M.D.
Medicine/Infectious Diseases
CB# 3368 1700 Airport Rd Ste 129
Carolina Campus

FROM: The Biomedical Institutional Review Board (IRB)

DATE: September 27 2005

SUBJECT: Research Application Review

STUDY: IRB# 05-MED-471 Title: BAN Study: Sub-Study on Infant Feeding Counseling Process

This research proposal has been considered by the Committee and it has been approved until September 27 2006.

(1) Review Type: Expedited

(2) This Committee complies with the requirements found in Part 56 of the 21 Code of Federal Regulations and Part 46 of the 45 Code of Federal Regulations. The assurance of compliance with DHHS regulations is on file in the Committee office for your perusal. Federalwide Assurance: FWA-4801.

(3) Re-review of this proposal is necessary before:
(a) making any significant alterations or additions to the proposal, except when necessary to eliminate apparent immediate hazards to the subject, or
(b) continuing beyond the approval date.

(4) It is required that all signed consent forms be retained on file.

(5) Approved consent form(s) enclosed.

Authorized Signature on behalf of the Committees

THE UNIVERSITY of NORTH CAROLINA at CHAPEL HILL

OFFICE OF HUMAN RESEARCH ETHICS

BIOMEDICAL INSTITUTIONAL REVIEW BOARD (IRB)

MEDICAL SCHOOL BUILDING 52
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Information Supplement to IRB approval document (page 2)

Date: September 27, 2005

Submission Type: New

Review type: Expedited

IRB Study#: 05-MED-471: BAN Study: Sub-Study on Infant Feeding Counseling Process

This study was reviewed in accordance with all applicable regulations governing human subjects research found at 45 CFR 46 (Common Rule) and 45 CFR 164 (HIPAA).

The Breastfeeding Antiretroviral and Nutrition (BAN) study is an ongoing clinical trial in Lilongwe, Malawi designed to evaluate the benefit of nutritional supplementation given to women during breastfeeding (IRB#03-MED-184). The proposed research is a sub-study of the BAN study. The purpose of this sub-study is to monitor and evaluate BAN study nurses implementation of the BAN study's infant feeding counseling protocol. The objectives of the sub-study are to assess: 1) to what extent do nurses adhere to key elements of the BAN study infant feeding counseling protocol; 2) what amount of key elements of the BAN study infant feeding counseling protocol do nurses implement during counseling and; 3) nurses attitudes toward the BAN study infant feeding counseling protocol. 120 Subject/mothers for this study will be recruited as they check-in with the registration nurse for their regularly scheduled BAN study clinical visit. 6 nurses that are a current BAN study research nurse who counsels BAN study HIV-infected mothers in infant feeding practices will be recruited into this study. Data collection methods will include observation of the infant feeding counseling sessions (to document the verbal and non-verbal communication) between the BAN study nurse and the HIV-infected mother, individual interviews with the BAN study nurses and review of existing documents (nurses CV). Appropriate measures are in place to protect confidentiality. Risk is no more than minimal. Expedited review per category 7. Based on the information provided, it is our determination that HIPAA does not apply.

This approval includes Protocol version 1.4, dated August 4, 2005.

Authorized Signature on Behalf of the Committees

THE UNIVERSITY
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OFFICE OF HUMAN
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TO: Yvonne Owens Ferguson, MPH
C/O Eugenia Eng, DrPH
HBHE CB# 7440
UNC Sch of Pub/Hlth,

FROM: The Biomedical Institutional Review Board (IRB)

DATE: February 17 2006

SUBJECT: Research Application Review

STUDY: IRB# 05-HBHE-941 Title: HIV & Infant Feeding Counseling in Malawi: A Process Evaluation of the Breastfeeding, Antiretroviral and Nutrition (BAN) Study Infant Feeding Counseling Protocol

This research proposal has been considered by the Committee and it has been approved until February 17 2007.

(1) Review Type: Expedited

(2) This Committee complies with the requirements found in Part 56 of the 21 Code of Federal Regulations and Part 46 of the 45 Code of Federal Regulations. The assurance of compliance with DHHS regulations is on file in the Committee office for your perusal. Federalwide Assurance: FWA-4801.

(3) Re-review of this proposal is necessary before:
(a) making any significant alterations or additions to the proposal, except when necessary to eliminate apparent immediate hazards to the subject, or
(b) continuing beyond the approval date.

Authorized Signature on behalf of the Committees

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Information Supplement to IRB approval document (page 2)

Date: February 17, 2006

Submission Type: New

Review type: Expedited

IRB Study#: 05-HBHE-941: HIV & Infant Feeding Counseling in Malawi: A Process Evaluation of the Breastfeeding, Antiretroviral and Nutrition (BAN) Study Infant Feeding Counseling Protocol

This study was reviewed in accordance with all applicable regulations governing human subjects research found at 45 CFR 46 (Common Rule) and 45 CFR 164 (HIPAA).

This dissertation research project is a secondary analysis of data previously collected (in 2005) as part of the IRB approved Breastfeeding Antiretroviral and Nutrition (BAN) Study (IRB# 05-MED-471). A data use agreement is in place. The purpose of this study is to evaluate BAN Study Nurses' implementation of the BAN Study's infant feeding counseling protocol. Specifically, this study will assess: 1) to what extent do nurses adhere to key elements of the BAN study infant feeding counseling protocol; 2) what amount of key elements of the BAN Study infant feeding counseling protocol do nurses implement during counseling; and 3) nurses' attitudes towards the BAN Study infant feeding counseling protocol. The risk is no more than minimal. Documentation of education in research ethics is provided. Confidentiality and privacy protections are in place. Criteria are satisfied for waiver of research consent [45 CFR 46.116(d)] and waiver of HIPAA authorization [45 CFR 164.512(i)(2)(ii)]. This study is approved by expedited review per Category 5.

Authorized Signature on Behalf of the Committees

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