THE FEASIBILITY OF REPLACEMENT FEEDING AS AN HIV PREVENTION METHOD: THE BREASTFEEDING, ANTIRETROVIRAL AND NUTRITION (BAN) STUDY IN LILONGWE, MALAWI

By
Megan Elizabeth Parker

A dissertation submitted to the faculty of the University of North Carolina at Chapel Hill in partial fulfillment of the requirements for the degree of Doctor of Philosophy in the Department of Nutrition.

Chapel Hill
2010

Approved by:
Margaret E. Bentley (Chair)
Linda Adair
Ellen Piwoz
Anna Maria Siega-Riz
Chirayath M. Suchindran
ABSTRACT

MEGAN E. PARKER: The Feasibility of Replacement Feeding as an HIV Prevention Method: the Breastfeeding, Antiretroviral, and Nutrition (BAN) Study in Lilongwe, Malawi
(Under the direction of Margaret E. Bentley)

Background: Exclusive breastfeeding (EBF) to 6 months is recommended for HIV-infected mothers choosing to breastfeed and cessation thereafter if replacement feeding is AFASS. Data for this study were collected from participants in the BAN Study provided a lipid-based nutrient supplement (LNS) to replace breastmilk between 6-12mo.

Objective: Examine dietary intakes after early breastfeeding cessation using LNS as a breastmilk substitute; Explore maternal attitudes and experiences performing EBF, weaning, and the use of LNS; Determine the prevalence of dietary inadequacy after exiting the BAN Study; Examine the effect of early weaning on child growth.

Methods: The dietary intakes of a random sample of BAN Study infants (N=400) were analyzed using generalized estimating equations. After exiting the BAN Study, a sub-sample of mothers (N=45) were interviewed to understand the acceptance and feasibility of implementing the HIV and infant feeding guidelines using LNS. Anthropometric measurements were obtained between 15-16 and 17-18mo from 41 BAN-exited (non-breastfed) and 41 matched (still-breastfed) children from the community; 2 diet recalls were collected from BAN-exited children at each time point.
**Results:** Between 6-12mo, dietary intakes followed a seasonal pattern with greatest intakes during the cool season and lowest intakes during the hungry season. The contribution of LNS to total intake was greatest during the hungry and cool seasons. Infants were dependent on LNS to provide fat, vitamin A, vitamin C, calcium, and iron. Mothers reported several weaning strategies, including gradual reduction of breastfeeding, expressing breastmilk into a cup, and separation of mother and child. LNS was accepted and incorporated into the traditional diet. After the BAN Study, non-breastfed children consumed adequate amounts of energy, protein, and carbohydrate but inadequate fat. The prevalence of inadequacy was: 46% for vitamin A; 20% for vitamin B6; 69% for folate; 13% for vitamin C; 19% for iron; 23% for zinc. Growth analyses found BAN-exited girls had significantly worse WAZ and LAZ scores over time (p=0.076) and significantly lower length and weight velocity (p<0.02).

**Conclusions:** Early breastfeeding cessation as an HIV prevention method proved feasible but has trade-offs in resource-poor settings such as inadequate dietary intakes and reduced infant growth.
ACKNOWLEDGEMENTS

‘Mutu umodzi susenza denga’ – a single head does not carry a roof.
(Malawian proverb)

I have come so far, but I did not walk alone. First and foremost I must thank my advisor, Peggy Bentley, for her instrumental guidance over the years and without whom I would not have attended UNC, joined the Carolina Population Center, been coerced into an epidemiology minor, found funding to move to Malawi, or completed this dissertation. At the time it seemed a terrifying feat to move south of the Mason Dixon line, but she assured me that it was for the best and I never looked back.

No child gets to choose their parents, but some of us get very lucky. Growing up in Toronto, my father told us stories from around the world (even though he had never been) and made us value other cultures by visiting ethnic markets and celebrating foreign holidays. He created an allure and it’s because of him that I am so curious about the world and I can dream so big. To my mother who taught me what women are made of and who encouraged me to pursue this degree so I wouldn’t know the same barriers she faced. From a very young age I remember her talking about ‘real people’ and ‘real problems’ and I went out in search of such characters. Her preaching provided a moral compass, instilled a sense of integrity, and created in me a drive to help others. I remember the horrified looks on their faces when I announced I was moving to Kenya at 22 to live in an AIDS orphanage. They were angry for a couple days … but then they came to visit (in FUBU no less). We have come far together.
I must thank my Dissertation Committee for their thoughtful insight and encouragement. Thank you to Dr. Suchindran, Dr. Siega-Riz, and Dr. Piwoz. I would especially like to thank Dr. Linda Adair for her wisdom, time, and effort fine-tuning my analysis skills. You are always generous with your time and caring with your words. You are a fabulous teacher and have greatly influenced many of us in the Nutrition Department. The dietary data I brought home from the BAN Study in Malawi was messy and I spent close to a year cleaning, organizing, and analyzing this data with the help of Dr. Phil Bardsley at CPC. Thank you Phil, you were instrumental to the success of the dietary analysis. During my time at UNC, I was privileged enough to be a pre-doctoral trainee with the Carolina Population Center. Through this center, I met many of my closest friends and my eyes were opened to a wide spectrum of research ideas. I will forever be grateful for the friends I made while at UNC, especially my girlfriends Leela Aertker, Stephanie Wheeler, Lucia Leone, Terri Clark, Erica Haney, and Kat Tumlinson.

The year I spent in Malawi was possibly one of the best years of my life because of the Malawian friends I made, the fascinating work and lives of other expats, and my day to day life with our research team. Chrissie Chilima, Tasila Zulu, Tonse Gauti, Joyce Mhone, Chalimba Lusewa, and James Chilima formed the backbone of this research team. They tirelessly conducted qualitative interviews, dietary recalls, and anthropometric measurements; their patience never waned even in the face of screaming children or when our office was converted into the Cholera quarantine ward. We drew strength from one other and were grateful for all the lessons learned.
# TABLE OF CONTENTS

LIST OF TABLES........................................................................................................ xii  
LIST OF FIGURES........................................................................................................ xiii  
LIST OF ABBREVIATIONS................................................................................................ xiv  

Chapter

<table>
<thead>
<tr>
<th>I. INTRODUCTION</th>
<th>1</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. Overview</td>
<td>1</td>
</tr>
<tr>
<td>b. Specific aims</td>
<td>2</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>II. BACKGROUND ON THE BAN STUDY</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. The HIV epidemic</td>
<td>5</td>
</tr>
<tr>
<td>b. Prevention of mother-to-child transmission</td>
<td>6</td>
</tr>
<tr>
<td>c. HIV and infant feeding guidelines</td>
<td>7</td>
</tr>
<tr>
<td>d. The BAN Study</td>
<td>9</td>
</tr>
<tr>
<td>e. Rationale for the BAN Study</td>
<td>10</td>
</tr>
<tr>
<td>f. BAN Study participants</td>
<td>10</td>
</tr>
<tr>
<td>g. Formative research on infant feeding</td>
<td>11</td>
</tr>
<tr>
<td>h. Infant feeding protocol</td>
<td>13</td>
</tr>
<tr>
<td>i. Diet composition and feeding patterns</td>
<td>14</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>III. LITERATURE REVIEW</th>
<th>19</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. Infant dietary trends</td>
<td>19</td>
</tr>
</tbody>
</table>
b. Child nutrition in Malawi ........................................... 20

c. Child growth .......................................................... 21

d. Infant feeding and HIV/AIDS ....................................... 23

e. Weaning ............................................................... 25

f. Deficiencies among non-breastfed infants ......................... 25

g. Infant dietary requirements .......................................... 26

h. Energy requirements ................................................ 27

i. Protein requirements ................................................ 28

j. Micronutrient requirements ........................................... 29

k. PMTCT trials .......................................................... 30

l. Weaning and LNS ...................................................... 32

m. Lipid-based nutrient supplements .................................. 32

n. Season and food security .............................................. 33

IV. THEORETICAL BASIS FOR THE FEASIBILITY STUDY .... 40

a. Maternal knowledge, attitudes, beliefs, and intentions ...... 41

b. Acceptance of LNS .................................................... 42

c. Fear and patterns of decision making .............................. 43

d. Institutional factors .................................................. 43

e. HIV stigma and infant feeding norms .............................. 43

f. Community factors .................................................. 44

g. Environmental factors ................................................. 45

h. Feasibility factors .................................................... 45

i. Specific research aims ............................................... 46
j. Summary and implications for research ............................. 46

V. SEASONAL DIETARY INTAKES OF HIV-EXPOSED INFANTS AFTER EARLY BREASTFEEDING CESSATION IN MALAWI: RESULTS FROM THE BAN STUDY ........................................ 50

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abstract</td>
<td>50</td>
</tr>
<tr>
<td>Introduction</td>
<td>51</td>
</tr>
<tr>
<td>Methods</td>
<td>53</td>
</tr>
<tr>
<td>Results</td>
<td>58</td>
</tr>
<tr>
<td>Discussion</td>
<td>63</td>
</tr>
<tr>
<td>Chapter V References</td>
<td>71</td>
</tr>
</tbody>
</table>

VI. THE ACCEPTANCE AND FEASIBILITY OF REPLACEMENT FEEDING AT 6 MONTHS AS AN HIV PREVENTION METHOD IN ILONGWE, MALAWI: RESULTS FROM THE BAN STUDY ......................... 82

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abstract</td>
<td>82</td>
</tr>
<tr>
<td>Introduction</td>
<td>83</td>
</tr>
<tr>
<td>Methods</td>
<td>85</td>
</tr>
<tr>
<td>Results</td>
<td>88</td>
</tr>
<tr>
<td>Discussion</td>
<td>96</td>
</tr>
<tr>
<td>Chapter VI References</td>
<td>101</td>
</tr>
</tbody>
</table>

VII. THE HEALTH OF HIV-EXPOSED CHILDREN AFTER EARLY WEANING ........................................ 108

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abstract</td>
<td>108</td>
</tr>
<tr>
<td>Introduction</td>
<td>109</td>
</tr>
<tr>
<td>Methods</td>
<td>111</td>
</tr>
</tbody>
</table>
d. Results.......................................................................................... 117

e. Discussion..................................................................................... 122

f. Chapter VII References............................................................. 129

VIII. SYNTHESIS............................................................................... 140

a. Summary of findings................................................................. 140

b. Public health and policy significance....................................... 141

c. Future research........................................................................... 144

d. References for chapters I, II, III, IV, VIII................................. 178

APPENDIX 1. BREASTFEEDING CESSATION COUNSELING AID....... 146

APPENDIX 2. COMPLEMENTARY FEEDING COUNSELING SCRIPT.... 149

APPENDIX 3. RECRUITMENT CARD.................................................. 153

APPENDIX 4. DEMOGRAPHIC QUESTIONNAIRE............................. 154

APPENDIX 5. MATCHED MOTHERS INTERVIEW GUIDE................. 159

APPENDIX 6. BAN-EXITED MOTHERS INTERVIEW GUIDE............. 166

APPENDIX 7. GROWTH RECORD....................................................... 177
# LIST OF TABLES

<table>
<thead>
<tr>
<th>Table</th>
<th>Title</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Table 2.1</td>
<td>Guidelines on frequency, quantity and quality of complementary foods</td>
<td>17</td>
</tr>
<tr>
<td>Table 2.2</td>
<td>Nutrient composition of LNS</td>
<td>18</td>
</tr>
<tr>
<td>Table 3.1</td>
<td>Dietary reference intakes</td>
<td>38</td>
</tr>
<tr>
<td>Table 3.2</td>
<td>Child nutrient requirements</td>
<td>39</td>
</tr>
<tr>
<td>Table 5.1</td>
<td>The nutrient content of LNS supplied by the BAN Study</td>
<td>77</td>
</tr>
<tr>
<td>Table 5.2</td>
<td>Maternal demographic characteristics prior to labor and delivery</td>
<td>78</td>
</tr>
<tr>
<td>Table 5.3</td>
<td>Descriptive statistics: infant dietary intake by age</td>
<td>79</td>
</tr>
<tr>
<td>Table 5.4</td>
<td>Infant nutrient intake by season</td>
<td>80</td>
</tr>
<tr>
<td>Table 5.5</td>
<td>Percent contribution of LNS to total nutrient intake by season</td>
<td>81</td>
</tr>
<tr>
<td>Table 6.1</td>
<td>Research questions used to develop the qualitative interview guide</td>
<td>106</td>
</tr>
<tr>
<td>Table 6.2</td>
<td>Sample demographics</td>
<td>107</td>
</tr>
<tr>
<td>Table 7.1</td>
<td>Demographics by child sample</td>
<td>137</td>
</tr>
<tr>
<td>Table 7.2</td>
<td>Macronutrient and select micronutrient intakes from the replacement diet</td>
<td>138</td>
</tr>
<tr>
<td>Table 7.3</td>
<td>Adjusted anthropometric measurements</td>
<td>139</td>
</tr>
</tbody>
</table>
## LIST OF FIGURES

<table>
<thead>
<tr>
<th>Figure</th>
<th>Title</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fig 2.1</td>
<td>The 2-by-3 factorial design of the BAN Study</td>
<td>16</td>
</tr>
<tr>
<td>Fig 3.1</td>
<td>The risk of nutrient inadequacy among a population</td>
<td>36</td>
</tr>
<tr>
<td>Fig 3.2</td>
<td>The estimated average requirement cut-point method</td>
<td>37</td>
</tr>
<tr>
<td>Fig 4.1</td>
<td>Factors affecting the child diet and nutritional status</td>
<td>48</td>
</tr>
<tr>
<td>Fig 4.2</td>
<td>Conceptual model for Aim 2</td>
<td>49</td>
</tr>
<tr>
<td>Fig 5.1</td>
<td>Flow chart illustrating the Aim 1 inclusion criteria</td>
<td>76</td>
</tr>
<tr>
<td>Fig 7.1</td>
<td>Subject enrollment flow chart</td>
<td>136</td>
</tr>
<tr>
<td>Term</td>
<td>Definition</td>
<td></td>
</tr>
<tr>
<td>--------</td>
<td>-------------------------------------------------------------------------------------------------------------------------------------------</td>
<td></td>
</tr>
<tr>
<td>AFASS</td>
<td>Acceptable, feasible, affordable, sustainable, and safe (the conditions that should be in place for replacement feeding).</td>
<td></td>
</tr>
<tr>
<td>AI</td>
<td>Adequate Intake: The recommended average daily intake level based on observed or experimentally determined approximations or estimates of nutrient intake for a group (or groups) of apparently healthy people that are assumed to be adequate.</td>
<td></td>
</tr>
<tr>
<td>AIDS</td>
<td>Acquired human immunodeficiency syndrome (the active pathological condition that follows the earlier, non symptomatic state of being HIV-positive)</td>
<td></td>
</tr>
<tr>
<td>ART</td>
<td>Triple combination of antiretroviral drugs; previously called Highly Active Antiretroviral Therapy (HAART)</td>
<td></td>
</tr>
<tr>
<td>EAR</td>
<td>Estimated average requirement: the average daily nutrient intake level estimated to meet the requirements of half of the healthy population in a particular life stage and gender group. It is used to plan and assess dietary adequacies for population groups.</td>
<td></td>
</tr>
<tr>
<td>EBF</td>
<td>Exclusive breastfeeding: when an infant consumes only breast milk and no other liquids (including water) or solids, with the exception of vitamins, mineral supplements, and medicines.</td>
<td></td>
</tr>
<tr>
<td>EER</td>
<td>Estimated energy requirement</td>
<td></td>
</tr>
<tr>
<td>GEE</td>
<td>An extension of generalized linear model theory used to analyze longitudinal and correlated response data.</td>
<td></td>
</tr>
<tr>
<td>HIV</td>
<td>The virus causing AIDS</td>
<td></td>
</tr>
<tr>
<td>LAZ</td>
<td>Length-for-age Z-Score</td>
<td></td>
</tr>
<tr>
<td>LNS</td>
<td>Lipid-based nutrient supplement</td>
<td></td>
</tr>
<tr>
<td>PMTCT</td>
<td>Prevention of mother-to-child transmission of HIV</td>
<td></td>
</tr>
<tr>
<td>SAM</td>
<td>Severe acute malnutrition, WLZ &lt;-3SD</td>
<td></td>
</tr>
<tr>
<td>Stunting</td>
<td>Length-for-age &lt; -2 standard deviations below WHO reference median</td>
<td></td>
</tr>
<tr>
<td>Underweight</td>
<td>Weight-for-age &lt; -2 standard deviations below WHO reference median</td>
<td></td>
</tr>
<tr>
<td>Wasting</td>
<td>Weight-for-length &lt; -2 standard deviations below WHO reference median</td>
<td></td>
</tr>
<tr>
<td>WAZ</td>
<td>Weight-for-age Z-Score</td>
<td></td>
</tr>
<tr>
<td>WLZ</td>
<td>Weight-for-length Z-Score</td>
<td></td>
</tr>
</tbody>
</table>
CHAPTER I
INTRODUCTION

Overview

Over the last decade, the World Health Organization has consistently recommended exclusive breastfeeding to 6 months for HIV-infected mothers living in resource-poor settings unless replacement feeding is acceptable, feasible, affordable, sustainable and safe (AFASS) for both the mother and child before that time (WHO, 2001; WHO, 2003; WHO, 2006; WHO, 2009). At 6 months, complementary foods need to be introduced to meet the infant’s increased nutrient needs but mixed feeding both breastmilk and complementary foods increases the risk of mother-to-child transmission (MTCT) (Coutsoudis et al., 2001). By 2004, the WHO guidelines suggested the best option for low income mothers living in sub-Saharan Africa was complete breastfeeding cessation at 6 months (WHO, 2003) if AFASS conditions could be fulfilled.

The data for this study were collected from a sample of HIV-exposed infants who participated in the Breastfeeding, Antiretroviral, and Nutrition (BAN) Study, a postnatal HIV transmission intervention designed to find the most effective combination of anti-retroviral drug treatments to prevent HIV transmission during the exclusive breastfeeding period (van der Horst et al., 2009; Chasela et al., 2010). This prevention of mother-to-child transmission (PMTCT) trial was conducted in Lilongwe, Malawi between 2004 and 2010. The BAN Study promoted the WHO HIV and infant feeding guidelines current at
its inception in 2004. Understanding if the WHO guidelines are AFASS within this social and cultural context, when supported by nutritional intervention, is imperative to inform future adaptations to maximize adherence.

This study aims to investigate maternal acceptance of the WHO guidelines in Malawi, and the feasibility of implementation by evaluating dietary adequacy and infant growth outcomes after early breastfeeding cessation. The present study was conducted among the participants of the BAN Study in urban Lilongwe, Malawi.

Specific Aims

**Aim 1:** Conduct a quantitative dietary analysis of 400 non-breastfeeding infants, ages 6 to 12 months, using 24-hour dietary recalls collected by the BAN Study between 2004 and 2007.

**Aim 1a:** Examine the role of seasonality on total dietary intake according to:

a. Total energy and protein consumption as a percent of individual estimated requirements.

b. Total consumption of vitamins A, B6, folate, and C.

c. Total consumption of minerals calcium, iron, and zinc.

**Aim 1b:** Examine the contribution of LNS to dietary intakes by season according to:

a. Percent contribution of LNS to total energy and protein intake.

b. Percent contribution of LNS to total micronutrient intake.
**Aim 2:** Conduct a qualitative study among a sub-sample of BAN Study participants to investigate maternal acceptance of the WHO HIV and infant feeding guidelines, and identify the facilitators of and barriers to adherence.

**Aim 3:** Evaluate dietary adequacy among a sub-sample of infants, ages 15 to 18 months, after their exit from the BAN Study when they were no longer breastfeeding or receiving a breastmilk substitute. We will also evaluate the nutritional status of this same sub-sample of BAN-exited infants in comparison to a matched comparison infant non-participants from the community.

**Aim 3a:** Examine the dietary intake of infants according to:

a. The percent adequacy of total energy and protein consumption

b. The percent adequacy of total consumption of vitamins A, B6, folate, and C.

c. The percent adequacy of total consumption of minerals calcium, iron, and zinc.

**Aim 3b:** Compare the growth outcomes of infants who participated in the BAN study to the growth outcomes of infant non-participants matched by age, gender, and community to investigate the effect of not breastfeeding on infant nutritional status in this environment.

a. Compare length-for-age measurements between infant samples

b. Compare weight-for-age measurements between infant samples

c. Compare weight-for-length measurements between infant samples
d. Compare length velocity Z-Scores between infant samples

e. Compare weight velocity Z-Scores between infant samples
CHAPTER II
BACKGROUND ON THE BAN STUDY

The HIV Epidemic

At the end of 2008, UNAIDS estimated 33.4 million people were infected with HIV worldwide but due to effective prevention and treatment programs the incidence of HIV infection was on the decline. Since 1981 when the HIV epidemic began, sub-Saharan Africa (SSA) has become the epicenter of the pandemic with 22.4 million infections, accounting for 68% of all HIV infections (UNAIDS, 2009; Malawi National AIDS Commission, 2008). SSA countries reporting the highest HIV prevalence include South Africa, Zimbabwe, Botswana, Zambia, and Malawi. Malawi has a national adult HIV prevalence rate of 12.7% which stands in contrast to the overall SSA adult HIV prevalence of 5.2% (UNAIDS, 2009). Due to social and sexual factors, Malawi’s epidemic disproportionately affects women of reproductive age (15-49 years) (Pettifor et al., 2007). High fertility rates and limited access to adequate health care have resulted in the majority of pediatric infections being localized to this region (UNAIDS, 2009); of the 2.5 million children infected worldwide, 88% live in sub-Saharan Africa (Malawi National AIDS Commission, 2008). To prevent infant infection, prevention of mother-to-child transmission (PMTCT) prophylaxis regimens became available in Malawi over the past decade.
MTCT accounts for 90% of these pediatric HIV infections but prevention methods are now available at urban hospitals within Malawi. Since 2004, urban antenatal clinics are required by the Malawi National AIDS Commission to test all pregnant women for HIV during their first visit unless a mother chooses to ‘opt-out’ of the voluntary counseling and testing procedure (Malawi National AIDS Commission, 2004). HIV prevalence among pregnant women attending antenatal clinics throughout Malawi has remained stable at 20% since 2001 (UNAIDS, 2006). More recent data from the Lilongwe Call-to-Action (CTA) program indicates a relatively stable HIV prevalence of 14% from 2005 to the present (BAN Weekly Summary Reports). Without prevention intervention efforts, vertical transmission of HIV can occur during pregnancy (5-10%), delivery (10-15%), or the postnatal period from breastfeeding (5-20%) (De Cock et al., 2000; WHO, 2003).

**Prevention of mother-to-child transmission (PMTCT)**

In 1999, a PMTCT trial (HIVNET 012 regimen) conducted within Uganda reported a short-course regimen of Nevirapine (NVP) to be effective and safe for preventing perinatal HIV-1 in 496 infants followed up to 14-16 weeks (Guay et al., 1999). Although other antiretroviral regimens are available for preventing MTCT, the single-dose of NVP for the mother at the onset of labor followed by a single-dose of NVP for the infant following birth is considered to be the most feasible and acceptable strategy for PMTCT programs. This prevention strategy, known as HIVNET 012 regimen, was quickly written into policy the following year by the WHO (WHO, 2004).
Voluntary counseling and testing (VCT) services first began in Malawi in 1992. By 2000, RAPID testing was available enabling people to know their HIV status the same day they were tested. By 2004, VCT was in widespread use at antenatal clinics but free antiretroviral treatment (ART) was limited to only 9 public facilities (Malawi National AIDS Commission, 2008). At this time, the WHO guidelines recommended every HIV-infected person with a CD4 cell count less than 250/µL should receive ART; PMTCT programs provided single dose nevirapine (sdNVP) to mother and infant at labor and delivery to prevent vertical transmission. Over the years, Malawi has rapidly scaled up free access to ART such that 140,000 HIV-infected adults and children were receiving treatment by 2008 (Malawi National AIDS Commission, 2008). Current ART guidelines in effect within Malawi state that HIV-infected patients with CD4 counts below 250cells/µL are eligible to receive ART; all HIV-infected pregnant women with CD4 counts below 350cells/µL should receive ART; all HIV-infected pregnant women with CD4 counts above 350cells/µL should receive triple combination antiretroviral therapy (d4T/3TC/NVP) and their infant receive sdNVP (Malawi National AIDS Commission, 2008).

**HIV and Infant Feeding Guidelines**

Approximately 1 million people are infected with HIV in Malawi; 500,000 are women of childbearing age (UNAIDS, 2006). Ten percent of HIV infections in Malawi are pediatric cases (between 0-14yrs) and MTCT is the most significant source of pediatric infection (UNAIDS, 2006). Prevention methods are now available to reduce MTCT at 3 different targeted phases: pregnancy, delivery, and breastfeeding (De Cock et
al., 2000; WHO, 2001). For the purpose of reducing transmission during the postnatal period, the World Health Organization developed the HIV and infant feeding guidelines, which recommend exclusive breastfeeding (EBF) for up to 6 months among HIV-infected mothers choosing to breastfeed, with cessation of breastfeeding once replacement feeding is acceptable, feasible, affordable, sustainable and safe (AFASS) (WHO, 2001; WHO, 2003; WHO, 2006). For low income populations in developing countries, safe and sustainable alternatives are not available to mothers, making breast milk their best option. Breastmilk is the most cost effective infant feeding strategy for food insecure families and supplies optimal nutrition and protection against common childhood infections (e.g. diarrhea, pneumonia), early cessation is potentially dangerous for infants living in resource-poor settings (Habicht et al., 1986; Victora et al., 1987). Adapting the WHO guidelines to populations in resource poor settings is a great challenge. It is already difficult for many mothers to provide a nutritionally adequate diet for infants when breast milk is included, making the withdrawal of breast milk an issue of major concern (Dewey et al., 2004).

To adapt the WHO guidelines to the Malawian context we must take into account both the risk of malnutrition and the lack of maternal acceptance for altered care practices. Early breastfeeding cessation carries many risks for the infant: dehydration, refusal to eat, loss of bonding with the mother, loss of sucking (comfort), psychological trauma, increased risk of neglect, malnutrition, illness or death (WHO, 2005). In addition, we cannot forget that maternal health is also likely to be affected by early rapid weaning leading the mother to experience: breast engorgement, mastitis, increased risks
of pregnancy, depression and social stigma. To ensure mother-infant pairs have a smooth transition they must receive counseling to discuss their concerns, learn ways to ease the infant transition and ensure infant diet adequacy (i.e. teaching cup feeding, comforting baby through physical contact without breastfeeding, managing night-time-crying/feeding without breastfeeding) (WHO, 2005).

The BAN Study

The data for this study were collected from participants in the Breastfeeding, Antiretroviral, and Nutrition (BAN) Study, a postnatal HIV transmission intervention designed to evaluate the efficacy of antiretroviral therapy (ART) beyond 6 weeks in a breastfeeding population (van der Horst et al., 2009; Chasela et al., 2010). In 2004, the BAN Study began as a randomized clinical trial of an ART and nutritional intervention among breastfeeding HIV-positive mothers with CD4$^+$ cell counts >250/mm$^3$ and their infants (van der Horst et al., 2009). The primary objectives of the BAN Study included evaluating: 1) the benefit of a nutrition supplement given to mothers during breastfeeding; 2) the benefit and safety of antiretroviral medications given to either infants or their mothers to prevent HIV transmission during breastfeeding; and 3) the feasibility of exclusive breastfeeding followed by early, rapid breastfeeding cessation (van der Horst et al., 2009). Enrollment for the BAN Study began on April 22, 2004; 2370 mother-infant pairs were enrolled and completed the trial by January 2010.
Rationale for the BAN Study

Prevention of mother-to-child transmission (PMTCT) programs have the potential to significantly reduce the prevalence of pediatric HIV infections in Malawi. Antiretroviral (ARV) medications are proven to reduce the risk of transmission during labor and delivery, and may also be able to reduce the risk of transmission while still enabling the infant health benefits of exclusive breastfeeding to be conveyed. Since there is no safe and feasible alternative to breastfeeding in resource-poor settings, strategies must be developed to make breastfeeding safer for infants among HIV-infected populations. The BAN Study was developed in response to the lack of research investigating the effects of ART during the postpartum period to either mother or infant. To date, this is the only study investigating the efficacy of using ART beyond 6 weeks postnatally in a breastfeeding population. Malawi provides an excellent population for this trial since 98% of pregnant women in urban areas seek prenatal care from antenatal clinics and 82% of infants are born under medical supervision (National Statistical Office and ORC Macro, 2001).

BAN Study Participants

In order to be eligible to participate in the BAN Study, mothers needed to receive 200mg of NVP during labor and all infants received 2mg/kg of NVP within 72 hours after delivery. This HIVNET 012 regimen significantly reduces HIV transmission during the intra-partum and peri-partum periods (van der Horst et al., 2009). All BAN mothers were additionally provided ART every 12 hours from the start of labor until 7 days post-partum, and their infants received ART as well during this time. Following delivery,
mother-infant dyads were only eligible to participate if 1) the mother had a CD4\(^+\) count >250 cells/µL (≥200 before July 24, 2006); 2) hemoglobin >7 g/dL; 3) infant had a birth weight >2000 g and no severe congenital malformations or other condition(s) not compatible with life; 4) mother intended to breastfeed (van der Horst et al., 2009). Upon enrollment, HIV-infected mothers were randomized to two main study interventions: a 2-arm maternal nutritional intervention to promote maternal health, and a 3-arm antiretroviral intervention—with drugs given for up to 6 months to the mother, the infant, or neither—to prevent HIV transmission during breastfeeding (Fig 2.1) (van der Horst et al., 2009).

Regardless of treatment assignment, all BAN mothers were counseled to exclusively breastfeed their infant to 6 months and then given a nutrient-dense breast milk replacement food to supplement the diet after 6 months. Mothers of uninfected infants were advised to perform early breastfeeding cessation at 6 months by rapidly transitioning their infant onto a complementary diet without any breastmilk by 7 months. The complementary diet included the lipid-based nutrient supplement (LNS) in addition to typical weaning foods (van der Horst et al., 2009). The small proportion of infants who became HIV infected by 6 months were advised to continue breastfeeding to 24 months for optimal health.

**Formative research on infant feeding**

Prior to the implementation of the BAN Study intervention, the BAN Nutrition team interviewed HIV-positive women residing in Lilongwe, Malawi to better understand
how HIV-positive mothers perceived their personal health and how these perceptions influence their infant feeding practices (Bentley et al., 2005). The women feared breastfeeding would accelerate disease progression causing them to lose more weight than desired. These findings infer that HIV-positive mothers may be more likely to adhere to the WHO exclusive breastfeeding recommendations if provided with nutritional supplements (Bentley et al., 2005).

A second formative study investigated the attitudes and concerns of the local community regarding infant feeding practices (Corneli et al., 2007) and found HIV-positive mothers were largely unaware of the HIV infant feeding guidelines; only 50% knew about EBF and 85% had introduced complementary foods (thin porridge) before the age of 4 months (Corneli et al., 2007). These women explained that when an infant cries this is interpreted as a sign of hunger in their culture and felt obliged to feed foods in addition to their own breast milk. Another cultural belief reported by 50% of HIV-infected mothers was that infants had high energy demands and “cannot grow properly with breast milk only” (Corneli et al., 2007). These findings illustrated the need for an educational intervention regarding infant feeding among BAN Study participants.

When investigating the acceptance of early breastfeeding cessation, HIV-positive mothers expressed their willingness to comply if it would prevent transmission but feared their inability to afford replacement feeds would result in malnutrition. Repeatedly, mothers explained that their ability to stop breastfeeding at 6 months was dependent on the availability of replacement foods (Corneli et al., 2007). To assist mothers in their
efforts to perform early breastfeeding cessation, the BAN Study provided a locally produced, fortified breast milk substitute to all participating infants to reduce the risk of malnutrition and increase the feasibility of replacement feeding. Also, mothers largely disagreed with the abrupt process of rapid cessation to wean their infant off the breast and onto semi-solid foods. This process was seen as damaging and cruel to the infant, potentially causing malnutrition if the infant refused the new foods (ie. new foods can cause an upset stomach) (Corneli et al., 2007). For the reasons stated above, HIV-positive mothers suggested infants to wean more gradually (3-4 weeks).

**Infant feeding protocol**

The third objective of the BAN Study was to evaluate ‘the feasibility of exclusive breastfeeding followed by early, rapid breastfeeding cessation’ (van der Horst et al., 2009). To address this objective, a protocol was developed to train the BAN Study nurses how to counsel all HIV-infected mothers to practice exclusive breastfeeding to 6 months, early and rapid cessation of breastfeeding before the 7th month, maintenance of breast health, and complementary feeding. Counseling session scripts included the rationale, methods and support for exclusive breastfeeding; preparation and practice during the transition to replacement feeding; and complementary feeding after 6 months. Mothers were counseled during their antenatal visits, labor and delivery, and post partum visits. At the 21st week post-partum visit, mothers received their first counseling session on how to prepare for breastfeeding cessation (Appendix 1) and this information was repeated at the 24th and 28th week visits. Mothers also received counseling on complementary feeding and maintenance of breastfeeding cessation from 24 to 48 weeks.
post partum. The Complementary Feeding Counseling Script (Appendix 2) was developed to guide BAN nurses to 1) instruct mothers when to introduce certain foods and 2) provide guidance on feeding frequency, quantity and quality of complementary foods.

**Diet composition and feeding patterns**

BAN mothers received dietary counseling on how to prepare an adequate complementary diet for their non-breastfeeding infant. These lessons informed mothers on the number of family meals an infant should receive in a day; the concepts of nutrient density and dietary variety; that infants should receive 2-3 snacks per day in addition to meals; and as a child grows the frequency and quantity of food consumed should increase. This information is illustrated in Table 2.1 below.

A locally produced breast milk substitute (LNS) was provided for infant daily consumption starting at week 24. Although LNS has been tested extensively for community therapeutic care, it has never been used as a breast milk substitute. LNS was regularly distributed to mothers at the BAN Study clinic with instructions to feed the infant a daily ration of 75g (400kcals, 9.5g protein, 30g fat). Mothers were given a small jar to measure the recommended daily dose. The nutrient content of LNS is listed in Table 2.2.

BAN Study nurses collected infant dietary recalls from mothers during the study visits at 28, 32, 42, and 48 weeks according to standardized BAN protocol (BAN-Protocol, 2004). Mothers were prompted to recall what their child had eaten over the
past 24 hours using food models, standard household dishes and utensils, and recording recipes. Recalls helped determine the prevalence of early breastfeeding cessation and the adequacy of replacement diets using LNS. IDRs were collected between November 2004 and July 2007.
Fig 2.1. The 2-by-3 factorial design of the BAN Study.
Table 2.1. Guidelines on frequency, quantity and quality of complementary foods.

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

*SOURCE: Complementary Feeding Counseling Script (Van der Horst et al., 2008)*
Table 2.2. Nutrient composition of LNS

<table>
<thead>
<tr>
<th>Nutrient</th>
<th>Food/ 100 g</th>
</tr>
</thead>
<tbody>
<tr>
<td>Energy</td>
<td>525 kcal</td>
</tr>
<tr>
<td>Protein</td>
<td>15 g</td>
</tr>
<tr>
<td>Fat</td>
<td>35 g</td>
</tr>
<tr>
<td>Vitamin A</td>
<td>910 µg</td>
</tr>
<tr>
<td>Vitamin B6</td>
<td>0.6 mg</td>
</tr>
<tr>
<td>Vitamin C</td>
<td>53 mg</td>
</tr>
<tr>
<td>Folic Acid</td>
<td>210 µg</td>
</tr>
<tr>
<td>Iron</td>
<td>11.5 mg</td>
</tr>
<tr>
<td>Zinc</td>
<td>14 mg</td>
</tr>
<tr>
<td>Calcium</td>
<td>320 mg</td>
</tr>
</tbody>
</table>
CHAPTER III
LITERATURE REVIEW

Infant dietary trends

In Malawi, prolonged breastfeeding of infants is common (median: 23.2 months), although the duration of exclusive breastfeeding is not (median: 2.5 months) (National Statistical Office and ORC Macro, 2005). This cultural norm has a long history, making WHO HIV and infant feeding recommendations difficult to implement (Infant and Young Child Nutrition Policy and Guidelines, 2003; Piwoz et al., 2006). Infant feeding norms tend toward the introduction of complementary foods by 4 months and consumption of a mixed diet (as it includes breast milk) into the 2nd year of life (National Statistical Office and ORC Macro, 2005).

The typical weaning diet is a maize-based cereal porridge and lacks diversity and animal-source foods due to economic, cultural, and religious constraints (Gibson et al., 2006). For young infants, two types of gruel are prepared called phala. Thin phala is prepared as a watery porridge with only 7% dry matter and is fed predominantly to infants under 6 months. Thick phala is slightly more energy dense with 10% dry matter (Gibson & Hotz, 2000). Diets based primarily on phala often result in deficiencies due to low nutrient intakes and high concentrations of phytic acid, polyphenols, and dietary fiber – all of which can inhibit nutrient absorption (Gibson & Hotz, 2000). Plant based complementary foods also have a low fat content reducing the bioavailability of vitamin
A, D, E, K, and carotenoids. According to the 2004 Demographic and Health Survey, only 50% of infants consumed fruits and vegetables, 16% legumes, and 11% roots and tubers on the day prior to the survey (National Statistical Office and ORC Macro, 2005). Less than 50% of infants regularly consume vitamin A rich foods and 20% are given meat, fish, poultry, or eggs (National Statistical Office and ORC Macro, 2005). Among our low income study population, the cost and poor quality of locally consumed foods are likely to prevent non-breastfed infants from meeting their nutritional needs.

Hotz and Gibson (2001) described the feeding practices and dietary intakes of weanlings 6-23 months in Malawi. Infants between 6 and 8 months had the most inadequate diet with median intakes of energy, vitamin A, C, iron, zinc, calcium, niacin, and riboflavin below 80% of estimated needs. Infants 9-11 months consumed marginally adequate amounts of energy and riboflavin but were still deficient in niacin, calcium, iron, and zinc. Among the oldest infant group 12-23 months, the typical diet provided inadequate amounts of energy, niacin, riboflavin, calcium, iron, and zinc (Hotz & Gibson, 2001). Major changes in food preparation and diet composition are needed to reduce the prevalence of malnutrition.

Child nutrition in Malawi

In developing countries, undernutrition among the under 5 population contributes to 53% of deaths from diarrhea, pneumonia, malaria, and measles (Caulfield et al., 2004). Malawi’s under-five mortality rate, defined as the probability of dying between birth and the fifth birthday, is currently estimated at 133/1,000 live births (National Statistical
Micronutrient deficiencies of vitamin A, iodine, and iron/folate are a major public health concern in Malawi. According to the 2001 National Micronutrient Survey, children under 5yrs are the worst affected with a 60% prevalence of vitamin A deficiency, and 80% prevalence of anemia (anemia under 3yrs is largely due to a lack of iron) (National Statistical Office and ORC Macro, 2005). Deficiencies of iron and zinc have also been well detailed among Malawian children by Gibson and Ferguson (Gibson & Ferguson, 1995).

**Child growth**

Early complementary feeding (< 3months) in Malawi has previously been found to be associated with increased risk of morbidity and lower weight-for-age at months 3, 6, and 9 (Kalanda et al., 2006). Following the Scrimshaw hypothesis, inadequate nutritional intakes impair the immune system allowing infections to develop which in turn lead to weight loss and/or prevent weight gain, consequently inhibiting linear growth (Dewey et al., 2005; Scrimshaw, 2003; Scrimshaw et al., 1969). Inadequate complementary feeding is hazardous to infant physical development and can lead to impaired intellectual development during childhood and short stature in adulthood (Adair & Guilkey, 1997). Traditional complementary foods are typically not nutrient dense and cannot support infant growth alone. In Cote d’Ivoire, HIV-positive mothers were counseled to practice EBF and initiate early cessation of breastfeeding from the fourth month. Low dietary diversity common among African weanlings was predictive of nutritional inadequacy and impaired growth during the next 12 months (37% increased probability of stunting).
(Becquet et al., 2006). It is for these reasons that infants weaned early must be closely monitored to prevent growth faltering.

Children with growth deficits in length-for-age, weight-for-length, and weight-for-age are identified as malnourished and categorized as stunted, wasted, or underweight respectively when measurements fall more than 2 standard deviations below the reference mean. Factors contributing to stunting among low SES populations include failure to meet nutrient requirements, a challenging environment, and inadequate provision of care. Other predictors of stunting include low birth weight, high morbidity, maternal short stature, low maternal BMI, male gender, and home delivery (Esopo et al., 2002). Growth retardation (stunting) is just one outcome of a complex syndrome involving developmental delay, impaired immune function, reduced cognitive function, and metabolic disturbances leading to increased prospective risk of obesity and hypertension (Allen, 1995; Branca & Ferrari, 2002). Stunting is an excellent indicator of malnutrition (chronic undernutrition) because linear growth can be easily measured at any age and is appropriate during infancy before other developmental tests are possible. Linear growth deficits parallel deficits in mental development among infants during the 2nd year of life and affect cognitive test performance in late childhood (Fernald et al., 2006; Mendez & Adair, 1999). Prevention efforts focus on exclusive breastfeeding to 6 months and the provision of nutritionally adequate complementary foods. Treatment before the age of 5yrs can potentially cause reversal of all symptoms (Branca & Ferrari, 2002).
Rates of underweight prevalence in Malawi steadily rise through the infancy period, peaking at 39% among 12-15 month olds (National Statistical Office and ORC Macro, 2001). Similarly, wasting trends (weight-for-length) climb during infancy ending at 13% among 12-15m. High rates of underweight and wasting contribute to high rates of stunting as body fatness precedes linear growth (Dewey et al., 2005). National Malawi DHS data reported stunting (-2SD) climbed from 26% (6-9m), to 32% (10-11m), to 47% (12-15m) (National Statistical Office and ORC Macro, 2001). More recently, Malawi DHS (2004) data reported the malnutrition prevalence among infants 6-11 months to be 32% stunted, 8% wasted, and 23% underweight. These rates were even higher among 12-17 month olds, (55% stunted, 30% underweight, and 7% wasted) (National Statistical Office and ORC Macro, 2005).

**Infant Feeding and HIV/AIDS**

In resource poor settings, exclusive breastfeeding (EBF) provides greater protection from infections other than HIV during the first 6 months of life (De Cock et al., 2000) while dually posing less risk of HIV transmission, in comparison to early mixed feeding (Coutsoudis et al., 1999; Iliff et al., 2005). The current hypothesis explaining the difference in MTCT by feeding style suggests EBF protects the gut mucosa providing a stronger barrier to the virus while mixed feeding increases the risk of damage by pathogens and large food proteins (Coovadia, 2007). Additionally, EBF yields a lower incidence of breast health problems such as mastitis and breast abscesses, both of which are associated with increased breast milk viral load and consequential increased risk of MTCT (Coovadia, 2007). Evidence from HIV trials conducted in South
Africa document significantly higher rates of transmission among mixed fed infants in comparison to exclusively breastfed infants. In the first South African study, 24.1% of infants receiving mixed diets were infected at 3 months while only 14.6% of infants exclusively breastfed were infected (Coutsoudis et al., 1999). More recently, Coovadia and coworkers (2007) reported 14.1% of EBF infants were infected by 6 weeks and 19.5% by 6 months, while infants receiving semi-solid foods in addition to breast milk were 11 times more likely to become infected (Coovadia, 2007). Similar findings have consistently been reported over the past decade of HIV research.

After 6 months, breast milk alone can no longer meet the nutrient requirements of growth infants and additional foods must be introduced. However, complementary feeding (semi-solid foods & breast milk) increases both the risk of illness and vertical transmission among HIV-negative infants. Therefore, at the age of 6 months, feeding recommendations diverge based on maternal and infant HIV status. Uninfected mothers (with uninfected infants) are recommended to continue breastfeeding up to 24 months in addition to providing complementary feeding. This same recommendation is logical for infected mothers of infected infants and became part of WHO recommendations in 2006 for HIV-infected mothers unable to sustain safe and adequate replacement diets after 6 months (WHO, 2006). HIV-infected mothers of uninfected infants are advised to stop breastfeeding at 6 months and rapidly transition to complementary foods to provide optimal nutrition and reduce MTCT by limiting mixed feeding (WHO, 2001; WHO, 2003). The Malawi Ministry of Health and Population (2003) supports and promotes the WHO infant feeding guidelines for HIV-infected mothers (Infant and Young Child
Nutrition Policy and Guidelines, 2003) thus the BAN Study was developed to incorporate these guidelines, unlike other trials in sub-Saharan Africa that distribute formula. At present, there is a lack of literature on the feeding patterns and nutrient composition of replacement diets fed by mothers as an HIV prevention method.

**Weaning**

Children are most susceptible to growth faltering during the first 2 years of life (Victora et al., 2010), and nutritional insult during this critical developmental window can have lifelong health consequences including increased risk of child mortality, short adult stature, reduced intellectual development and economic productivity, and low offspring birth weight (Grantham-McGregor et al., 2007; Black et al., 2008; Victora et al., 2008).

**Deficiencies among non-breastfed infants**

Breast milk is the most cost effective infant feeding strategy for food insecure families since it provides optimal nutrition and protection against common childhood infections (e.g. diarrhea, pneumonia) (Habicht et al., 1986; Victora et al., 1987). Achieving nutrient adequacy once breastfeeding is withdrawn from the infant diet is a major concern, since traditional diets are often inadequate even when breast milk is included (Dewey et al., 2004).

For non-breastfeeding infants, Dewey and coworkers (2004) identified 10 nutrient deficiencies as particularly problematic in developing countries: vitamin A, thiamin,
riboflavin, niacin, vitamin B6, folate, vitamin C, calcium, iron, and zinc (Dewey et al., 2004). Diets focused on unfortified plant-based foods are unlikely to meet the iron, zinc, calcium, and B12 micronutrient needs of growing infants (Dewey et al., 2004) and animal products (ie. milk, eggs, meat, poultry, fish) must be incorporated into the diet to combat deficiencies. Infants will also be susceptible vitamin B6 and folate deficiencies unless a wide variety of foods is served (B6: meat, poultry, fish, banana, green leafy vegetables, potato, peanuts; Folate: legumes, green leafy vegetables, orange juice). This proposal will evaluate the adequacy of iron, zinc, calcium, vitamin A, B6, folate, and vitamin C in replacement diets since non-breastfeeding infants are most susceptible to these deficiencies.

**Infant dietary requirements**

During the second 6 months of life, daily energy and protein needs increase with body size. Estimated energy requirements should be determined per individual based on an infant’s weight. Similarly, the protein estimated average requirement (EAR) and recommended daily allowance (RDA) equations allow an infant’s requirements to be determined individually based on weight. Conversely, during the 7-12 month period adequate intakes of carbohydrate and fat hold constant at 95g/day and 30g/day, respectively (FNB/IOM, 2005). After 12 months, the infant’s rapid growth rate begins to slow resulting in slightly lower requirements of energy and protein (0.87g/kg/day). Carbohydrate needs rise to 100g/day and fat is recommended to contribute 30% of total energy intake (FNB/IOM, 2005). The acceptable ranges for child macronutrient intakes between 1-3yrs are listed below in Table 3.1.
**Energy requirements**

Energy requirements for growing infants must support physical activity levels consistent with normal development and provide the energy required to deposit tissues at a rate consistent with good health (FNB/IOM, 2005). The total energy requirement of an infant (0-2yrs) varies by age, gender, and feeding mode (FNB/IOM, 2005). The Estimated Energy Requirement (EER) for infants is designed to support basal metabolism (basal energy expenditure), the thermic effect of food (TEF), physical activity, thermoregulation, and growth (tissue deposition). The energy cost of growth (tissue deposition) is estimated at 22 kcal/day for infants 7-12 months using calculations based on findings from Butte et al., (2000) and Guo et al., (1991) (Butte et al., 2000; FNB/IOM, 2005; Guo et al., 1991). EER values published by the IOM in 2005 for infants at each month of development are based on the median (50th percentile) weight of the reference population (www.who.int/childgrowth/standards). In light of the difference between the Malawi BAN infant population and the reference population on which the Dietary Reference Intakes (DRI) were based, the original EER formulas will be used to accurately determine energy requirements per infant based on their body weight. The equations below are used to calculate the estimated energy requirement for children 7 through 12 months and 15 through 18 months, respectively:

- **7-12 months:** \[ \text{EER} = (89 \times \text{weight [kg]} - 100) + 22\text{kcal} \]
- **15-18 months:** \[ \text{EER} = (89 \times \text{weight [kg]} - 100) + 20\text{kcal} \]
EER formulas are suitable for infants with body weights within 2 standard deviations of the WHO median. Cases of moderate malnutrition have greater energy requirements due to catch up growth; such infants were referred to a pediatrician and their mothers counseled to feed at least 200g RUTF (about 1079Kcals/day) in addition to family foods. BAN Study nutritionists reviewed these infants weekly until recovery. Community nurses also made home visits to assess these infant’s feeding practices. Severe malnutrition cases were referred to the Nutrition Rehabilitation unit at Kamuzu Central Hospital for further management.

Protein requirements

Evaluating protein adequacy among BAN infants is important since deficiencies can impair brain function, immunity, kidney function, gut mucosal function and permeability which in turn can affect absorption and possibly enable bacterial invasion from the gut resulting in septicemia (Reynolds et al., 1996). To evaluate protein adequacy among the group of BAN infants, the proportion of the group not meeting the estimated average requirement was determined to estimate the prevalence of inadequacy. The EAR is used as a cut point against which to determine the prevalence of inadequate intakes (ie. the proportion of the group below the EAR) (Murphy et al., 2006). This cut point method is a simplification of the full probability approach which demands the probability of inadequacy be calculated for each infant in the group and then averaged (Murphy et al., 2006). The EAR represents the amount expected to satisfy the needs of 50% of the people in that age group, thus there is a 50% chance that infants meeting the EAR threshold may still be consuming inadequate amounts of protein (Fig 3.1).
Estimated average protein requirements for infants 7 months through 18 years are calculated using the factorial method which takes into account 1) estimates of the maintenance requirement, 2) measurement of the rates of protein deposition, and 3) estimates of the efficiency of protein utilization (FNB/IOM, 2005). The protein EAR for infants 7 through 12 months of age is 1.0g/kg/day; Between 15 and 18 months of age, the protein EAR for boys and girls is 0.87g/kg/day.

**Micronutrient requirements**

For infants 7 through 12 months of age, micronutrient requirements are somewhat unknown due to ethical issues precluding the experimentation needed to develop estimated average requirements (EAR). Instead, adequate intakes (AI) are often the only DRI published and are estimated from the average intakes of full-term infants born to healthy, well-nourished mothers. The extent to which these AIs exceed actual requirements is unknown making them undesirable as an adequacy cut point. For vitamin A, B6, folate, vitamin C, and calcium only AI levels have been determined. Adequate intakes can only be used to evaluate the mean intake of a group, such that if the mean intake of folate falls below the AI then it could be recommended to increase intakes. AIs for the following vitamins are: vitamin A 500µg/day, vitamin B6 0.3mg/day, folate 80µg/day, vitamin C 50mg/day, and calcium 270mg/day (FNB/IOM, 1998; FNB/IOM, 2000; FNB/IOM, 2005). Fortunately, for infants between 7 and 12 months, EAR values have been set by the Institute of Medicine for iron and zinc. The EAR for groups is set at 6.9mg/day for iron and 2.5mg/day for zinc. **Table 3.2** lists the EAR and AI levels for infant macronutrient and micronutrient needs between 7 and 12 months of age.
More precise DRI measures are available for children 1-3yrs due to a greater number of child diet studies. Estimated average requirements for groups have been published for vitamin A (210µg/d), vitamin B6 (0.4mg/d), folate (120µg/d), and vitamin C (13mg/day) (FNB/IOM, 2005). Unfortunately, only an adequate intake level is available for calcium within this age range (500mg/day). In the second year of life, the EAR for zinc holds constant at 2.5mg/d while the iron EAR is reduced to 3.0mg/d (FNB/IOM, 2005). When determining the prevalence of inadequacy among a group, it is more accurate to compare usual intake distributions to the EAR which covers 50% of the population, than the RDA which would grossly overestimate the risk of deficiency (Carriquiry, 1999). Fig 3.2 illustrates the Estimated Average Requirement cut-point method which calculates the proportion of infants consuming intakes below the EAR and uses this to estimate the proportion with inadequate intakes (i.e. prevalence of inadequacy) (FNB/IOM, 2000). Table 3.2 lists the EAR and AI levels for infant macronutrient and micronutrient needs between 1-3 yrs of age.

**PMTCT trials**

PMTCT trials that were conducted in sub-Saharan Africa and promoted replacement feeding from birth found significantly higher rates of adverse events, hospitalizations, non-HIV related infections and mortality among formula fed infants in comparison to breastfed infants. In both Botswana and Cote d’Ivoire, researchers found no difference in HIV-free survival by 18 months between infants who were formula fed or breastfed between 3 and 6 months (Thior et al., 2006; Becquet et al., 2007;
www.aidsmap.com). In resource poor settings, formula feeding is not a viable alternative to breastfeeding due to the lack of clean water which presents as great a risk to infants as the risk of HIV infection from breastmilk. Among infants enrolled in the Zambia Exclusive Breastfeeding Study (ZEBS), early abrupt weaning was associated with greater mortality in comparison to infants following traditional weaning practices and therefore early breastfeeding cessation did not improve HIV-free survival by 24 months (Kuhn et al., 2010). Provision of a nutrient supplement after cessation for a longer duration than 2 months and more regular assessment would likely have improved survival rates.

Trials within Malawi, Uganda, Zimbabwe, and Kenya advocated exclusive breastfeeding to 6 months, unless replacement foods were AFASS before this age. In Kenya, the Kibs Study administered combination ART to mothers from week 34 of gestation to 6 months after delivery. Mothers were counseled to exclusively breastfeed to 6 months and then rapidly transition to locally available foods over the 2 weeks before ART was discontinued. Infants in this study had a low incidence of diarrheal infection at 5.7/1000 infant months (of observation), experiencing peak diarrheal rates around the time of weaning (www.aidsmap.com). In Zimbabwe, ZVITAMBO trial mothers were motivated to perform early breastfeeding cessation upon learning their child’s HIV-negative status at 6 months even when they could not provide an adequate replacement diet (Lunney et al., 2008). The 2 year infant mortality rate among the ZVITAMBO control population of HIV-negative mothers was 2.9% and yet the 2 year mortality rate among the uninfected infants of HIV-positive mothers was 9.2%; grossly inadequate replacement diets likely contributed to increased mortality (Marinda et al., 2007).
**Weaning and LNS**

Only the UNC CDC Breastfeeding, Antiretroviral, and Nutrition (BAN) Study in Malawi supported early weaning by providing a breastmilk substitute between 6 and 12 months of age. Furthermore, the BAN Study provided LNS instead of formula as a replacement food because it is nutrient-dense, bacteria resistant, does not require water for preparation, and can be consumed directly from the container without cooking, making its use safe even in poor hygienic conditions (Briend, 2002; van der Horst et al., 2009). Achieving replacement diet adequacy during early infant stages has proved difficult in previous trials but the BAN Study’s use of LNS holds new promise.

**Lipid-based nutrient supplements**

Over the past decade, research studies have consistently found LNS to successfully promote the rehabilitation of severe acute malnutrition (WLZ <-3SD) (Ciliberto et al., 2005; Diop et al., 2003; Manary et al., 2004; Sandige et al., 2004) and moderate malnutrition among young children in sub-Saharan Africa (Lagrone et al., 2010; Matilsky et al., 2009; Nackers et al., 2010; Defourney et al., 2007). More recently, LNS supplementation has shown to improve linear growth (Phuka et al., 2008; Adu-Afarwuah et al., 2007) and prevent severe stunting and wasting (Phuka et al., 2009; Isanaka et al., 2009; Kuusipalo et al., 2006; Patel et al., 2005).

Although lipid-based nutrient supplements have been tested extensively for community therapeutic care, they have never been used as a breastmilk substitute. The
high fat content increases energy density and enhances absorption of fat-soluble vitamins. LNS products are also an economical replacement food since they are intended for 'point-of-use' fortification and limit wastage (Chaparro and Dewey, 2010).

Acceptance

Previous studies among mothers of unknown HIV status in Ghana and Malawi reported LNS was well accepted by mothers and infants in terms of ease of use and palatability, value as a food, and perceived benefit to infant’s health (Adu-Afarwuah et al., 2008; Flax et al., 2009). Since mothers are primarily responsible for infant feeding in Malawi, their attitudes and beliefs regarding EBF, early cessation, and LNS need to be understood in order to effectively design interventions that promote the HIV and infant feeding guidelines among low-income families in this social and cultural setting (Corneli et al., 2007; Flax et al., 2009).

Season and food security

In Malawi, 52% of the population lives below the poverty line (<$103 USD/year) and spends most 76% their income on food (Malawi IHS, 2005). When money is short, a family’s grocery list is typically the most flexible expense and can be reduced. Food insecurity at the household level is characterized by inadequate resources to buy enough food, decreased diet quality, 1 or more family member (i.e. parent) reducing their food consumption to the extent that they repeatedly experience the physical sensation of hunger (Cohen, 2002). Household food security is typically dictated by financial resource constraints but in the developing world seasonal availability plays a role.
It has long been recognized that seasons can affect diet quality, especially among low income families living in sub-Saharan Africa. In Ethiopia, the nutritional status of pastoral children improved following the rainy season because they consumed cereals and animal foods; the health of agricultural children improved following the main harvest because they mostly ate cereals. Significantly greater rates of stunting were found among agricultural children (55% prevalence) in comparison to pastoral children (20%) reflecting differences in the quality of diet (Lindtjorn et al., 1993). In Kenya, food consumption and nutritional status were examined within pre-school aged children at the end of the dry season. The child diet consisted mainly of maize and milk rendering the children energy and nutrient deprived and when compounded by the dry season, the prevalence of underweight grew significantly above regional statistics. As expected, seasonal fluctuations in food supply had the worst impact on the youngest age group (6-12 months) who exhibited the largest deficit in weight (Geuns et al., 1991). In rural Malawi, Maleta et al (2003) reported the length-for-age and weight-for-age z scores of infants declined most rapidly between December to April (rainy season) and least in June-July (cool season) (Maleta et al., 2003).

The growing season in Malawi occurs between January and April when the country receives the majority of its rainfall. This rainy season is appropriately named the ‘hungry season’, representing the hardships faced during these months when the family food supply runs low. Although a variety of traditional foods are available or could be cultivated for consumption during this time, they are often stigmatized (ie. blackjack
leafy green) or overlooked due to the preference for highly processed white maize flour (nsima) (Stacia Nordin, personal communication). Season and traditional dietary practices compound problems of food insecurity and malnutrition by limiting nutrient intake during the rainy season.
Fig 3.1. The risk of nutrient inadequacy among a population. When an individual’s nutrient intake is equal to the EAR, there is a 50% risk of deficiency (i.e. the EAR level is inadequate for half the targeted population) (FNB/IOM, 2000).
Fig 3.2. The estimated average requirement cut-point method (FNB/IOM, 2000).
Table 3.1. Dietary Reference Intakes (DRIs): Acceptable Macronutrient Distribution Ranges Food and Nutrition Board, Institute of Medicine, National Academies

<table>
<thead>
<tr>
<th>Macronutrient</th>
<th>Range (percent of energy)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Children, 1–3 y</td>
</tr>
<tr>
<td>Fat</td>
<td>30–40</td>
</tr>
<tr>
<td>n-6 Polyunsaturated fatty acids(^a) (linoleic acid)</td>
<td>5–10</td>
</tr>
<tr>
<td>n-3 Polyunsaturated fatty acids(^a) (α-linolenic acid)</td>
<td>0.6–1.2</td>
</tr>
<tr>
<td>Carbohydrate</td>
<td>45–65</td>
</tr>
<tr>
<td>Protein</td>
<td>5–20</td>
</tr>
</tbody>
</table>

\(^a\) Approximately 10 percent of the total can come from longer-chain n-3 or n-6 fatty acids.

### Table 3.2 Child nutrient requirements

<table>
<thead>
<tr>
<th>Micronutrient</th>
<th>7-12 months</th>
<th>1-3 years</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>EAR</td>
<td>AI</td>
</tr>
<tr>
<td>Energy</td>
<td>EER=(89 x weight [kg] – 100) + 22kcal</td>
<td>--</td>
</tr>
<tr>
<td>Protein</td>
<td>1.0g/kg/day</td>
<td>--</td>
</tr>
<tr>
<td>Carbohydrate</td>
<td>--</td>
<td>95g/day</td>
</tr>
<tr>
<td>Fat</td>
<td>--</td>
<td>30g/day</td>
</tr>
<tr>
<td>Vitamin A</td>
<td>--</td>
<td>500µg/day</td>
</tr>
<tr>
<td>Vitamin B6</td>
<td>--</td>
<td>0.3mg/day</td>
</tr>
<tr>
<td>Folate</td>
<td>--</td>
<td>80µg/day</td>
</tr>
<tr>
<td>Vitamin C</td>
<td>--</td>
<td>50mg/day</td>
</tr>
<tr>
<td>Iron</td>
<td>6.9mg/day</td>
<td>--</td>
</tr>
<tr>
<td>Zinc</td>
<td>2.5mg/day</td>
<td>--</td>
</tr>
<tr>
<td>Calcium</td>
<td>--</td>
<td>270mg/day</td>
</tr>
</tbody>
</table>

*Adapted from FNB/IOM, 1997; FNB/IOM, 1998; FNB/IOM, 2000; FNB/IOM, 2001; FNB/IOM, 2005*
In Malawi, stunting, wasting, and underweight are manifestations of a multi-sectoral problem developing from 3 different levels of causal factors: Immediate causes of malnutrition are inadequate dietary intake and infectious disease; Underlying causes include household food security, inadequate maternal and child care, early introduction of complementary foods, poor food preparation and hygiene, inadequate health services, inappropriate care of child illness, and a poor health environment; Basic causes include political, economic, cultural and social systems (ie. women’s status), and potential resources (Engle, 2000; Pollitt et al., 1993; Pollitt et al., 1995). The conceptual framework below, Fig 4.1, was adapted from the UNICEF 1990 model to explain the determinants of child nutritional status among our study population.

The social ecological framework is often used by public health researchers as a tool for understanding the determinants of health behaviors. This framework was originally developed from Bronfenbrenner’s work on the ecology of human development proposing child development is guided and supported by the system of relationships (ie. layers of the environment) that provide constant interaction (Bronfenbrenner, 1977). The social ecological model recognizes human environments are multi-dimensional, resulting
from the complex interplay between individual, interpersonal, institutional, community, and social policy factors.

While the UNICEF 1990 conceptual framework clearly illustrates the spectrum of problems contributing to malnutrition, it is our aim to investigate the immediate and underlying causal factors of undernutrition as they are perceived by caregivers. The ability and willingness of BAN Study mothers to comply with the HIV infant feeding guidelines is likely influenced by maternal attitudes and beliefs surrounding the guidelines; knowledge of infant feeding and care practices; interpersonal relationships and decision-making patterns; the attitudes and counseling messages of BAN health workers; infant feeding norms practiced in the community; HIV stigma in the community; and food security.

To investigate the determinants of infant feeding and care practices among BAN Study mothers we developed a conceptual model to illustrate the factors influencing a mother’s decision and ability to provide a replacement diet for their infant (Fig 4.2). The multiple levels of the socio-ecological framework are contextualized below to the Malawian context.

**Maternal knowledge, attitudes, beliefs, and intentions**

Knowledge and understanding of MTCT is likely to influence maternal attitudes and motivation regarding the HIV and infant feeding guidelines. A small qualitative study conducted among low-income mothers in Lilongwe found mothers were willing to
take the necessary steps to prevent their child from becoming infected (Piwoz et al., 2006). Attitudes and beliefs are therefore likely to influence initiation and adherence to the guidelines. In Zimbabwe, the ZVITAMBO intervention educated mothers infected with HIV (and those with unknown status) to practice exclusive breastfeeding with their infant. This knowledge and counseling effort alone increased the rate of EBF by 8.4 times (Piwoz et al., 2005). Equipped with knowledge, HIV-infected mothers are likely to adopt preventative behaviors unless it puts them at risk of domestic abuse, abandonment, or ridicule by their surrounding community.

Acceptance of LNS

Formative data found BAN Study mothers were highly accepting (88% of mothers) of LNS; mothers requested additional LNS before the end of the month (Corneli et al., 2007). Non-formula weaning foods are uncommon in African settings and have never been used as a daily complementary food for infants 6-12 months. Among women who choose not to disclose their HIV status, LNS use within the home or marketplace may equate with disclosure. Ethnographic research conducted among BAN-exited mothers will retrospectively probe mothers for factors influencing their acceptance of LNS. Potential determinants of LNS use include infant care experience, maternal age, maternal education, food security, number of household members, HIV-status disclosure, and infant health. This study aims to understand the determinants and cultural perceptions of LNS-use in order to successfully promote exclusive replacement diets in the future.
Fear and patterns of decision-making

Women’s willingness to follow the HIV and infant feeding guidelines is likely to be influenced by her disclosure status. Women fear HIV disclosure will result in domestic violence and abandonment (Tembo, 2006). If atypical infant feeding patterns are indicative of HIV status, women will be reluctant to follow the guidelines. However, women in long term relationships (>2yrs) were more likely to disclose their HIV status to their partner than women in shorter term relationships (Medley et al., 2004). The quality of marital relations may influence the acceptance and ability of the mother to follow the WHO guidelines.

Institutional factors

Piwoz et al. (2006) explored health workers (N=19) attitudes toward WHO guidelines and found only 11 of 19 thought mothers could feasibly follow the recommendations. The cultural norm of early complementary feeding (<4 months) was listed as a major barrier to adherence and most expressed concerns that early cessation would lead to malnutrition. The attitudes and counseling messages delivered by BAN health workers are likely to have influenced the infant feeding decisions of BAN participants (Piwoz et al., 2006).

HIV stigma and infant feeding norms

Strict adherence to the HIV and infant feeding guidelines over traditional practice, is likely to carry substantial stigma and identify mothers as infected to their community
Women in Nigeria agreed the perceived stigma associated with not breastfeeding was a determining factor in feeding an exclusive replacement diet and that only certain foods were culturally acceptable (i.e., infant formula, cow’s milk, soy milk) (Abiona et al., 2006). Previous support group meetings held with BAN participants identified fear of abandonment, spousal violence, stigma, and discrimination as impediments to accessing HIV-care and status disclosure, potentially hindering adherence to non-normative feeding practices (Tembo, 2006).

Community factors

Malawian culture is largely rooted in Christian and Muslim values which promote purity and form the basis of societal intolerance towards sexually transmitted infections. Of all the sub-Saharan countries affected by the HIV/AIDS epidemic, Uganda was the first nation to successfully confront the epidemic and dramatically reduce their prevalence from 15% in the early 1990’s to 6.5% by 2004 (www.usaid.gov). This nation used a successful combination of ABC strategies which rose above cultural religious values to educate the people and cultivate open discussions while promoting 1) Abstinence; 2) Being faithful (reducing number of partners); and 3) Correct and consistent condom use (www.usaid.gov) (Low-Beer D, 2003; Stoneburner R, 2004). Increasing the public’s knowledge of HIV helps to create a more accepting society in which people will be more likely to participate in PMTCT interventions (Eide et al., 2006). In recent years, the Malawian government declared 1 week in July as “National HIV Testing and Counseling Week” (Malawi National AIDS Commission, 2004).
number of people choosing to be tested has exponentially increased over the past 3 years indicating the nation is becoming more aware of the disease.

**Environmental factors**

In Malawi, maize accounts for 70-80% of daily energy intake but among non-farming urban families the cost of food can be prohibitive (www.projectpeanutbutter.org; Conroy et al., 2006). The rains primarily dictate national maize production, in turn affecting market prices and food accessibility. Maize prices are lowest following the harvest and rise as reserves are depleted, reaching their peak price in February ‘the hungriest month’ (Conroy et al., 2006; FEWSNET/WFP, 2005). Seasonality is a predictor of food availability and accessibility and therefore household food security (Quinn et al., 1990).

**Feasibility factors**

The practicality of replacement feeding among low-income populations in resource poor settings is reduced by barriers such as the high cost of feeds, the need for cooking fuel, unreliable power supply, and poor access to both clean water and adequate storage facilities (Abiona et al., 2006). The cost and complexity of preparation were listed as deterrents for using replacement foods in Tanzania (Burke, 2004). Recent ethnographic research in South Africa and Cote d'Ivoire identified 1) the social stigma of HIV, 2) maternal age and family influences, and 3) economic circumstances (ie. food security) as socio-cultural determinants of maternal compliance to the HIV and infant feeding guidelines (Becquet et al., 2005; Thairu et al., 2005). Mothers returning to the
work force after delivery spend most of the day far from the child. Mothers working as domestic help or independently (ie. local market) may be more likely to practice EBF if they can keep the child with them. A small qualitative study conducted in Lilongwe, Malawi found mothers without work were more likely to practice EBF than working mothers (Piwoz et al., 2006). Most BAN Study mothers are unemployed making EBF to 6 months more feasible (Tembo, 2006).

**Specific Research Aims**

**Aim 1:** Conduct a quantitative dietary analysis of 400 non-breastfeeding infants, ages 6 to 12 months, using 24-hour dietary recalls collected by the BAN Study to examine seasonal differences in dietary intakes and consumption of LNS.

**Aim 2:** Conduct a qualitative study among a sub-sample of mothers-infant pairs after their exit from the BAN Study to explore maternal acceptance and perceived feasibility of exclusive breastfeeding, early breastfeeding cessation, and the use of LNS as a breastmilk substitute to identify barriers to implementation.

**Aim 3:** Assess the dietary composition, nutrient adequacy, and nutritional status (LAZ, WAZ, WLZ, growth velocity) among a sub-sample of 40 BAN-exited infants between 15 and 18 months in relation to a matched sample of breastfeeding infant non-participants.
Summary and Implications for Research

The strengths of the proposed research include our access to a rich dataset in the context of an important PMTCT clinical trial and the use of both quantitative and qualitative methods. The BAN Study data offers us a unique opportunity to: (1) evaluate LNS for use among HIV positive mothers who wean their infants at 6 months and (2) follow-up with a sub-sample of BAN mothers and infants into the second year of life when infants are not being breastfed and LNS is not provided by the BAN study. In the following chapters we present each aim as a separate scientific paper detailing the study objectives, design, sample population, results, and discussion.

Aim 1 of this dissertation uses secondary data previously collected by the BAN Study team; Appendixes 1 and 2 were used during the BAN Study as counseling guides for HIV-positive mothers. The Feasibility Study, described above as Aims 2 and 3, was developed as a follow-up to the BAN Study; Appendix 3 was used to recruit mother-infant pairs into the Feasibility Study after exiting the BAN Study; Appendix 4 was the demographic survey used by the Feasibility Study; Appendixes 5 and 6 were developed for Aim 2 to interview matched and BAN-exited mothers, respectively; Appendix 7 shows the template used to collect infant anthropometric measurements for Aim 3.
Fig 4.1. Factors affecting the child diet and nutritional status. A conceptual model illustrating the multiple inter-related factors affecting dietary intake and nutritional status among non-breastfed children who participated in the BAN Study. Adapted from the 1990 UNICEF Framework on the causes of malnutrition.

*Adapted from UNICEF 1990 Conceptual Framework*
Fig 4.2 Conceptual model for Aim 2

A conceptual model of the social and ecological factors influencing maternal choice to follow the HIV and infant feeding guidelines and her ability to adhere to the recommendations.
CHAPTER V

SEASONAL DIETARY INTAKES OF HIV-EXPOSED INFANTS AFTER EARLY BREASTFEEDING CESSATION IN MALAWI: RESULTS FROM THE BAN STUDY

Abstract

Background: The data for this study were collected from participants in the Breastfeeding, Antiretroviral, and Nutrition Study, a postnatal intervention designed to find the most effective combination of ART to prevent MTCT during the EBF period. Mothers of HIV-negative infants were advised to perform early breastfeeding cessation at 6-7 months. The BAN Study provided a lipid-based nutrient supplement (LNS) to replace breastmilk in the diet between 6-12 mo. Objective: To examine infant dietary intakes after early breastfeeding cessation using LNS as a breastmilk substitute; investigate the influence of season on intakes and determine if LNS consumption varied seasonally. Design: A random sample of infants contributed up to four 24-hour dietary recalls between 6 and 12 months. Dietary intakes were calculated using a Malawian food composition table. Seasonal differences in intake and LNS consumption were examined using generalized estimating equations. Results: Dietary intakes followed a seasonal pattern with greatest intakes during the cool season and lowest intakes during the hungry season. LNS was primarily consumed added to porridge; the least amount was eaten during the hot season and greatest during the harvest season. Percent contribution of LNS to total intake was greatest during the hungry and cool seasons. Infants were dependent on LNS to provide adequate fat, vitamin A, vitamin C, calcium, and iron.
Conclusions: In this resource-poor setting, early cessation of breastfeeding proved feasible as an HIV prevention method when supported by LNS; infants were more dependent on LNS to meet their nutrient needs during the hungry season.

Introduction

Over the past decade, the World Health Organization has consistently advised HIV-infected mothers living in resource-poor settings to exclusively breastfeed (EBF) their infants to 6 months of age unless replacement feeding is acceptable, feasible, affordable, sustainable, and safe (AFASS). At 6 months, complementary foods must be introduced to meet the infant’s increased nutrient needs but mixed feeding increases the risk of vertical transmission, thus early cessation at 6 months was promoted if replacement feeding was AFASS because it carried the least risk of transmission among breastfeeding populations (Coutsoudis et al., 2001; WHO, 2001; WHO, 2003; WHO, 2006). Although early weaning could potentially reduce HIV transmission, non-breastfed children in resource-poor settings are at heightened risk of malnutrition and stunted growth due to difficulties procuring an adequate range of nutrient dense foods to replace breastmilk in the diet (Becquet et al., 2006). To reconcile this, the WHO guidelines were recently revised to promote maternal or infant antiretroviral prophylaxis to 12 months making mixed feeding safer and prolonging the breastfeeding period (WHO, 2009).

Previous African HIV prevention trials advocating exclusive breastfeeding and early cessation at 6 months have not provided breastmilk substitutes upon weaning and while caregivers were motivated to perform early cessation to prevent pediatric infection,
the replacement diets they could feasibly provide were grossly inadequate (Lunney et al., 2008). Only the Breastfeeding, Antiretroviral, and Nutrition (BAN) Study in Malawi supported early cessation by providing a breastmilk substitute. The BAN Study was a postnatal HIV transmission intervention in Malawi designed to evaluate the efficacy of antiretroviral therapy beyond 6 weeks in a breastfeeding population. Infants were provided a lipid-based nutrient supplement [LNS] to promote diet adequacy upon weaning (Adu-Afarwuah et al., 2007) from 6-12 months. LNS was distributed instead of formula because it is nutrient-dense, bacteria resistant, does not require water for preparation, and can be consumed directly from the container without cooking, making its use safe even in poor hygienic conditions (Briend, 2002; van der Horst et al., 2009). Achieving replacement diet adequacy during early infant stages has proved difficult in previous trials but the BAN Study’s use of LNS holds new promise.

In Malawi, 52% of the population lives below the poverty line (<$103 USD/year) and spends most of their income on food (Malawi IHS, 2005). Maize accounts for 80% of daily energy intake but among non-farming urban families the cost of food can be prohibitive (Conroy et al., 2006). The rains primarily dictate national maize production, in turn affecting market prices and food accessibility. Maize prices are lowest following the harvest and rise as reserves are depleted, reaching their peak price in February ‘the hungriest month’ (Conroy et al., 2006; FEWSNET/WFP, 2005). Seasonality is therefore a predictor of household food security (Quinn et al., 1990). LNS is nutrient dense and sufficient to replace breastmilk in the diet, however, total nutrient intakes may still be
susceptible to fluctuation but infants could maintain adequacy by consuming greater amounts of LNS during lean times.

The purpose of this study was to examine infant dietary intakes among a sub-sample of BAN-enrolled infants after early cessation using LNS as a breastfeeding substitute. We were specifically interested in the influence of season on dietary intakes and if infant reliance on LNS varied by season.

Methods

The BAN Study

A complete description of the BAN Study protocol, eligibility criteria, and its objectives were detailed by van der Horst and colleagues (2009). HIV-positive mothers, who carried babies to term (>36 weeks), were enrolled into the BAN Study and counseled to exclusively breastfeed for 24 weeks postpartum and perform rapid breastfeeding cessation within an additional 4 weeks. Starting at week 21, mothers with HIV-negative infants were counseled to prepare for weaning. At week 24, BAN Study nurses began to teach mothers how to feed their child an adequate diet without breastmilk (Ferguson et al., 2009). The topics covered included: appropriate age for each food introduction, food amounts, nutrient density and variety, feeding frequency, food safety, feeding during illness, responsive feeding, and how to incorporate LNS into the diet. This information was reiterated at weeks 28, 32, 42, and 48. LNS was regularly distributed to mothers at the BAN Study clinic with instructions to feed the infant a daily ration of 75g (400kcals, 9.5g protein, 30g fat). Mothers were given a small jar to help
measure the recommended daily dose. The nutrient content of LNS is listed in Table 5.1. Due to seasonal food shortages, all BAN Study families received a 2kg bag of maize each week, providing approximately 200kcal/person/day for a family of five (van der Horst et al., 2009). Ethical approval for this study was obtained from 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.

**Dietary data collection**

BAN Study nurses collected 24-hour infant dietary recalls (IDR) from mothers to monitor feeding patterns at weeks 28, 32, 42, and 48. IDRs were collected between November 2004 and July 2007. By July 2007, 817 BAN enrolled infants had reached week 28 and contributed their first dietary recall; 547 BAN enrolled infants had completed the study to 48 weeks. To prevent a selection bias, a random sample of 400 infants was selected from the total that reached week 28 by July 2007; each infant had therefore contributed at least 1 recall but no more than 4. Mothers were prompted to recall what their child had eaten over the past 24 hours using food models, standard household dishes and utensils, and recording recipes.

**Dietary data analysis**

Infant dietary recalls were entered into Microsoft Access in Malawi and then transferred into STATA for analysis. Portion sizes were converted into grams consumed. The nutrient values of each raw food or mixed dish was listed in a Malawian food composition database, created by Rosalind Gibson (Ferguson et al., 1995). Additional
nutrient information was added from a Tanzanian FCT (Lukmanji et al., 2008), the USDA nutrient database (USDA, 2010), or directly from the manufacturer (i.e. Mahewu, LNS, Lactogen infant formula). Standard dishes with consistent ingredients were analyzed at the dish level (i.e. nsima). The nutrient composition of prepared foods that varied by household (e.g. porridge) was calculated by summing ingredient nutrients and dividing by the total number of grams in the recipe to generate a nutrient value per 100g. This nutrient composition value was then applied to the total number of grams the child consumed of the prepared dish. In resource poor settings, the non-breastfed child is most at risk of deficiencies in energy, protein, vitamin A, vitamin B6, folate, vitamin C, iron, zinc, and calcium thus total intakes of these nutrients were measured (Dewey et al., 2004). Food choices and feeding patterns were examined over time to accurately characterize the infant diet.

From the random sample of 400 infants selected, diet recalls could only be found for 380 infants. The total number of infant diet recalls entered for weeks 28, 32, 42, and 48 were 354, 324, 315, and 329, respectively. At each of these 4 time points, the number of diet recalls reporting breastmilk consumption was 53 (15%), 16 (5%), 9 (3%), and 9 (3%), respectively. To accurately assess diet adequacy among non-breastfeeding infants, all recalls that included breastmilk had to be excluded leaving 301, 308, 306, 320 at 28, 32, 42, and 48 weeks, respectively (Fig 5.1). A sensitivity analysis was also conducted excluding the 53 infants still breastfeeding at 28 weeks from all recalls (i.e. 28, 32, 42, 48 weeks) to examine if their inclusion altered the dietary intake findings but no significant differences were found.
Seasonality

The Malawian climate is characterized by 4 seasons: rainy (mid-November to April), post-rainy (April to May), cool (May to August), and hot (September to mid-November) (National Statistical Office, 2005). Farmers plant crops in late October before the rains. The rainy months are appropriately known as the ‘hungry season’ because the harvest occurs in April-May and for some households there is little left to eat three seasons later. The national shortage in food supply during the hungry season causes market prices to soar, further compounding household food insecurity (Chirwa, 2009; Quinn et al., 1990). The main growing season ends after the rains, thus the post-rainy months are also known as the ‘harvest season’. Three dummy variables were created to represent the harvest, cool, and hot seasons leaving the hungry season as the referent for statistical analyses.

Demographic questionnaire

A background survey was administered to each BAN Study mother to collect data on age, marital status, education, occupation, socio-economic status, and household food security. Parental occupations were divided into dichotomous categories to represent the percent currently working, percent with salaried employment, and percent self-employed; all estimates were calculated from the total sample. Household characteristics (i.e. building materials) served as indicators of socio-economic status. Household food security was measured using the USDA scale and inquired about food shortages, receipt of free food, quantity received, and overall perception of personal nutritional status (Bickel et al., 2000).
Statistical Analysis

Descriptive statistics were calculated to summarize nutrient intakes at each visit (28, 32, 42, and 48 weeks) and then for each season. For infants 7-12 months of age, estimated average requirements are available for energy, protein, iron, and zinc; adequate intakes exist for fat, vitamin A, vitamin B6, folate, vitamin C, and calcium. The EAR equivalent for energy is EER (expected energy requirement) and can be calculated for each individual (7-12mo) based on their body weight \[\text{EER} = (89 \times \text{weight [kg]} - 100) + 22\text{kcal}\]. For the purpose of this study both EAR and AI values served only as a reference point against which to view infant intakes but were not used to evaluate the prevalence of inadequacy.

Multiple diet recalls were collected from most infants, each in a different month, comprising a longitudinal dataset with correlated response data. To control for this we used generalized estimating equations (GEE) to estimate the population-averaged response to seasonality. GEE accounts for intra-individual correlations and does not need an equal number of observations per subject (McCullagh & Nelder, 1983). Weighted combinations of observations are used by generalized estimating equations to garner the appropriate amount of information from correlated data (Hanley, Negassa, Edwardes, & Forrester, 2003). The effect of each month on dietary intake was evaluated before creating seasonal categories to ensure there was a consistent effect within season. The log of each nutrient was modeled onto season, while controlling for infant age and maternal age. Multiple comparisons were made between nutrient intakes during the
referent hungry season and the other 3 seasons. Using the Bonferroni correction, the statistical significance level was adjusted from $\alpha=0.05$ to $\alpha=0.05/3$ (Schaffer, 1995). The log of each nutrient was also modeled on age to identify intake trends over follow-up.

**Results**

**Demographics**

Almost all households in this sample were headed by males; 91% of mothers were married. Most married women did not have paid employment (79%) and were reliant on their husband’s income. Although 89% of fathers were currently employed, only 32% had salaried employment. Selected socioeconomic and demographic characteristics of the sample are shown in Table 5.2.

**Household food security**

At 28 weeks a food security questionnaire was administered to participants of the BAN Study. Among this random sample (N=380), 17% reported household food shortages within the past month, 46% reported current shortages, and 78% were receiving monthly rations of corn soya blend (9kg) from the World Food Program. While most mothers (60%) described themselves to be in good health and well nourished; a third (33%) reported good health but with an inadequate diet.

**Characterization of the diet**

A close examination of the diet revealed that as infants aged they were less frequently fed nutrient-dense foods such as LNS, fortified porridge, infant formula, and
powdered milk; both the proportion eating the food and the number of daily servings declined over time. Over the 6 months of follow-up, the proportion of infants consuming porridge remained the same (~100%) but daily servings declined from 3.2 bowls per day to 2.7 bowls per day. Powdered milk was served to 23% of the sample at 6 months but only 8% at 12 months; fortified infant formula (Lactogen 2) was served to 28% at 6 months and 10% at 12 months. On the contrary, as infants aged they were increasingly fed traditional family foods such as nsima served with relish. A typical Malawian relish has a standard base of boiled tomatoes, onions, and salt; the addition of ingredients such as leafy greens, beans, fish, vegetable oil, and meat are dictated by household economic status. During the 20 weeks of follow-up, serving sizes remained similar but the proportion of infants reporting nsima increased from 39% to 77%; leafy greens increased from 12% to 33%, beans increased from 13% to 26%, and fish increased from 8% to 18%. Intake of more expensive, nutrient-dense foods like meats, eggs, and soya flour remained low over the duration of follow up, peaking in consumption by 12 months at 8%, 10%, and 13%, respectively. Groundnut flour was consumed by 27% of the sample at 28 weeks and 43% of the sample by 48 weeks. When groundnut flour was eaten it was typically added to porridge (75%) or various forms of relish (25%).

Total nutrient intake by age

The amount of food in grams consumed by infants increased steadily over the 20 weeks of follow-up (Table 5.3) but total energy and protein intakes declined with age (p<0.001) to be 80% of what they were originally at 28 weeks. Regardless, both energy and protein consumption exceeded infant estimated requirements (>100%). Total fat
intake never exceeded the suggested adequate intake level of 30g and declined significantly with age (p<0.01) (Table 5.3). Micronutrient intakes generally exceeded the EAR or AI level, the exceptions being vitamin A and vitamin C. Intakes of vitamin A, vitamin B6, vitamin C, calcium, iron, and zinc declined significantly with age (p<0.01). Only folate did not follow this trend (Table 5.3).

Total nutrient intake by season

Infants typically consumed their greatest nutrient intakes during the cool season, with the exception of fat during the harvest and calcium during the hot season (Table 5.4). Energy intake was significantly lower during the hungry season (β= -0.18; 95% CI: -0.28, -0.08; p<0.016) but still remained above the EER (Table 5.4). Protein intake was over 300% of infant needs in every season; intakes during the hungry season were lower than the cool season but this difference was only marginally significant (β=0.14; 95% CI: 0.017, 0.26; p<0.05). Fat intake was greatest during the harvest season; fat intake was marginally greater during the cool season in comparison to the hungry season (β=0.18; 95% CI: 0.03, 0.33; p<0.05). Higher energy and protein intakes during the harvest and cool seasons were related to larger serving sizes of grains (i.e. porridge, nsima), fats (i.e. vegetable oil), and legumes (i.e. groundnut flour, soya).

Diet diversity across seasons did not differ, thus differences in micronutrient intakes were due to greater food availability during the harvest and cool seasons. Vitamin A and vitamin C intake never reached the AI level and were not affected by seasonality. Vitamin B6 intake consistently exceeded the AI level (0.3mg/day), reaching
its greatest level during the cool season and lowest during the hungry season (p<0.05); higher vitamin B6 intakes during the cool season were due to greater intakes of LNS, fish, beans, nuts, and maize flour. Similarly, folate intake exceeded the AI level and was significantly greater during the cool season when compared to the hungry season (p<0.016); lower folate intakes during the hungry season were due to less grains (i.e. maize flour), groundnut flour, soya flour, beans, fish, and LNS consumption. Calcium intake exceeded the AI level throughout the year and was not affected by season; calcium intake was greatest during the hot season when infant formula consumption was highest. Iron intakes consistently exceeded the EAR of 6.8mg/day and were significantly greater during the cool season in comparison to the hungry season (p<0.016). Zinc intake far exceeded the EAR cut point of 2.5mg/day in every season; the difference in intakes between the cool and hungry season was significant (p<0.016). Iron and zinc intake was greater during the harvest and cool season due to greater intakes of LNS, beans, fish, and maize.

**LNS intake by age**

At 28 weeks, 18% of infants consumed LNS in its unadulterated form, but intake declined in subsequent visits 8%, 6%, and 4% at weeks 32, 42, and 48, respectively. Instead, LNS was incorporated into the traditional maize-porridge and less commonly eaten with rice or fruit. The proportion of the sample eating LNS on the day prior to their 24-hour recall was inversely related to age; LNS was reported by 73%, 70%, 59%, 37% of the sample in their diet recall at weeks 28, 32, 42, and 48, respectively. When combining all dietary recalls, only 54% of the sample reported LNS in the 24 hours prior.
Among only consumers, the average intake was 76 grams (+70.3) but among the total sample, average intake was lower at 41 grams (+63.8).

**LNS intake by season**

The proportion of infants reporting LNS in each season was: hungry (55%), harvest (52%), cold (65%), hot (55%). Among only consumers, LNS consumption was 71g (+67) in the hungry season, 86g (+80) in the harvest season, 75g (+66) in the cold season, and 59g (+47) in the hot season. On average across the whole sample, LNS intake was greatest during the harvest season (48g) and lowest during the hot season (34g) (Table 5.5). Average LNS intake during the hungry season was 41g, significantly greater than intakes during the hot season (34g) (p<0.016); lower intakes during the hot season were due to less consumption of hot porridge.

Total dietary intake was composed of home-prepared foods and LNS, and the quality of home-prepared foods was expected to differ by season. To understand if infants relied more on LNS during the hungry season we examined the percent contribution of LNS to total nutrient intakes in each season. In relation to the total intake, LNS contributed similar proportions of energy and protein to the diet regardless of season. Of the total intake for all other nutrients, LNS contributed varying amounts by season implying the fat and micronutrient quality of home-prepared foods varied by season. Infants obtained a significantly greater proportion of total dietary fat from LNS during the hungry season (41%) in comparison to the harvest season (34%) (p<0.016) (Table 5.5).
As per vitamins, infants consumed more than half (53%) their vitamin A intake from LNS during the hungry season which was a significantly greater proportion in comparison to the harvest (p<0.016) and hot seasons (p<0.016); infants consumed 40% of total folate from LNS during the hungry season but only 33% during the harvest season (p<0.016); LNS contributed nearly half of total vitamin C intake to the diet during the hungry season but only 36% during the harvest season (p<0.016) and 40% during the hot season (p<0.016); infants were equally dependent on LNS for vitamin B6 across seasons (Table 5.5). Regarding minerals, the LNS contribution of iron to total dietary intakes did not differ across seasons; LNS contributed 35% to total calcium intake during the hungry season but only 29% during the hot season (p<0.05). Infants obtained nearly half their zinc intake from LNS during the hungry season but were less dependent on LNS for zinc during the harvest season (p<0.016) and hot season (p<0.05) (Table 5.5).

**Discussion**

In this study we investigated infant dietary intakes after early breastfeeding cessation at multiple time points between 6 and 12 months of age. The study population exhibited high rates of food insecurity and were dependent on the World Food Program family food basket and food rations from the BAN Study (maize flour, LNS). Total nutrient intake followed a seasonal pattern; for most nutrients the greatest intake occurred during the cool season and the lowest intake during the hungry season due to larger serving sizes. Consumption of LNS varied by season and infants ate the least amount during the hot season. The percent contribution of LNS to total intake of each nutrient
varied by season and indicated seasonal differences in complementary diet quality. Although infants received a constant amount of LNS for their duration in the BAN Study, both LNS intake and total nutrient intake declined with age. This finding was unexpected because the total amount of food consumed by infants increased consistently with age.

African HIV prevention studies to date have documented inadequate diets among infants after early breastfeeding cessation (Becquet et al., 2006; Lunney et al., 2008). The complementary diet among BAN Study infants, as it included LNS, was rich in nutrients and surpassed most recommended nutrient intakes. Intakes of fat, vitamin A, and vitamin C were however below the adequate intake level suggesting either a greater quantity of LNS should be consumed or fortification of these 3 nutrients be increased.

LNS was highly accepted by the BAN Study population as evidenced by consistent consumption and easy incorporation into the diet. These findings are consistent with previous studies in Ghana and Malawi that reported high acceptance of LNS among infants and mothers due to its palatability and ease of use; mothers valued LNS as a food and believed it benefited infant health (Parker et al., 2010; Flax et al., 2009; Adu-Afarwuah et al, 2008). The LNS feeding patterns of infants in this study are consistent with Flax and colleagues (2008) who observed the total number of LNS feeding episodes and the number of LNS alone episodes were highest at the start of distribution and then gradually declined. However, Flax and colleagues reported consumption of LNS in porridge remained consistent and in constrast we report a decline in LNS-porridge intake. As children progressed through the BAN Study, fewer mothers
reported feeding their child LNS on the day prior to the clinic visit. This may have been because LNS ran out the day before the mother was scheduled to return to the clinic to replenish the supply and that was the day recalled in the 24-hour dietary recalls; we hypothesize this because approximately 94% of mothers reported feeding LNS daily up until the end of the study. Since mothers perceived LNS to benefit their infant’s health it is likely that LNS sharing increased with each month among family members. In Malawi, porridge is specifically prepared for infants and valued as an age-appropriate food; the incorporation of LNS into porridge was accepted by the infants as well as mothers because it did not increase cooking or feeding time (Flax et al., 2008).

According to BAN Study protocol, mothers were counseled to feed 75 grams (400 kcal) of LNS per day but instead fed an average of 44 g (van der Horst et al., 2009). Average intake was lower than expected because only half the diet recalls reported LNS; intake declined with age and this greatly impacted the overall percent of infants reporting LNS. Infants were capable of consuming the recommended dose, as evidenced by LNS consumers eating almost double the average (76 g). Sufficient quantities of LNS were distributed to families to feed 75 g/day to the target infant but food sharing is pervasive in Malawian culture so other children in the household were likely fed LNS reducing the amount available for the index child. At an average dose of 41 grams, infant nutrient requirements were largely met except for fat, vitamin A, and vitamin C.

Although it is difficult to predict the complementary feeding patterns of BAN Study infants had LNS never been provided, studies have consistently documented
deficiencies of calcium, iron, and zinc, in the Malawian complementary diet and deficiencies of energy, protein, vitamin A, vitamin B6, folate, vitamin C, calcium, iron, and zinc in the non-breastfed child diet (Hotz & Gibson, 2001; Ferguson et al., 1989; Ferguson et al., 1993; Briand & Darmon, 2000; Dewey et al., 2004; Ferguson et al., 2006). Although it is difficult to know how mothers would have fed their children without LNS, receiving this product and dietary counseling likely promoted dietary adequacy among non-breastfed children.

With age, the average amount of food eaten in grams increased but diet quality decreased. Mothers were more likely to feed nutrient-dense, breastmilk replacements such as LNS, infant formula, and powdered milk closer to the time of weaning and less as the child aged. Mothers likely perceived a greater need for breastmilk replacements closer to the time of weaning but felt typical family foods such as nsima and relish were more appropriate as the child aged. Amongst a sub-sample interviewed after exiting the BAN Study, the mothers would refer to nsima as an essential ‘body building food’ that promotes weight gain, insist nsima needed to be consumed to achieve satiety, and believed a meal was not complete without nsima (unpublished). Nsima and age appropriate relishes (i.e. soups) are not as nutrient-dense as LNS or infant formula and as a result, infants were increasingly fed nutrient-poor family foods with time. As infants aged, LNS was fed less frequently but groundnut flour was fed more often; groundnuts are rich in energy, protein, and fat but contain much smaller amounts of micronutrients and no vitamin A or vitamin C. These two trends were likely related because during qualitative interviews mothers recalled their infants craved LNS due to its sweet nutty
taste (Parker et al., 2010) and expressed concerns that their child would resist porridge once LNS supplements stopped and began substituting it with groundnut flour in an attempt to adapt the infant palate prior to exiting (unpublished).

Nutrient intakes were typically lowest during the hungry season; intakes of energy, fat, folate, iron, and zinc were significantly lower than the cool season; the difference in intakes between the hungry and cool season was only marginally significant for both protein and vitamin B6. Based on the limited number of studies evaluating the effect of season on diet and growth, we expected nutrient intakes during the hungry season to be significantly lower than all other seasons (Quinn et al., 1990; Conroy et al., 2006; Maleta et al., 2003). This was not the case and it possible that deficits during the hungry season were muted due to the distribution of World Food Program rations to families enrolled between February 2005 and August 2006 and adequate rainfall during the growing seasons of 2005/06 and 2006/07. In addition, policies were implemented at the national level to protect households against famine and included the distribution of fertilizer subsidies to farmers, the governmental ban on maize exports between 2005-2007; and national maize production reaching the self-sufficiency goal of 2.2 MT per year (Dorward and Chirwa, 2009; JAICAF, 2008). The cool season (June, July, August) is characterized by having the shortest daylight hours, cold weather, full pantries (silos), and lowest food prices. These environmental factors increase food accessibility and may influence the amount of time mother and child spend indoors and the frequency of meal preparation.
As expected, LNS made greater contributions to nutrient intake during the hungry season since energy intake was lowest and total LNS intake remained consistent with other seasons. The average amount of LNS consumed was greatest during the post-rainy season and lowest during the hot season. LNS was the main source of fat in the diet, thus fat intake was also highest during the post-rainy season. Since LNS was mostly consumed with porridge, more was eaten during the harvest and cool season when maize was plentiful and less during the hot season when less hot porridge was prepared.

In this study, we were fortunate to have longitudinal dietary data which affords greater credibility and covered all seasons over multiple years. It is unclear if dietary intakes truly decreased as infants aged or if mothers grew tired of long study visits and reported less with time to shorten the interview. Another research team in Malawi reported LNS mixed into porridge was more likely to be shared with other members of the family than LNS fed alone (Flax et al., 2010). During qualitative interviews BAN-exited mothers admitted they would feed what the index child could not finish to other children so as not to waste the porridge-LNS mixture but never shared the LNS supplement directly; this finding highlights that infants do not always finish meals, thus we may have slightly over-estimated intake for some cases. Although it was not evident from the dietary recalls, interviews from a BAN Study sub-sample indicated almost 30% of mothers fed LNS melted and diluted in water within a baby bottle, although this was never promoted as part of the counseling by nurses. The diet recall method was not sensitive enough to capture this detail but more importantly mothers apparently failed to report infant water consumption (Parker et al., 2010). Typically, the 24-hour dietary
recall method underestimates actual intake when compared to weighed food records by 10% due to memory error of snacks consumed, the use of average recipes, and underestimations of the amount eaten during main meals (Ferguson et al., 1989; Ferguson et al., 1995). These errors were likely minimized among BAN Study mothers because they had over 6 months experience self-reporting 24-hour maternal dietary recalls and we did not use average recipes for dishes with varying ingredients. To increase recall accuracy when reporting infant consumption, BAN Study nutrition officers used standard household dishes and food models which generated dietary data of very high quality. While the weighed food record method may have increased accuracy, it was not practical for use in this large scale study.

It is likely not possible for the majority of non-breastfeeding mothers living in resource-poor settings to provide an affordable, age-appropriate, nutrient-dense complementary diet for their infant from local foods alone (Dewey et al., 2004). Furthermore, providing formula as a replacement food to non-breastfeeding infants in this setting is unwise and increases the child’s risk of malnutrition, morbidity, and mortality (Thior et al., 2006). Future HIV prevention trials promoting early breastfeeding cessation should stress the importance of feeding breastmilk substitutes for longer durations. The local perception that nsima and ordinary family foods are adequate for the growth and development of infants should be addressed during counseling. The provision of LNS as a breastmilk substitute is unique to the BAN Study and is practical for sub-Saharan Africa because it does not require refrigeration or water for preparation. The study population widely accepted LNS as a breastmilk substitute and its incorporation into the
diet promoted dietary adequacy across seasons. There is a paucity of research on the seasonal fluctuations of dietary intakes among children in Malawi and this has become more important in recent years due to the promotion of early breastfeeding cessation as an HIV prevention method. This paper will contribute to the literature on seasonality of diet, the use of LNS as a breastmilk replacement, and offer insight into the development of successful strategies to promote dietary adequacy among non-breastfeeding children.
REFERENCES


24. JAICAF. Japan Association for International Collaboration of Agriculture and Forestry. The Maize in Zambia and Malawi. URL: http://www.jaicaf.or.jp


34. Parker ME, Bentley ME, Chasela C, Adair L, Piwoz EG, Jamieson DJ, Ellington S, Kayira D, Soko AD, Mkhomawanthu C, Tembo M, Martinson F, Van der Horst CM, and the BAN Study Team. The acceptance and feasibility of replacement feeding at 6 months as an HIV prevention method in Lilongwe, Malawi: Results from the BAN Study. 2010;Submitted to AIDS Prevention and Education.


**Fig 5.1.** Flow chart illustrating the Aim 1 inclusion criteria
Table 5.1. The nutrient content of LNS supplied by the BAN Study.

<table>
<thead>
<tr>
<th>Nutrient</th>
<th>Food/ 100 g</th>
</tr>
</thead>
<tbody>
<tr>
<td>Energy</td>
<td>525 kcal</td>
</tr>
<tr>
<td>Protein</td>
<td>15g</td>
</tr>
<tr>
<td>Fat</td>
<td>35g</td>
</tr>
<tr>
<td>Vitamin A µg</td>
<td>910</td>
</tr>
<tr>
<td>Vitamin B6 mg</td>
<td>0.6</td>
</tr>
<tr>
<td>Vitamin C mg</td>
<td>53</td>
</tr>
<tr>
<td>Folic Acid µg</td>
<td>210</td>
</tr>
<tr>
<td>Iron mg</td>
<td>11.5</td>
</tr>
<tr>
<td>Zinc mg</td>
<td>14</td>
</tr>
<tr>
<td>Calcium mg</td>
<td>320</td>
</tr>
</tbody>
</table>
Table 5.2. Maternal demographic characteristics prior to labor and delivery (N=380).

<table>
<thead>
<tr>
<th>Maternal age in years (±SD)</th>
<th>26.5 (±5)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Marital Status</td>
<td></td>
</tr>
<tr>
<td>Married</td>
<td>91%</td>
</tr>
<tr>
<td>Never Married</td>
<td>2%</td>
</tr>
<tr>
<td>Separated</td>
<td>2%</td>
</tr>
<tr>
<td>Divorced</td>
<td>2.5%</td>
</tr>
<tr>
<td>Widowed</td>
<td>2%</td>
</tr>
<tr>
<td>Maternal education level</td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>11%</td>
</tr>
<tr>
<td>Completed Primary School</td>
<td>53%</td>
</tr>
<tr>
<td>Completed Secondary School</td>
<td>34%</td>
</tr>
<tr>
<td>Maternal occupation</td>
<td></td>
</tr>
<tr>
<td>Currently working</td>
<td>21%</td>
</tr>
<tr>
<td>Salaried</td>
<td>7%</td>
</tr>
<tr>
<td>Self-employed (household enterprise)</td>
<td>12%</td>
</tr>
<tr>
<td>Paternal occupation</td>
<td></td>
</tr>
<tr>
<td>Currently working</td>
<td>89%</td>
</tr>
<tr>
<td>Salaried</td>
<td>32%</td>
</tr>
<tr>
<td>Self-employed (household-enterprise)</td>
<td>28%</td>
</tr>
<tr>
<td>Household Characteristics</td>
<td></td>
</tr>
<tr>
<td>0 children &lt; 5 yrs</td>
<td>38%</td>
</tr>
<tr>
<td>1 child &lt; 5 yrs</td>
<td>45%</td>
</tr>
<tr>
<td>Refrigerator</td>
<td>3%</td>
</tr>
<tr>
<td>Electricity</td>
<td>19%</td>
</tr>
<tr>
<td>Concrete floor</td>
<td>72%</td>
</tr>
<tr>
<td>Iron sheet roof</td>
<td>82%</td>
</tr>
<tr>
<td>Personal water pipe</td>
<td>20%</td>
</tr>
<tr>
<td>Community water standpipe</td>
<td>60%</td>
</tr>
<tr>
<td>Pit latrine toilet</td>
<td>97%</td>
</tr>
</tbody>
</table>
Table 5.3. Descriptive statistics: infant dietary intake by age.

<table>
<thead>
<tr>
<th></th>
<th>28 Weeks</th>
<th>32 Weeks</th>
<th>42 Weeks</th>
<th>48 Weeks</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Food consumption</strong></td>
<td>668g</td>
<td>725g</td>
<td>865g</td>
<td>935g</td>
</tr>
<tr>
<td><strong>Energy</strong></td>
<td>160%</td>
<td>160%</td>
<td>128%</td>
<td>126%</td>
</tr>
<tr>
<td></td>
<td>[148, 171]</td>
<td>[148, 170]</td>
<td>[119, 138]</td>
<td>[117, 135]</td>
</tr>
<tr>
<td><strong>Protein</strong></td>
<td>374%</td>
<td>372%</td>
<td>295%</td>
<td>309%</td>
</tr>
<tr>
<td></td>
<td>[341, 408]</td>
<td>[342, 403]</td>
<td>[268, 322]</td>
<td>[281, 337]</td>
</tr>
<tr>
<td><strong>Fat</strong></td>
<td>28g</td>
<td>30g</td>
<td>25g</td>
<td>26g</td>
</tr>
<tr>
<td></td>
<td>[25, 31]</td>
<td>[27, 32]</td>
<td>[22, 28]</td>
<td>[23, 28]</td>
</tr>
<tr>
<td><strong>Vitamin A</strong></td>
<td>418μg</td>
<td>393μg</td>
<td>312μg</td>
<td>287μg</td>
</tr>
<tr>
<td></td>
<td>[365, 471]</td>
<td>[343, 442]</td>
<td>[266, 357]</td>
<td>[238, 336]</td>
</tr>
<tr>
<td><strong>Vitamin B6</strong></td>
<td>0.83mg</td>
<td>0.83mg</td>
<td>0.67mg</td>
<td>0.73mg</td>
</tr>
<tr>
<td></td>
<td>[0.75, 0.91]</td>
<td>[0.75, 0.91]</td>
<td>[0.61, 0.74]</td>
<td>[0.66, 0.81]</td>
</tr>
<tr>
<td><strong>Folate</strong></td>
<td>157μg</td>
<td>165μg</td>
<td>148μg</td>
<td>156μg</td>
</tr>
<tr>
<td></td>
<td>[141, 172]</td>
<td>[148, 181]</td>
<td>[132, 164]</td>
<td>[140, 173]</td>
</tr>
<tr>
<td><strong>Vitamin C</strong></td>
<td>39mg</td>
<td>36mg</td>
<td>33mg</td>
<td>31mg</td>
</tr>
<tr>
<td></td>
<td>[33, 45]</td>
<td>[31, 41]</td>
<td>[27, 38]</td>
<td>[26, 37]</td>
</tr>
<tr>
<td><strong>Calcium</strong></td>
<td>484mg</td>
<td>436mg</td>
<td>281mg</td>
<td>303mg</td>
</tr>
<tr>
<td></td>
<td>[416, 551]</td>
<td>[374, 499]</td>
<td>[238, 325]</td>
<td>[252, 354]</td>
</tr>
<tr>
<td><strong>Iron</strong></td>
<td>8.7mg</td>
<td>8.9mg</td>
<td>7.2mg</td>
<td>7.4mg</td>
</tr>
<tr>
<td></td>
<td>[7.9, 9.5]</td>
<td>[8.0, 9.6]</td>
<td>[6.5, 7.9]</td>
<td>[6.7, 8.0]</td>
</tr>
<tr>
<td><strong>Zinc</strong></td>
<td>7.8mg</td>
<td>7.8mg</td>
<td>6.1mg</td>
<td>5.8mg</td>
</tr>
<tr>
<td></td>
<td>[7.1, 8.5]</td>
<td>[7.1, 8.4]</td>
<td>[5.5, 6.7]</td>
<td>[5.2, 6.4]</td>
</tr>
</tbody>
</table>
Table 5.4. Infant nutrient intake by season.

<table>
<thead>
<tr>
<th></th>
<th>Expected total intake</th>
<th>Rainy Season</th>
<th>Post-Rainy Season</th>
<th>Cool Season</th>
<th>Hot Season</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Energy</strong></td>
<td>EER=(89*weight [kg]−100) + 22kcal</td>
<td>135%† [127, 143]</td>
<td>146% [132, 160]</td>
<td>157%† [147, 168]</td>
<td>142% [130, 155]</td>
</tr>
<tr>
<td><strong>Protein</strong></td>
<td>EAR=1.0g/kg/day</td>
<td>326%* [303, 349]</td>
<td>340% [301, 379]</td>
<td>361%* [330, 392]</td>
<td>337% [301, 373]</td>
</tr>
<tr>
<td><strong>Fat</strong></td>
<td>AI = 30g/day</td>
<td>26g† [24, 28]</td>
<td>30g [26, 34]</td>
<td>28g† [26, 31]</td>
<td>26g [22, 29]</td>
</tr>
<tr>
<td><strong>Vitamin B6</strong></td>
<td>AI = 0.3mg/day</td>
<td>0.73* [0.67, 0.79]</td>
<td>0.79 [0.69, 0.88]</td>
<td>0.83* [0.75, 0.91]</td>
<td>0.78 [0.69, 0.87]</td>
</tr>
<tr>
<td><strong>Folate</strong></td>
<td>AI = 80μg/day</td>
<td>150† [138, 163]</td>
<td>167 [147, 188]</td>
<td>168† [152, 185]</td>
<td>152 [134, 171]</td>
</tr>
<tr>
<td><strong>Vitamin C</strong></td>
<td>AI = 50mg/day</td>
<td>30 [26, 34]</td>
<td>36 [30, 43]</td>
<td>42 [35, 50]</td>
<td>37 [31, 44]</td>
</tr>
<tr>
<td><strong>Iron</strong></td>
<td>EAR = 6.8mg/day</td>
<td>7.5† [7.0, 8.1]</td>
<td>8.2 [7.3, 9.1]</td>
<td>9.1† [8.3, 9.9]</td>
<td>7.9 [7.0, 8.8]</td>
</tr>
<tr>
<td><strong>Zinc</strong></td>
<td>EAR = 2.5mg/day</td>
<td>6.6† [6.1, 7.1]</td>
<td>6.9 [6.0, 7.7]</td>
<td>7.7† [7.0, 8.4]</td>
<td>6.7 [5.9, 7.4]</td>
</tr>
</tbody>
</table>

† Differences in intake are significant (p<0.016); *Differences in intake are marginally significant (p<0.05)
Table 5.5. Percent contribution of LNS to total nutrient intakes by season.

<table>
<thead>
<tr>
<th></th>
<th>Rainy Season (Hungry season)</th>
<th>Post-Rainy Season (Harvest)</th>
<th>Cool Season</th>
<th>Hot Season</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average grams consumed</td>
<td>39g† [34, 45]</td>
<td>45g [34, 55]</td>
<td>49g [41, 57]</td>
<td>33g† [27, 39]</td>
</tr>
<tr>
<td>Energy</td>
<td>20%</td>
<td>20%</td>
<td>20%</td>
<td>20%</td>
</tr>
<tr>
<td>Protein</td>
<td>21%</td>
<td>21%</td>
<td>22%</td>
<td>21%</td>
</tr>
<tr>
<td>Fat</td>
<td>41%†</td>
<td>34%†</td>
<td>44%</td>
<td>38%</td>
</tr>
<tr>
<td>Vitamin A</td>
<td>53%†</td>
<td>47%†</td>
<td>54%</td>
<td>47%†</td>
</tr>
<tr>
<td>Vitamin B6</td>
<td>28%</td>
<td>28%</td>
<td>29%</td>
<td>26%</td>
</tr>
<tr>
<td>Folate</td>
<td>40%†</td>
<td>33%†</td>
<td>39%</td>
<td>38%</td>
</tr>
<tr>
<td>Vitamin C</td>
<td>46%†</td>
<td>36%†</td>
<td>42%</td>
<td>40%†</td>
</tr>
<tr>
<td>Calcium</td>
<td>35%*†</td>
<td>33%</td>
<td>38%†</td>
<td>29%*</td>
</tr>
<tr>
<td>Iron</td>
<td>39%</td>
<td>38%</td>
<td>38%</td>
<td>36%</td>
</tr>
<tr>
<td>Zinc</td>
<td>47%*†</td>
<td>41%†</td>
<td>47%</td>
<td>42%*</td>
</tr>
</tbody>
</table>

† Statistically significant difference from the hungry season (p<0.016); *marginal statistical significance (p<0.05)
CHAPTER VI

THE ACCEPTANCE AND FEASIBILITY OF REPLACEMENT FEEDING AT 6 MONTHS AS AN HIV PREVENTION METHOD IN LILONGWE, MALAWI: RESULTS FROM THE BAN STUDY

Abstract

International guidelines recommend exclusive breastfeeding to 6 months among HIV-infected mothers choosing to breastfeed and cessation thereafter if replacement feeding is acceptable, feasible, affordable, sustainable and safe. When mothers wean they are challenged to provide an adequate replacement diet. This study investigates the use and acceptability of a lipid-based nutrient supplement (LNS) as a breastmilk substitute when provided to infants (6-12mo) of HIV-positive mothers, as part of the Breastfeeding, Antiretroviral, and Nutrition (BAN) Study. A sub-sample of mothers (n=45) participated in interviews that explored exclusive breastfeeding, weaning, and strategies to feed LNS. Mothers reported several weaning strategies, including gradual reduction of breastfeeding, expressing breastmilk into a cup, and separation of mother and child. LNS, a peanut-based micronutrient fortified paste, was highly accepted and incorporated into the traditional diet. Weaning is a feasible HIV prevention method among this population in Malawi when supported by the provision of LNS as a breastmilk substitute.
Introduction

Mother-to-child transmission (MTCT) of HIV through breastmilk presents challenges and difficult decisions for HIV positive mothers in resource-poor settings (Piwoz and Bentley, 2005). The risks associated with not breastfeeding include infections that result from the contamination of replacement foods or the use of fluids or foods that are inadequate to support growth and development. At the time of this study, the WHO HIV and infant feeding guidelines recommended exclusive breastfeeding to 6 months, introducing complementary foods at 6 months, limiting the duration of mixed feeding, and cessation of breastfeeding once a nutritionally adequate, affordable, feasible, acceptable, sustainable and safe (AFASS) replacement diet could be provided (WHO, 2006). Recent revisions to the guidelines recommend the provision of antiretroviral drugs during pregnancy and breastfeeding, continued breastfeeding to 12 months, and gradual cessation over the duration of 1 month (WHO, 2009). These guidelines conflict with infant feeding patterns in many countries, such as Malawi, where complementary feeding typically begins at 2 months of age and continued breastfeeding to 2 years is the norm (NSO, 2005; Vaahtera et al. 2001; Corneli et al., 2007). Maternal and cultural acceptance of the WHO HIV and infant feeding guidelines is crucial for implementation and adherence.

The data for this study were collected from a sample of HIV-infected mothers who participated in the Breastfeeding, Antiretroviral, and Nutrition (BAN) Study, a postnatal HIV transmission intervention designed to evaluate the efficacy of antiretroviral therapy beyond 6 weeks in a breastfeeding population (van der Horst et al., 2009; Chasela
et al., 2010). BAN Study participants were counseled to exclusively breastfeed their infants from 0-6 months, perform rapid breastfeeding cessation at 6 months, and feed a lipid-based nutrient supplement [LNS] provided to 12 months. This energy-dense, micronutrient fortified supplement was produced locally from full-cream powdered milk, peanut butter, sugar, oil, and micronutrients and procured from one of several local producers. LNS was provided by the BAN Study to all infants to reduce the risk of malnutrition following early cessation (van der Horst et al., 2009). The supplement was designed to fulfill infant micronutrient requirements and replace the energy (400kcal) and protein (9.5g) that would have been provided by breastmilk (van der Horst et al., 2009). LNS is bacteria resistant, does not require water for preparation, and can be consumed directly from the container without cooking, making its use safe even in poor hygienic conditions (Briend, 2002).

Although a decade of research has proven this class of supplements to effectively rehabilitate severe acute malnutrition in children, and more recently moderate malnutrition (Ciliberto et al., 2005; Diop et al., 2003; Manary et al., 2004; Matilsky et al., 2009; Sandige et al., 2004; Phuka et al., 2008; Adu-Afarwuah et al., 2007; Kuusipalo et al., 2006), little is known about its acceptance and use as a breastmilk substitute among HIV-positive mothers performing early breastfeeding cessation. Previous studies among mothers of unknown HIV status in Ghana and Malawi reported LNS was well accepted by mothers and infants in terms of ease of use and palatability, value as a food, and perceived benefit to infant’s health (Adu-Afarwuah et al., 2008; Flax et al., 2009). Since mothers are primarily responsible for infant feeding in Malawi, their attitudes and beliefs
regarding EBF, early cessation, and LNS need to be understood in order to effectively
design interventions that promote the HIV and infant feeding guidelines among low-
income families in this social and cultural setting (Corneli et al., 2007; Flax et al., 2009).
This study aims to assess the feasibility of EBF, early weaning, and use of LNS as a
replacement food among HIV positive mothers to inform future guideline
implementation, thereby increasing adherence and reducing pediatric HIV infection.

Methods

The BAN Study Intervention

HIV-infected mothers enrolled in the BAN Study were counseled to exclusively
breastfeed for 24 weeks postpartum and to stop breastfeeding within an additional four
weeks. Starting at week 21, mothers with HIV-negative infants were counseled to
prepare for weaning using the following strategies: 1) Patiently teach your baby to drink
from a cup by practicing cup feeding with expressed milk in-between breastfeeds; 2)
Gradually reduce breastfeeding frequency, by lengthening time interval between feeds, at
around 5 months; 3) Set routines to help the baby learn the difference between day and
night, by breastfeed your baby late at night and reducing the number of night feedings by
using other methods to soothe the child back to sleep. BAN nurses tailored the
counseling sessions based on each mother’s experience with weaning her previous
children (Ferguson et al., 2009).

At week 24, BAN Study nurses began to teach mothers how to feed their child an
adequate diet without breastmilk. The topics covered included: appropriate age for each
food introduction, food amounts, nutrient density and variety, feeding frequency, food safety, feeding during illness, responsive feeding, and how to incorporate LNS into the diet. This information was reiterated at weeks 28, 32, 42, and 48. LNS was distributed to mothers by the BAN Study every fortnight at the clinic with instructions to feed the infant a daily ration of ~75 grams (400kcals, 9.5g protein). Mothers were given a small jar to help measure the recommended daily dose.

Overview of the Feasibility Study

Sample selection and location: Participants were eligible for this study if they were HIV-infected women, had completed the BAN Study to 12 months, lived in Lilongwe, and had an infant 15-16 months of age. As only infant feeding behaviors were investigated in this sub-study, infant HIV status was not considered. Recruitment of the sample for this sub-study took place at the same three clinics as for the BAN Study. Women were recruited in one of the following ways: at the BAN clinic following the exit interview; at a catchment clinic following HIV+ support group meetings or healthy baby clinic visits; or using home locator maps left on file for future research at the BAN Study. Forty-five HIV-positive mothers participated in the semi-structured interviews. Interviews were conducted by two trained Malawians in Chichewa within a private office at Bwaila Hospital. The interviews were audio-recorded and transcribed into Chichewa then translated into English text. Remuneration included 600MK ($4) for transport and 1kg fortified corn-soya blended flour.
Background questionnaire: The Malawian interviewers administered a background survey completed by each mother to collect data on age, marital status, education and occupation of both parents, number of household members, household socio-economic indicators, and food availability.

Research Questions & Interview Questionnaire: The interview guide was developed based on the socio-ecological model, which recognizes that human environments are multi-dimensional, resulting from the complex interplay between individual, interpersonal, institutional, community, and social policy factors (Bronfenbrenner, 1977; McLeroy, Bibeau, Steckler, Glanz, 1988; Bentley, Dicken, Mebrahtu, et al., 1991). The core research questions around which the interview guide was built are listed in Table 6.1. Ethical approval for this study was obtained from 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. Most importantly, participants in the original BAN Study had signed a consent form to be contacted after the study was completed.

Data Analysis

Transcripts were coded using MAXQDA 2007. Descriptive summaries were written immediately following each interview to capture concepts and emergent themes. Qualitative findings were summarized within four days of data collection to ensure topics needing further exploration were incorporated into the fieldwork. Data display matrices (Miles and Huberman, 1994) were created following themes to conceptualize and
compare responses between mothers. The first author and 2 interviewers developed the
coding scheme, which consisted of 13 themes, and 93 deductive and inductive codes. For
each topic, quotes were extracted from the transcripts to identify themes and mother’s
response patterns. Data reduction methods helped identify natural groupings within the
sample (e.g. food security status, household head).

**Results**

**Demographics**

Of the 45 mothers interviewed, 35 lived with their husband, 4 lived with extended
family, and 6 supported children on their own. While most married women did not have
paid employment, mothers in female-headed households earned money selling goods in
the market. Selected socioeconomic and demographic characteristics of the sample are
shown in Table 6.2.

**Exclusive Breastfeeding**

When mothers were asked to define exclusive breastfeeding they explained it as
‘breastfeeding frequently’, which is consistent with the Chichewa translation for
exclusive breastfeeding. Upon further probing, nearly every mother described the correct
protocol. The following excerpts highlight mothers’ understanding of the EBF protocol
and its purpose.

“They told me that exclusive breastfeeding means that the baby not be given any
type of foods. So it required breastfeeding the child as frequent as possible so that
he does not get hungry at any other moment.”

(Married mother, 27yrs old)
“Up to the sixth [month] you don’t give water or food because when you give food with breastmilk the baby gets the virus because the baby’s intestines are not mature and they can be scratched with the food and have sores inside. So when you feed your baby, the virus can get in.”

(Married mother, 30 yrs old)

All mothers in the sample, with the exception of one, reported following the EBF protocol. This mother worked far from home to support 7 children so the infant began mixed feeding at 2 months. Adherence, however, was challenging for women who had family members visiting the household, concerned friends, or who left the child with another caregiver for short periods of time. Among our sample of mothers, 6 (13%) were advised to feed porridge before 6 months by grandmothers, and 10 (22%) by sisters or acquaintances. Mothers were able to maintain EBF by restating the nurse’s advice or lying about feeding a mixed diet.

“They (relatives) were saying it’s better you should be giving your baby foods… So I was just saying "Ah, I will make porridge when I get home" ... but it wasn’t that I will make the porridge because I knew the truth.”

(Married mother, 23 yrs)

“[My friends] they were asking ‘Why are you not giving this child food? How about porridge?’ I was telling them that ‘No, he’s not old enough. I will start feeding him after 6 months’. So they were saying ‘No. you need to be giving him porridge to eat because in the breast he will not find anything and it only contains a little bit of milk’.”

(Married mother, 21 yrs old)

Early breastfeeding cessation

Adherence to the counseling guidelines for weaning was high when infants were 6-7 months of age: 23 mothers (51%) achieved complete breastfeeding cessation within 2 weeks, 17 mothers (38%) took 4 weeks to complete the process, and 3 mothers (7%) took approximately 6 weeks. Approximately 89% of mothers performed rapid weaning within
the recommended 4 week time period and 91% completed cessation by 28 weeks. The quotes below illustrate their motivations for performing rapid weaning.

“[The nurse] said that when the child reaches the age of 7 months… he will have started teething, right? So the child may start biting you when breastfeeding, and may get the HIV so it’s important that when he reaches 6 months, he should stop breastfeeding.”

(Widowed mother, 29 yrs old)

“Ee! I was just thinking that my baby would get infected. I was just feeling pity for my baby. It’s an injustice for him to get infected with such a virus, an innocent child.”

(Married mother, 30yrs old)

Mothers credited their ability to perform early weaning to the knowledge and skills they learned from counseling sessions; the social support received from the BAN Study nurses and fellow participants; and the provision of a breastmilk substitute. The following quote highlights a mother’s attitudes and experiences with the weaning process.

“I was happy about [getting this advice] because at first I was ignorant about it. Because otherwise I could have just abruptly stopped him without knowing how to do it well. But for them to give us that advice, it meant that the child should slowly stop.”

(Married mother, 30yrs old)

BAN Study nurses provided mothers with strong support and empowered them to think of HIV/AIDS not as a death sentence but rather as a challenge. In this quote, a mother repeats what the nurse had said to her during enrollment:

“Don’t be worried because most of the people, even us the doctors, we have this problem – this problem like yours - so you don’t have to be worried by saying that you are going to die today. But the most important thing is that you’ve come here for the first month so that you can start the antenatal care in order to protect the baby, the one you are expecting.”

(Married mother, 41yrs old)

Throughout the interviews mothers consistently expressed their positive perceptions of LNS, the breastmilk substitute, stating that it tasted great and promoted infant health.
“Ah! I used to see the chiponde [LNS] as good food for the child. When I gave him the chiponde he used to like it and you could see that his body also is becoming healthier and more energetic. And actually I was wondering is it the chiponde that is making my child to grow like this? And then I knew that there is indeed a lot of good nutrients in chiponde - especially those that give energy.”

(Married mother, 26yrs old)

The main perceived barrier to performing early cessation was household food insecurity and the fear of causing malnutrition. Most mothers expressed concerns about having enough money to provide an adequate diet, child weight loss, and the child’s age. Although mothers had fears and their attitudes towards cessation oscillated, they still believed they should follow the hospital’s advice.

“I was worried because I was stopping him while he was still very young, because I normally stop breastfeeding my children when they have reached 2 years, but this one, I stopped too early. Although I was worried, I had no choice, because if I continued breastfeeding then I was doing harm to the child.”

(Single mother, 33yrs old)

There were four women who did not disclose their HIV status to their husband at the start of the BAN Study. They faced barriers to performing early cessation. These quotes highlight some of the issues they encountered:

“So at night the breasts were swollen and my husband was like ‘why is the baby just crying’ and ’why are you not breastfeeding him’ and I said ‘he is not sucking’, but I was doing that for him not to see that I don’t want to breastfeeding the baby.”

(Married mother, 30 yrs old)

“[My ex-husband] hated that I should stop the baby from breastfeeding … when I told him that he should buy milk he was refusing…”

(Single mother, 22 yrs old)

Three mothers admitted that they did not follow the early cessation protocol. One mother was told by the BAN Study to continue breastfeeding because her child contracted HIV before 6 months and two mothers explained that they were too poor to provide an adequate diet.
“When I told the father of the child that I am supposed to stop breastfeeding the child by the 6th month, he also used to refuse. He said ‘No, don’t stop breastfeeding him at that age. Do you want him to lose weight or what? Where are you going to get the food for him when you stop breastfeeding him?’ So I stopped breastfeeding him when he was 12 months old … and actually they criticized me here at BAN to say ‘Why have you not stopped breastfeeding him yet?’”

(Mother, 42 yrs old, 7 children, earns $3.50/wk)

**Weaning Techniques:**

Most mothers reported using two or more of the weaning strategies suggested by the BAN Study. Most reduced the number of breastfeeding episodes per day and had the child drink expressed breast milk out of a cup or bottle. Additional strategies reported by mothers included leaving the child with an alternate caregiver (10); abrupt cessation (9); sleeping clothed to cover breasts (4); finding ways to soothe the child back to sleep (7); bringing food to bed (6); serving melted/diluted LNS in a baby bottle (5); supplementing with porridge (11), milk or infant formula (18); juices, tea, water, and yoghurt (8); and bananas (3). Mothers reported a wide range of effective strategies:

“So I made up my mind that he would stop breastfeeding completely. I decided to go to sleep with my clothes on so that he does not get any chance to breastfeed. During the next day I did not even breastfeed him but instead I went to the shops…”

(Married mother, 31 yrs old)

“I stopped on the 7th month because he was difficult. On that day I took him to my mother’s [house], and he slept with her. I just prepared bottled milk so that he drinks later on. The next day my mother told me not to take him [so that he gets used to it].”

(Married mother, 19 yrs old)

“To wean my child I had to use a [baby] bottle which I bought from the shops… And they gave us chiponde [LNS] … So I took the chiponde and melted it in a cup. And then I used boiled water to mix the chiponde well [water + chiponde] and poured the contents into the bottle. So I could use the cooled chiponde to feed the child whenever he starts crying.”

(Divorced mother, 31 yrs old)
Weaning Problems:

Some mothers described problems when trying to rapidly transition their baby off the breast and onto semi-solid foods. Typical infant reactions to the rapid weaning process are explained in these excerpts:

“At first he used to refuse the drinking from the bottle, but then he could cry a lot. After about 3 days he started getting used to it.”

(Married mother, 26 yrs old)

“He was difficult. I tried to give him porridge although he used to refuse it since he was eating this for the first time – he was used to the breast. So those were the problems. He could cry refusing the food that was being given to him. But I used to force him until he eats it.”

(Married mother, 26 yrs old)

Stigma of Early Breastfeeding Cessation

The recent implementation of PMTCT trials in resource-poor areas has increased public awareness in Malawi of the HIV and infant feeding guidelines and attached HIV-stigma to early breastfeeding cessation (Piwoz and Bentley, 2005). Half of the mothers in this sample believed that friends and neighbors had become suspicious of their HIV status due to early cessation. Stigma related to LNS rations was much less common. Nearly 1/3 of the sample believed they were the victim of back-biting or discrimination because they followed the HIV infant feeding guidelines. A quarter of the sample reported successfully deflecting stigma, while 1/3 third of the women had to contend with the comments of neighbors and with peer-pressure to resume breastfeeding. The women had a variety of explanations about early cessation that they used with friends or neighbors, including the following:
“I say, ‘like nowadays he will be breastfeeding in the evenings only while it’s not true… I just say ‘Ah, he only breastfeeds in the evening [because] when he breastfeeds very much I might lose weight’.”

(Married mother, 23 yrs old)

“…they also used to ask why I stopped breastfeeding my child, so I told them that it is because my child was very sick at a certain time and from that time on she has been refusing to breastfeed.”

(Divorced mother, 31 yrs old)

“They say that ‘How can I stop breastfeeding a child who is so young’. So I could tell them that ‘It’s because I would like to start work – so I will be leaving the child with my mother’’.

(Married mother, 19 yrs old)

**Lipid-based nutrient supplements**

**Acceptance of LNS**

Maternal attitudes and beliefs towards LNS were very positive. Mothers believed LNS was good for their child’s health (84%), tasted sweet and the child liked eating it (75%), increased the child’s appetite (38%), helped maintain child health without breastmilk (56%), promoted weight gain (53%), improved the child’s health (31%), and gave the child energy (29%). Our interviews revealed that most mothers attributed their infant’s good health after breastfeeding cessation to LNS consumption.

“(His weight) was increasing every month…because of the supplement that I put in his porridge. The chiponde [LNS] must have good nutrients that we could not afford to provide without it… With good appetite, he could even finish the whole plate of porridge - because it was sweet.”

(Married mother, 30 yrs old)

Mothers felt safe feeding LNS to their child as a breast milk substitute because they knew it contained substantial nutrition.

“Because I think all the nutrients that are in chiponde [LNS] are also available in the breast milk - so it is like an equivalent to breast milk.”

(Married mother, 30 yrs old)
“E! I don’t know what they put in the chiponde [LNS], but I understand there is everything that is required for growth of a child.”

(Married mother, 32 yrs old)

LNS introduction at 6-7 months:

LNS was first introduced to the infant diet between 24 and 28 weeks. Eight (18%) of the mothers reported that their babies had side-effects such as diarrhea or vomiting, and 1 experienced constipation. Only 1 infant experienced persistent vomiting and diarrhea; this mother temporarily switched to formula and reintroduced LNS later using smaller amounts and it was tolerated when mixed with porridge.

Incorporating LNS into family foods:

The traditional infant diet includes maize porridge, nsima (a thicker, more starchy version of maize porridge), & vegetable relish, meat or fish broths, fruits, and sugary juices. Most mothers listed 2 different ways they incorporated LNS into the infant diet; these methods included serving it in the staple maize porridge (100%) or cold on a spoon (53%). A third of mothers served LNS warm and diluted with water in a baby bottle (27%). Less commonly, LNS was also served as a spread on bread (9%); mixed into nsima (2%); and mixed with milk or juice (4%). Almost all infants enjoyed eating LNS mixed into hot porridge; nearly half the mothers explained their child developed cravings for the sweet LNS and would cry for it.

“I used to give chiponde [LNS] by mixing it with porridge…Yes. She used to like it a lot - up to the point that when I finish feeding the child using the (baby) bottle and put it somewhere she could cry and crawl towards it to get it herself.”

(Married mother, 30 yrs old)

Nearly half refused to eat cold LNS on a spoon or finger straight out of the jar.
“He was refusing to eat the LNS alone and when I offered it to him alone he reached the point that he could vomit. So to avoid those problems, I was just mixing it with porridge only.”

(Married mother, 28 yrs old)

Discussion

The aim of this study was to investigate the acceptance and feasibility of the WHO HIV and infant feeding guidelines and the acceptance of LNS as a breastmilk substitute among low-income, HIV-infected mothers living in a resource-poor setting. Exclusive breastfeeding was accepted and feasible as demonstrated by the high adherence rate. Early breastfeeding cessation was challenging due to maternal fears, household food insecurity and social stigma. Mothers learned to accept early weaning as an HIV prevention strategy with consistent counseling and support. The variety of weaning techniques learned during infant feeding counseling sessions made this strategy feasible. LNS was highly accepted as a breastmilk substitute and easily incorporated into the traditional infant diet.

In contrast to other studies in Malawi and elsewhere in sub-Saharan Africa (de Paoli et al., 2001; Sibeko et al., 2005; Shirima et al., 2001; Kerr et al., 2007; Kamudoni et al., 2009; NSO, 2005; Vaahtera et al., 2001), which found that exclusive breastfeeding during the first six months was not commonly practiced, nearly all mothers (98%) in the present study reported adherence to the BAN Study exclusive breastfeeding protocol. This finding was confirmed when we examined the entire BAN sample of 2,369 mothers (Chasela et al., 2010). The self-reported frequency of exclusive breastfeeding at 21 weeks post-partum was 97% on the infant-nevirapine arm and 96% on the maternal-
antiretroviral and control arms. Although it is possible that self-reports of EBF were inflated in this study due to social desirability, exclusive breastfeeding to 6 months is widely promoted for optimal feeding within the general population of Malawi, regardless of HIV status, and thus carries no stigma. Other HIV-breastfeeding interventions in southern Africa have also reported success using counseling sessions to promote exclusive breastfeeding. In Zimbabwe, the ZVITAMBO education and counseling intervention for HIV-positive mothers increased the rate of EBF by 8.4 times (Piwoz et al., 2005). In KwaZulu-Natal, South Africa, an intensive counseling intervention significantly increased the duration of EBF among HIV-positive mothers from 6% to 60% at 4 months and to 40% at 6 months (Bland et al., 2008).

The results of the present study are consistent with research reporting psychological stress and household food insecurity (Lunney et al., 2008; de Paoli et al., 2008) as barriers to early breastfeeding cessation. Similar to other qualitative study findings, mothers were motivated to stop breastfeeding early to protect their child from HIV transmission and were empowered by the knowledge that HIV infection is common (Lunney et al., 2008; Paoli et al., 2008). Among the total BAN Study population (N=2,369), only 67-68% of mothers reported completing breastfeeding cessation by 28 weeks, however, 91% of mothers in the present study retrospectively reported cessation by 28 weeks (Chasela et al., 2010). Rates of early breastfeeding cessation in this study were also much higher than reports from other larger quantitative studies (Becquet et al., 2005; Goga et al., 2009). It is likely that women in this follow-up study were more likely to be cooperative having completed 12 months of follow-up and agreed to this follow-up
study. Among the greater BAN Study population, there were some anecdotal reports that mothers who had reported weaning their infants were seen breastfeeding in the clinic hallway while waiting to be seen by research staff, creating some doubt about the integrity of self-reported cessation. In future studies, it may be useful to verify cessation by testing samples of infant blood and breastmilk for elevated levels of prolactin that are present after weaning (Thea et al., 2006).

Mothers in this sample used some of the weaning techniques suggested by the study nurses, including reducing the frequency of breastfeeding episodes and teaching the child to drink expressed breast milk out of a cup or bottle. They also reported using weaning methods that have been described in other studies in Malawi and South Africa, such as leaving infants in the care of grandmothers, wearing bras or clothes to bed, not sleeping in the same bed with the child, feeding infant formula, and taking a baby bottle to bed (Bezner-Kerr et al., 2008; Goga et al., 2009; de Paoli et al., 2008).

Among participants in the Zambia exclusive breast-feeding study (ZEBS), early breastfeeding cessation at 4 months significantly increased the risk of growth faltering, severe morbidity, and death (Arpadi et al., 2009; Kuhn et al., 2010). ZEBS participants were not provided with a breastmilk substitute upon weaning thus it is likely that such deleterious outcomes could be reduced by providing LNS. The impact of early breastfeeding cessation on infant growth among BAN Study participants is undergoing analysis currently.
The acceptability and patterns of LNS use found in this study were similar to another study in Malawi where LNS was used for rehabilitating moderately malnourished children (Flax et al., 2009). In both studies, LNS was most commonly served mixed in porridge or alone on a spoon. Unique to this study was the use of LNS served in a bottle as though it were infant formula. Mothers in the BAN Study were advised to feed the child plain LNS, but they reportedly adapted their feeding strategies to the needs of the child and household situation to ensure adequate intake.

For this study, we were fortunate to have in-depth qualitative data from a large sample size. We gained insight into the maternal perspective on the guidelines, if and why mothers followed the guidelines, and how they adapted them to their personal situation. Since mothers were counseled several times about exclusive breastfeeding, early cessation, and the use of LNS as a breastmilk substitute they may have felt uncomfortable admitting that they did not comply with the guidelines, resulting in inflated rates of guideline adherence due to a social desirability bias (Bezner Kerr et al., 2008). The retrospective nature of our data collection process may have hindered mother’s ability to accurately recall their attitudes and beliefs towards the guidelines and exact actions. In addition, our findings stemmed from a research intervention and thus measure best case scenario efficacy. It is also important to measure the effectiveness of the guidelines when implemented on a larger scale. Although guideline implementation was feasible, there may be associated health consequences in this environment thus guideline safety must still be evaluated. Additional papers will be published from this
same research group evaluating the child growth outcomes associated with early cessation and LNS feeding.

To our knowledge, this study is the first qualitative investigation into the use of LNS as a breastmilk substitute for the purpose of reducing HIV transmission. Our findings show that exclusive breastfeeding with early cessation at 6 months can be accepted and practiced by HIV-infected mothers receiving consistent counseling and an adequate breastmilk substitute. The most recent revisions to the WHO HIV and infant feeding guidelines recommend continued breastfeeding to 12 months coupled with the receipt of maternal or infant antiretroviral medications during the breastfeeding period. However, some women may not have access to or may not want to take antiretroviral medications. For these women, who wish to stop breastfeeding early, another option would be the coupling of early cessation and LNS provisions.
REFERENCES


Table 6.1. Research questions used to develop the qualitative interview guide.

<table>
<thead>
<tr>
<th>Individual Level</th>
<th>Interpersonal Level</th>
<th>Institutional Level</th>
<th>Community Level</th>
<th>Environmental Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>• What challenges do mothers face when trying to perform exclusive breastfeeding?</td>
<td>• To whom did you disclose your HIV+ diagnosis? Why or Why not?</td>
<td>• How did the BAN Study affect adherence to the HIV infant feeding guidelines?</td>
<td>• How did community social issues &amp; cultural norms influence adherence to the HIV and infant feeding guidelines?</td>
<td>• How did household food security and season influence the weaning process?</td>
</tr>
<tr>
<td>• What methods did caregivers use to perform early breastfeeding cessation?</td>
<td>• How did family members respond to non-traditional infant feeding practices?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• What are the barriers and facilitators of performing early breastfeeding cessation?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• What methods are used to feed LNS?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Table 6.2. Sample demographics

<table>
<thead>
<tr>
<th></th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age in years (±SD)</strong></td>
<td>28.5</td>
</tr>
<tr>
<td><strong>Marital Status</strong></td>
<td></td>
</tr>
<tr>
<td>Married</td>
<td>78%</td>
</tr>
<tr>
<td>Separated</td>
<td>16%</td>
</tr>
<tr>
<td>Divorced</td>
<td>4%</td>
</tr>
<tr>
<td>Widowed</td>
<td>2%</td>
</tr>
<tr>
<td><strong>Socio-economic status</strong></td>
<td></td>
</tr>
<tr>
<td>Fridge</td>
<td>9%</td>
</tr>
<tr>
<td>Electricity</td>
<td>22%</td>
</tr>
<tr>
<td>Personal water pipe</td>
<td>18%</td>
</tr>
<tr>
<td>Cement floor</td>
<td>67%</td>
</tr>
<tr>
<td>Mud floor</td>
<td>31%</td>
</tr>
<tr>
<td>Iron sheet roof</td>
<td>84%</td>
</tr>
<tr>
<td><strong>Highest level of education</strong></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>2%</td>
</tr>
<tr>
<td>&lt; 8 yrs</td>
<td>40%</td>
</tr>
<tr>
<td>8 yrs</td>
<td>24%</td>
</tr>
<tr>
<td>8-12 yrs</td>
<td>13%</td>
</tr>
<tr>
<td>12 yrs</td>
<td>20%</td>
</tr>
<tr>
<td><strong>Mother’s Occupation</strong></td>
<td></td>
</tr>
<tr>
<td>Labor (non-agriculture)</td>
<td>7%</td>
</tr>
<tr>
<td>Labor (agriculture)</td>
<td>2%</td>
</tr>
<tr>
<td>Paid employment with salary</td>
<td>4%</td>
</tr>
<tr>
<td>Self employed (non farming)</td>
<td>31%</td>
</tr>
<tr>
<td>Health Worker</td>
<td>2%</td>
</tr>
<tr>
<td>None</td>
<td>53%</td>
</tr>
<tr>
<td><strong>Primiparous</strong></td>
<td>18%</td>
</tr>
<tr>
<td><strong>Total number of Living Children</strong></td>
<td>2.8 (±1.4)</td>
</tr>
</tbody>
</table>
CHAPTER VII

THE HEALTH OF HIV-EXPOSED CHILDREN AFTER EARLY WEANING

Abstract

Concerns have been raised about the nutritional status of children in resource-poor settings who are weaned early to prevent mother to child transmission of HIV.

Objective: To examine growth and the prevalence of nutrient inadequacies of Malawian children (15-18mo) whose HIV-infected mothers had weaned them by 6 months in comparison to a sample of still-breastfed children matched on age, gender, and neighborhood. Methods: Length and weight measurements were collected from 39 community children (95% still-breastfed) and 39 non-breastfed children between 15 and 16 months, and again 2 months later between 17 and 18 months. Four 24-hour dietary recalls were collected to assess nutrient inadequacy in non-breastfed children. Results: Non-breastfed children consumed adequate amounts of energy, protein, and carbohydrate but inadequate amounts of fat. The prevalence of inadequate micronutrient intakes was: 46% for vitamin A; 20% for vitamin B6; 69% for folate; 13% for vitamin C; 19% for iron; 23% for zinc. Regarding growth, BAN-exited girls exhibited significantly lower length and weight velocity than their matched community comparison (p<0.02) and lower length velocity than BAN-exited boys (p<0.10). Conclusions: Early breastfeeding cessation caused children to consume deficient diets; non-breastfeeding girls experienced reduced growth velocity in comparison to matched breastfeeding girls. Importance:
Early breastfeeding cessation has trade-offs in resource-poor settings such as inadequate dietary intakes and reduced infant growth. Long-term intervention such as nutritional supplementation is needed to make this HIV prevention method safer.

**Introduction**

HIV-infected mothers living in resource-poor settings are advised to exclusively breastfeed (EBF) from 0-6 months, take antiretroviral drugs during pregnancy and breastfeeding, introduce complementary foods at 6 months, and stop breastfeeding once a nutritionally adequate, affordable, feasible, acceptable, sustainable and safe (AFASS) replacement diet can be provided (WHO, 2006; WHO, 2009). Since breastmilk is the most cost effective infant feeding strategy for food insecure families and supplies optimal nutrition and protection against common childhood infections (e.g. diarrhea, pneumonia), early cessation is potentially dangerous for infants living in resource-poor settings (Habicht, DaVanzo, & Butz, 1986; Victora et al., 1987). Malawian infants are traditionally fed a complementary diet based on maize porridge, in addition to breastmilk (Corneli et al., 2007; National Statistical Office, 2005; Hotz and Gibson, 2001). The combination of traditional complementary foods and breastmilk often cannot meet infant nutrient needs thus the traditional diet alone increases the risk of malnutrition (Dewey, Cohen, & Rollins, 2004; Adu-Afarwuah et al., 2007; Dewey and Brown, 2003). Among low-income families in Malawi, the addition of nutrient dense foods to the child diet is essential but often limited by seasonality and cost (Chirwa, 2009). Children are most susceptible to growth faltering during the first 2 years of life (Victora, de Onis, Hallal, et al., 2010), and nutritional insult during this critical developmental window can have
lifelong health consequences including increased risk of child mortality, short adult stature, reduced intellectual development and economic productivity, and low offspring birth weight (Grantham-McGregor et al., 2007; Black et al., 2008; Victora et al., 2008). Considering the potential health risks associated with early breastfeeding cessation, we aimed to evaluate the effects of using early breastfeeding cessation as an HIV prevention strategy in a resource-poor setting by investigating dietary adequacy and growth after early weaning.

The data for this study were collected from a sub-sample of HIV-infected mothers and their infants, who participated in the Breastfeeding, Antiretroviral, and Nutrition (BAN) Study. The BAN Study was a randomized clinical trial designed to evaluate antiretroviral interventions to reduce mother-to-child transmission of HIV (van der Horst et al., 2009). Upon early breastfeeding cessation at 6 months, infants were provided with a lipid-based nutrient supplement (LNS) as a breastmilk substitute to ensure adequate nutrition to 12 months. When infants exited the BAN Study at 12 months they no longer received LNS. Of concern are the dietary intakes and nutritional status of non-breastfed children after LNS supplementation ceased, and this forms the basis of the current study. In particular, nutrients of concern for the non-breastfed child in urban Malawi include energy, protein, fat, vitamin A, vitamin B6, folate, vitamin C, calcium, iron, and zinc (Dewey, Cohen, Rollins, 2004; National Statistical Office, 2005).

We evaluated dietary intakes among a sample of 15 to 18 month old children after exiting the BAN Study to determine the prevalence of nutrient inadequacies. To
determine if BAN-exited children exhibited significantly greater growth faltering, we also compared the anthropometric status of BAN-exits (non-breastfeeding) to a sample of non-participants (95% still breastfeeding) from the community matched on age, gender, and local health clinic. The purpose of this paper is to provide evidence to organizations such as the WHO regarding the best options for infant feeding in resource constrained settings where breastfeeding increases the risk of HIV transmission.

**Methods**

**The BAN Study**

The Breastfeeding, Antiretroviral, and Nutrition (BAN) study was a randomized controlled clinical trial conducted in Malawi between 2004 and 2010. 2370 HIV-infected mothers were assigned to two main study interventions: a 2-arm maternal nutritional intervention to promote maternal health, and a 3-arm antiretroviral intervention—with drugs given for up to 6 months to the mother, the infant, or neither—to prevent HIV transmission during breastfeeding (Chasela et al., 2010; van der Horst et al., 2009). All mothers were counseled to exclusively breastfeed to 6 months (~24 weeks), and then rapidly transition to a replacement diet, achieving early breastfeeding cessation by 7 months. To reduce the risk of malnutrition following early breastfeeding cessation, mothers were provided with LNS made locally from full-cream powdered milk, peanut butter, sugar, oil, and micronutrients (Briend, 2001). This breastmilk substitute was designed to fulfill infant micronutrient requirements and replace the energy (400kcal) and protein (9.5g) that would have been provided by breastmilk (van der Horst et al., 2009). Lipid-based nutrient supplements are bacterial resistant, do not require water for
preparation, and can be consumed directly from the container without cooking, making its use safe even in poor hygienic conditions (Briend, 2002). LNS was provided after weaning until infants exited the study at 12 months.

Between 24 and 48 weeks, mothers were taught how to feed their child an adequate diet without breastmilk using a Complementary Feeding Counseling Script that emphasized the appropriate age for each food introduction, serving sizes, nutrient density and variety, feeding frequency, food safety, feeding during illness, and responsive feeding (Ferguson et al., 2009). Specifically, mothers were instructed to practice responsive feeding; feed frequently with patience to ensure a maximum amount was consumed; prepare soft, thick porridge; enrich porridge with cooking oil, groundnut flour, sugar, honey, groundnuts, milk, soybeans, meat, or fish; ensure diet diversity to prevent micronutrient deficiencies; avoid sweets and soft drinks; feed 4 to 5 meals and 2 to 3 snacks per day.

**Follow-up Study**

A follow-up was conducted at Bwaila Hospital in central Lilongwe, Malawi between April 2008 and March 2009. This study evaluated the dietary intakes of a sample of children after exiting the BAN Study (BAN-exits) when they were between 15 and 18 months of age to determine the prevalence of nutrient inadequacies among non-breastfed children; and the anthropometric status of BAN-exited (non-breastfeeding) infants in comparison to a matched sample of infant non-participants. BAN-exited children were eligible to participate in this follow-up study if they: were singletons at
birth, carried to term (>36 weeks), and had completed the BAN Study to 12 months, were 15-16 months of age for their first follow-up study visit, and were willing to return 2 months later. For each child in the BAN-exited group, a non-participant child was recruited into a comparison group matched on age, gender, and local health center.

The sample size of 40 children per group was determined from power calculations described in the growth comparison section, below. Recruitment occurred at the same 3 urban health clinics as the BAN Study and continued until a minimum of 80 children completed the study. Mother-child pairs were recruited in one of the following ways: at the BAN clinic following the exit interview; at a catchment clinic following HIV+ support group meetings; at a catchment clinic following healthy baby clinic visits; or using home locator maps left on file for future research at the BAN Study. Compensation to participants included 600MK ($4) for transport and 1kg fortified corn-soya blended flour for each follow-up study visit.

**Dietary consumption**

Dietary intake data were collected only from BAN-exited children. Two 24-hour diet recalls were collected from each child within one week between 15 and 16 months of age, and again between 17 and 18 months of age, for a total of 4 recalls. Diet recalls were conducted by BAN nutrition officers. Mothers were prompted to recall what their child had eaten over the past 24 hours using food models, standard household dishes and utensils, and recording recipes. Nutrient consumption was calculated using a Malawi food composition table (FCT) developed by Rosalind Gibson (Ferguson et al., 1995).
Additional nutrient information was added from a Tanzanian FCT (Lukmanji et al., 2008), the USDA nutrient database (USDA, 2010), or directly from the manufacturer (i.e. Mahewu, LNS, Lactogen infant formula). The resulting database had the nutritional value of individual food items as well as mixed dishes based on standard recipes (e.g. nsima).

**Anthropometrics**

Anthropometrics were obtained from each child, once between 15 and 16 months and again between 17 and 18 months. The sample size of 40 per group was feasible to recruit within our time frame and allowed us to be able to detect a 0.78 difference in mean Z-scores between samples, with 80% power and significance set at 10% (National Statistical Office, 2005).

Two trained Malawian research assistants recorded recumbent length following standardized protocol using the UNICEF standard Pediatric Length board (to the nearest 0.1cm) and a calibrated Tanita infant scale (to the nearest 0.01kg) (MCHB, 2000). All measurements were conducted at the BAN Study clinic, made in triplicate and averaged to generate a final value. Length-for-age Z scores (LAZ), weight-for-age Z scores (WAZ), and weight-for-length Z scores (WLZ) were calculated in Microsoft Excel using the LMS method (Box-Cox power, L(t); median, M(t); and coefficient of variation, S(t)) and standards from the 2006 international WHO Child Growth Standards for breastfed children (Cole and Green, 1992). Stunting, underweight, and wasting were respectively defined as having an LAZ, WAZ or WLZ score less than 2SD below the WHO median.
Background questionnaire

A background survey was administered to obtain data from each mother on age, marital status, education and occupation of both parents, number of household members, household socio-economic indicators, and food availability. Ethical approval for this study was obtained from 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. Most importantly, participants in the original BAN Study had signed a consent form to be contacted after the study was completed.

Seasonality

The Malawian climate is characterized by 4 seasons: rainy (November to April), post-rainy (April to May), cool (May to mid-August), and hot (mid-August to November). The rainy season is known locally as the ‘hungry season’ because food is limited during this time. For each BAN-exited child, a matched child was recruited and measured within the same month; however, high attrition among the matched comparison extended their enrollment period and reduced seasonal overlap between the samples. Since child growth velocity is affected by season (i.e. weight gain peaks in cool season and lags in rainy season), a variable was created to measure percent exposure to the hungry season during the 2 months prior to each study visit. All regression models used to compare growth outcomes controlled for the extent of exposure to the hungry season.
Diet recalls were collected from BAN-exited infants between April 2008 and December 2008 and did not greatly overlap the hungry season.

**Data analysis**

Nutrient intake adequacy was analyzed only within the BAN-exited sample, since the comparison group was still receiving breastmilk. Nutrient intake distributions were calculated from the 24-hour dietary recalls. The prevalence of inadequacy for each nutrient, approximated from the proportion of children consuming less than the Estimated Average Requirement cut-point (IOM, 1997; IOM, 1998; IOM, 2000; IOM, 2001; IOM, 2002/2005), was estimated using computer Software for Intake Distribution Estimation (C-SIDE, version 1.0, 1996; Department of Statistics, Iowa State University) (Carriquiry, 2003; Dodd, 1996; Guenther et al., 1997). C-SIDE requires multiple dietary recalls per individual to reduce within-individual day-to-day variation and enable an estimation of within- and between-individual variation (Dodd et al., 2006; Dodd, 1996). The EAR equivalent for energy is EER (expected energy requirement) and can be calculated for each individual (15-18mo) based on their body weight \[
EER = (89 \times \text{weight [kg]} - 100) + 20\text{kcal}.
\] For calcium, only an adequate intake (AI) level exists preventing the calculation of inadequacy prevalence. Total protein, carbohydrate, and fat intakes were compared to the Acceptable Macronutrient Distribution Ranges (AMDR) (IOM, 2002/2005). Typical foods consumed and sources of certain vitamins will also be examined using the dietary recalls.
We used longitudinal random effects sex-stratified models to evaluate group differences in WAZ, LAZ, WLZ, stunting, wasting, and underweight. The models accounted for exposure to the hungry season, maternal age, parity, visit (at 15 vs 17 months), and an interaction between visit number and group. Child’s age was not included because the age range was small and groups were age-matched; maternal age and parity were highly correlated so only maternal age was used. Based on the findings from the longitudinal models, we did further group comparisons of weight and length velocity between the 2 visits using one-way ANOVA (Lepage et al., 1996).

**Results**

**Subjects**

A total of 99 children were recruited into the study, 81 children completed the study, and 78 were included in the analysis *(Fig 7.1)*. Three children were excluded because they had anthropometric Z-Scores more than 4 standard deviations from the WHO median. A sensitivity analysis found their exclusion did not change the direction of the relationships but attenuated the growth velocity differences between groups in girls as well as boys. Of the 39 community comparison children, 37 (95%) were still breastfeeding at 15 months. Of the 39 BAN-exited children, none were breastfed past 7 months.

**Socio-demographic characteristics**

In both samples, most households were headed by males and had more than 1 child younger than 5 years. Selected socioeconomic and demographic characteristics of
the sample are shown in Table 7.1. Two notable differences between groups were that non-BAN mothers were younger and more likely to be primiparous.

**Nutrient adequacy**

On average, the diet of this non-breastfeeding BAN-exited sample exceeded protein and carbohydrate requirements but was deficient in energy and fat, resulting in inadequacy prevalence rates of 0.5% and 6.6%, respectively (Table 7.2). Nutrient intakes at 15-16 months were similar to intakes at 17-18 months. Overall, energy intake was composed of carbohydrate (66%), protein (11%), and fat (22%). Approximately 65% of BAN-exited children consumed energy deficient diets and 81% consumed an inadequate amount of fat (Table 7.2). Micronutrient intakes were not normally distributed (skewed right) and are therefore presented as medians. Median intakes of vitamin B6, vitamin C, iron, and zinc were above their respective EAR but median vitamin A and folate intake fell below. The prevalence of inadequate micronutrient intakes was: 46% for vitamin A; 20% for vitamin B6; 69% for folate; 13% for vitamin C; 19% for iron; 23% for zinc (Table 7.2). Mean calcium intake was below the adequate intake level at 172mg and thus there is a reasonable likelihood that dietary intakes were inadequate (Table 7.2).

In addition to the general diet description above, we further explored if any dietary differences existed between genders. The only difference was that girls consumed significantly less fat (Student’s t-test, p<0.05) and more carbohydrate as a proportion of their total energy intake (Student’s t-test, p<0.05) than boys. Boys
consumed 24% of total calories from fat and 64% from carbohydrate sources; girls consumed only 20% from fat calories and 69% from carbohydrate.

**Typical Food Consumption**

Diets were based primarily on maize flour and consumed in the form of porridge and nsima. Nsima is a stiff porridge made from maize flour and eaten with a relish, an accompanying vegetable, bean, fish or meat side dish. Together porridge and nsima provided 60% of total energy. On average, children received 2.25 servings of porridge (200g) per day which provided 350kcal (53g carbohydrate; 12g protein; 10g fat). The typical recipe included maize flour, water, sugar, and salt but the frequent addition of soya (26%) and groundnut flour (33%) increased protein and fat consumption. Child intakes were deficient in fat but surpassed the protein recommendation (Table 7.2). Protein was mainly consumed from porridge (10.5g/day) due to the presence of soya flour, groundnut flour, and large quantity of maize flour.

When we examined food choices by gender we found boys were 3.9 times more likely to receive fresh or powdered milk, 1.2 times more likely to receive animal products, 1.2 times more likely to consume vegetable oil in their mixed dishes. Girls were 1.44 times more likely to consume fruits. The frequency of groundnut and soya flour consumption was similar between genders. Overall, boys were fed slightly more frequently and slightly larger portion sizes.
Sources of vitamin A, folate, fat

Dietary intakes were deficient in fat, vitamin A, and folate. The primary sources of vitamin A in the diet were leafy green vegetables and tomatoes (vitamin A precursors). Less frequent were animal products (e.g. liver, eggs, and milk) and sweet potatoes. Folate was mostly consumed from groundnut flour and soya flour in porridge. Additional sources included fruits, other vegetables, beans, and leafy green vegetables but small portion sizes limited intake. The main source of fat in the child diet was derived from groundnut flour and soya flour.

Growth Comparison

Both BAN-exited and comparison children were below the WHO reference median but still of moderately healthy weight. Table 7.3 lists the WAZ scores of each sub-group adjusted for exposure to the hungry season, maternal age, visit number, and an interaction between visit and group. The interaction term was significant (p=0.076) implying that BAN-exited girls had a different pattern of change in their WAZ scores over time. Weight velocity significantly differed between the groups among girls; BAN-exited girls gained an average of 0.02g/kg/day and the community girls gained an average of 0.05g/kg/day (Student’s t-test p=0.015) (Table 7.3). The WAZ scores of BAN-exited and community boys did not significantly differ; velocity of weight gain among BAN boys was 0.02g/kg/day and community boys was 0.03g/kg/day (Table 7.3).

Both groups were on average shorter than the WHO 2006 reference median. Table 7.3 lists the LAZ scores of each sub-group adjusted for exposure to the hungry
season, maternal age, visit number, and an interaction between visit number and ban. Overall, the LAZ scores of BAN-exited and community comparison boys did not differ, nor did length velocity differ by group among boys (Table 7.3). The LAZ scores of BAN-exited and community girls did not differ but the group by visit interaction term was significant suggesting that BAN-exited girls did worse over time (p=0.076). This is further shown by the lower length velocity of BAN-exited girls (Student’s t-test p=0.014) (Table 7.3).

The combination of short stature and moderately healthy weight status resulted in WLZ scores above the WHO median. The adjusted WLZ scores are listed below in Table 7.3. WLZ scores did not significantly differ between girl samples or boy samples. The LAZ, WAZ, and WLZ scores did not significantly differ between genders within either sample. Weight velocity did not differ between genders in either group, however, length velocity differed between males and females within the BAN-exited (p=0.08).

**Malnutrition**

At 15-16 months, 36% of BAN-exits and 49% of community children were stunted; at 17-18 months, 31% of BAN-exited children were stunted and 31% of community children were stunted. Stunting was more prevalent in community boys than BAN-exited boys (p=0.02). At 15-16 months, 5% of BAN-exits and 13% of the community comparison were underweight; at 17-18 months, 5% and 2% of BAN and community children were underweight, respectively. While none of BAN-exited children
were wasted, 5% of community children were wasted at 15-16 months and 5% were wasted at 17-18 months.

**Discussion**

This study provides insight into the diets of 15-18 month old children, living in a resource-poor setting within Malawi, who were weaned from the breast at 6 months and who received a lipid-based nutrient supplement (LNS) through 12 months of age as a substitute for breastmilk. After children stopped receiving LNS as a breastmilk substitute, their diet was maize-based but enriched with purchased ingredients, such as groundnuts and soya. Overall, the diet without breastmilk was rich in carbohydrate and protein but deficient in energy, fat and micronutrients. In comparison to BAN-exited children, the breastfed comparison sample had better growth outcomes over the 2 month follow-up.

The results of the present study are consistent with dietary modeling studies that reported difficulties constructing affordable child diets from traditional food sources to provide sufficient energy, 30% of calories from fat, and adequate amounts of vitamin A, thiamine, riboflavin, vitamin B6, folate, vitamin C, calcium, iron, and zinc (i.e. ‘problem nutrients’) (Dewey, Cohen, Rollins, 2004). A previous complementary diet study in Malawi found that young children were fed mainly maize flour, few animal-source foods, and inadequate amounts of energy, calcium, iron and zinc (Hotz and Gibson, 2001; Ferguson et al., 1993). The Malawi Demographic and Health Survey reported that meat/fish/shellfish/poultry/eggs are consumed by children 16-19mo less than once a day,
breastfeeding or not breastfeeding, but small servings of fruits and vegetables are eaten 3 to 4 times a day. Also consistently reported are high rates of childhood anemia and sub-clinical A deficiency, thus our findings of inadequate intakes of iron, vitamin C, folate, and vitamin A are not surprising (National Statistical Office, 2005; MOHP, 2003).

Stunting is an indicator of chronic malnutrition. We believe BAN-exited children were less stunted at 15-16m than the comparison sample because they consumed LNS from 6-12mo and which offered them protection against growth faltering up to 12 months (Adu-Afarwuah et al., 2007). Wasting is indicative of acute malnutrition and a greater proportion of the community comparison was measured during the hungry season which may explain their greater wasting prevalence. Regardless, the prevalence of stunting, wasting, and underweight within these 2 child samples were lower than national average for this age group in Malawi (National Statistical Office, 2005). Previous studies in Malawi found height and weight velocity vary according to a seasonal pattern after 12 months of age (Maleta et al., 2003) possibly due to greater dependence on the external environment. Children experience negative weight velocity during the hungry season (Dec-Jan), peak weight gains following the harvest (May, June, and July), and greatest height gains 3 months after the harvest (August-October).

In this region of the world, there is little evidence of gender preference; the anthropometric Z-scores of boys and girls under 5 years are similar within the Malawi Demographic and Health Survey (National Statistical Office, 2005). While the adjusted Z-scores presented in this study do not differ between boys and girls in either sample,
length velocity significantly differed between genders within the BAN-exited sample, suggesting that we might expect to see greater differences between their Z-Scores as they age. Both the length and weight velocity of BAN-exited girls fell significantly below that of community girls, and the same difference was not observed between boy samples. We suspect the growth of BAN-exited girls was negatively impacted by social factors such as traditional differences in diet quality (Ferguson et al., 1995). Families were 4 times more likely to purchase milk products for male children than female children; suggesting households with boys allocated their resources to ensure boys continued receiving milk in the absence of breastmilk; this finding may be restricted to low-income, non-breastfeeding, HIV-infected populations. Girls consumed a significantly lower proportion of calories from fat and made up the difference in carbohydrate. While neither gender achieved the AMDR for fat, girls fell further from the 30-40% recommendation which may have contributed to their reduced growth outcomes (Lifschitz and Moses, 1989).

There is limited prior evidence of son preference in sub-Saharan Africa (Basu & de Jong, 2006; Klasen & Wink, 2003; Kabeer, 2003), especially Malawi, where vaccination coverage is equal, the percent of sick children receiving adequate health care does not differ by gender, and the under 5 child mortality rate is greater among boys than girls (166 vs. 149 per 1,000) (National Statistical Office, 2005). Thus our findings could be the consequence of a small sample size, indicate differences between HIV infected families and the general population, or more likely be attributable to factors currently unknown. Poor growth outcomes among girls are particularly problematic because the
deleterious effects of malnutrition can be passed on to their future offspring (Victora et al., 2008).

All BAN-exited children tested HIV-negative therefore we cannot attribute their lack of growth to HIV infection. We hypothesize that the community comparison had better growth outcomes because most were still breastfeeding at 15 months (mean intended duration = 28 months) and were buffered against seasonal changes. Non-breastfeeding children are more vulnerable to dietary deficiencies and are not protected against infections by maternal antibodies; thus their recovery from infection is impaired which can have negative impacts on growth and recovery from growth faltering.

Breastmilk provides a superior diet, contains anti-infective properties, promotes gastrointestinal tract development, a healthy immune system, and lower morbidity incidence (Goldman, 1993; Hanson, 1998; Duncan et al., 1993; Dewey et al., 1995; Cushing et al., 1998; Bachrach et al., 2003). Early breastfeeding cessation as an HIV-prevention method has been associated with increased risk of serious gastroenteritis (Onyango-Makumbi, 2009), gastroenteritis-associated mortality (Kafulafula, 2010), growth faltering (Arpadi et al., 2009), nutrient deficiencies (Lunney et al., 2008) and failed to improve the rate of HIV-free survival (Kuhn et al., 2008).

Infants who participated in the BAN Study were all indirectly exposed to antiretroviral medicines during labor, delivery and the first 2 weeks of life, a third received ARVs directly during the 6 month breastfeeding period, and a third ingested
their mother’s ARVs indirectly through breastmilk to 6 months (van der Horst et al., 2009). While maternal HIV infection is documented to impair prenatal growth (Bulterys et al., 1994) there is conflicting evidence on whether or not it negatively impacts postnatal growth (Hankin et al., 2005; Paul et al., 2005). Exposure to ARVs during pregnancy and delivery does not affect postnatal growth (Briand et al., 2006) and research to date has not evaluated if postnatal ARVs impact infant growth. It is possible that HIV-exposed infants do not develop sufficient nutrient stores due to combination of inadequate maternal intake or bodily stores and the increased energy and nutrient needs of HIV infection (Grinspoon et al., 1998; Friis et al., 2001; Friis et al., 2001a). Such inadequate infant stores would be quickly depleted after birth if breastmilk was only consumed for a short time and replaced by inadequate complementary foods, resulting in growth faltering.

The greatest limitation to our study was the accuracy and comparability of recumbent length measurements. Children consistently prove difficult to measure using a length board and we were forced to omit 3 due to suspected measurement error in an attempt to improve validity. Differences in the timing of participation between the 2 groups created systematic bias and limited the conclusions we could draw by comparing the growth of non-breastfeeding children to community children. We suspect that the difference in growth velocities documented here would be further amplified had there been greater seasonal overlap between breastfeeding and non-breastfeeding samples. In addition, differences in morbidity incidence would have provided great insight. Our results suggest that LNS protected child growth up to 12 months and provided a buffer
for the first months after exiting the BAN Study. WAZ and WLZ scores were relatively healthy at 15 months but LAZ scores were not, and growth velocity scores were negatively impacted between 15 and 18 months by early breastfeeding cessation, when no substitute was provided after 12 months. Lack of information on nutritional adequacy of the comparison group is also a limitation.

Previous studies among Malawian children found mean intakes derived from the 24-hour recall were within 10% of values calculated from weighed food records (Ferguson et al., 1989). The 24-hour recall underestimated actual intake due to memory error reporting snack consumption, the use of average recipes, and underestimations of the quantity consumed from the main meal (Ferguson et al., 1989; Ferguson et al., 1995). In comparison, the present study was less affected by such error because BAN Study mothers had 12 months experience reporting 24-hour dietary recalls, we did not use standard recipes for dishes with varying ingredients, and mothers were prompted to remember accurate intakes using standard household measures and food models.

To our knowledge, this is the first study to investigate growth outcomes one year after performing early breastfeeding cessation as an HIV prevention method, and in comparison to a matched community sample. By conducting this assessment, we were able to investigate the dietary deficits of non-breastfeeding children and confirm that the traditional child diet was in fact deficient in macronutrients and micronutrients, the most concerning of which were fat, vitamin A, and folate. This information will help tailor
future complementary feeding guides used to counsel HIV-infected mothers choosing to not breastfeed in resource-poor settings.

Our findings aim to inform organizations such as the WHO regarding best infant feeding practices where breastfeeding increases the risk of HIV transmission. Recent revisions to the WHO HIV and infant feeding guidelines recommend continued breastfeeding to 12 months coupled with the receipt of maternal or infant antiretroviral medications during the breastfeeding period (WHO, 2009). While we agree with the WHO revisions, we must not forget that starting at 12 months these young children will still require adequate supplementation to support growth and development. Early breastfeeding cessation as an HIV prevention method appears to have trade-offs in resource-poor settings such as inadequate dietary intakes and reduced infant growth. This study raises concerns about the safety of breastfeeding cessation prior to 2 years without long-term intervention such as nutritional supplementation. Further investigation is needed to determine if gender differences in susceptibility to growth faltering do exist. Future public health programs implementing early breastfeeding cessation should consider providing long term supplementation with LNS.
REFERENCES


49. Lunney KM, Jenkins AL, Tavengwa NV, Majo F, Chidhanguro D, Iliff P, Strickland GT, Piwoz E, Iannotti L, Humphrey JH. HIV-positive poor women may stop breast-


Fig 7.1. Subject enrollment flow chart.
Table 7.1. Demographics by child sample

<table>
<thead>
<tr>
<th></th>
<th>BAN-exit Sample N=39</th>
<th>Matched Sample N=39</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age in years (+SD)</strong></td>
<td>28.8 (+5.9)</td>
<td>23.6 (+3.8)</td>
</tr>
<tr>
<td><strong>Marital Status</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Married</td>
<td>75.6%</td>
<td>93%</td>
</tr>
<tr>
<td>Separated</td>
<td>17%</td>
<td>7%</td>
</tr>
<tr>
<td>Divorced</td>
<td>5%</td>
<td>0</td>
</tr>
<tr>
<td>Widowed</td>
<td>2%</td>
<td>0</td>
</tr>
<tr>
<td><strong>Maternal Education</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>2%</td>
<td>0</td>
</tr>
<tr>
<td>&lt; 8 yrs</td>
<td>39%</td>
<td>46%</td>
</tr>
<tr>
<td>8 yrs</td>
<td>27%</td>
<td>27%</td>
</tr>
<tr>
<td>8-12 yrs</td>
<td>15%</td>
<td>10%</td>
</tr>
<tr>
<td>12 yrs</td>
<td>17%</td>
<td>17%</td>
</tr>
<tr>
<td><strong>Mother’s Occupation</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Currently working</td>
<td>45%</td>
<td>39%</td>
</tr>
<tr>
<td>Self-employed (non-farming)</td>
<td>30%</td>
<td>24%</td>
</tr>
<tr>
<td><strong>Husband’s Occupation</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Salaried employment</td>
<td>58%</td>
<td>58%</td>
</tr>
<tr>
<td>Self-employed (non-farming)</td>
<td>30%</td>
<td>37%</td>
</tr>
<tr>
<td>Other (military, landlord)</td>
<td>6%</td>
<td>2.5%</td>
</tr>
<tr>
<td>Unemployed</td>
<td>3%</td>
<td>2.5%</td>
</tr>
<tr>
<td><strong>Fertility</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Proportion primiparous</td>
<td>17%</td>
<td>46%</td>
</tr>
<tr>
<td>Parity</td>
<td>3.4 (+1.9)</td>
<td>2.1 (+1.4)</td>
</tr>
<tr>
<td>Total number of Living Children</td>
<td>2.9 (+1.4)</td>
<td>2.0 (+1.3)</td>
</tr>
<tr>
<td>Number of Children &lt; 5 yrs in Household</td>
<td>1.7 (+0.9)</td>
<td>1.5 (+0.6)</td>
</tr>
<tr>
<td><strong>Socio-economic Status</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Refrigerator</td>
<td>7%</td>
<td>5%</td>
</tr>
<tr>
<td>Electricity</td>
<td>22%</td>
<td>12%</td>
</tr>
<tr>
<td>Personal water source</td>
<td>29%</td>
<td>17%</td>
</tr>
<tr>
<td>Traditional latrine with roof</td>
<td>66%</td>
<td>75%</td>
</tr>
<tr>
<td>Cement floor</td>
<td>66%</td>
<td>78%</td>
</tr>
<tr>
<td>Iron sheet roofing</td>
<td>83%</td>
<td>80%</td>
</tr>
</tbody>
</table>
Table 7.2. Macronutrient and select micronutrient intakes from the replacement diet

<table>
<thead>
<tr>
<th>Nutrient</th>
<th>Expected total intake</th>
<th>Median intake</th>
<th>Mean (SD) intake</th>
<th>Inadequacy prevalence (adjusted)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Energy</strong></td>
<td>EER = (89 x weight[kg] – 100) + 20kcal</td>
<td>91.5%</td>
<td>92% (+40%)</td>
<td>65%</td>
</tr>
<tr>
<td><strong>Protein</strong></td>
<td>EAR = 0.87g/kg/day</td>
<td>250%</td>
<td>221% (+105%)</td>
<td>0.5%</td>
</tr>
<tr>
<td><strong>Protein AMDR</strong></td>
<td>5 - 20% of Energy</td>
<td>11.2%</td>
<td>11.5% (+2%)</td>
<td>2.3%</td>
</tr>
<tr>
<td><strong>Fat AMDR</strong></td>
<td>30 - 40% of Energy</td>
<td>21.7%</td>
<td>22% (+6%)</td>
<td>80.8%</td>
</tr>
<tr>
<td><strong>Carbohydrate AMDR</strong></td>
<td>45 - 65% of Energy</td>
<td>66.7%</td>
<td>66% (+7%)</td>
<td>6.6%</td>
</tr>
<tr>
<td><strong>Vitamin A</strong></td>
<td>EAR = 210µg/day</td>
<td>143µg</td>
<td>235µg (+228)</td>
<td>46%</td>
</tr>
<tr>
<td><strong>Vitamin B6</strong></td>
<td>EAR = 0.4mg/day</td>
<td>0.58mg</td>
<td>0.7mg (+0.58)</td>
<td>20%</td>
</tr>
<tr>
<td><strong>Folate</strong></td>
<td>EAR = 120µg/day</td>
<td>113µg</td>
<td>104µg (+67)</td>
<td>69%</td>
</tr>
<tr>
<td><strong>Vitamin C</strong></td>
<td>EAR = 13mg/day</td>
<td>25mg</td>
<td>38mg (+39)</td>
<td>13%</td>
</tr>
<tr>
<td><strong>Iron</strong></td>
<td>EAR = 3.0mg/day</td>
<td>4.7mg</td>
<td>4.4mg (+2.4)</td>
<td>19%</td>
</tr>
<tr>
<td><strong>Zinc</strong></td>
<td>EAR = 2.5mg/day</td>
<td>3.5mg</td>
<td>3.5mg (+1.7)</td>
<td>23%</td>
</tr>
<tr>
<td><strong>Calcium</strong></td>
<td>AI = 500mg/day</td>
<td>137mg</td>
<td>172mg (+150)</td>
<td>--</td>
</tr>
</tbody>
</table>
Table 7.3. Adjusted anthropometric measurements (N=78)

<table>
<thead>
<tr>
<th>Group</th>
<th>Sample size (N)</th>
<th>Weight for age Z-score</th>
<th>Length for age Z-score</th>
<th>Weight for length Z-score</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>15-16 Months</td>
<td></td>
<td></td>
</tr>
<tr>
<td>BAN-exited girls</td>
<td>N=16</td>
<td>-0.41 [-0.98, 0.17]</td>
<td>-1.34 [-1.88, -0.79]</td>
<td>0.30 [-0.36, 0.95]</td>
</tr>
<tr>
<td>Matched girls</td>
<td>N=18</td>
<td>-0.41 [-0.95, 0.13]</td>
<td>-1.52 [-2.03, -1.01]</td>
<td>0.36 [-0.25, 0.97]</td>
</tr>
<tr>
<td>BAN-exited boys</td>
<td>N=23</td>
<td>-0.10 [-0.58, 0.38]</td>
<td>-1.49 [-2.02, -0.95]</td>
<td>0.80 [0.20, 1.39]</td>
</tr>
<tr>
<td>Matched boys</td>
<td>N=21</td>
<td>-0.56 [-1.1, -0.05]</td>
<td>-2.03 [-2.60, -1.47]</td>
<td>0.50 [-0.12, 1.12]</td>
</tr>
<tr>
<td></td>
<td></td>
<td>17-18 Months</td>
<td></td>
<td></td>
</tr>
<tr>
<td>BAN-exited girls</td>
<td>N=16</td>
<td>-0.41 [-0.99, 0.16]</td>
<td>-1.53 [-2.07, -0.98]</td>
<td>0.43 [-0.22, 1.08]</td>
</tr>
<tr>
<td>Matched girls</td>
<td>N=18</td>
<td>0.07 [-0.48, 0.61]</td>
<td>-1.30 [-1.82, -0.79]</td>
<td>0.90 [0.28, 1.52]</td>
</tr>
<tr>
<td>BAN-exited boys</td>
<td>N=23</td>
<td>-0.01 [-0.50, 0.48]</td>
<td>-1.34 [-1.89, -0.80]</td>
<td>0.83 [0.22, 1.44]</td>
</tr>
<tr>
<td>Matched boys</td>
<td>N=21</td>
<td>-0.53 [-1.05, 0.00]</td>
<td>-1.73 [-2.32, -1.15]</td>
<td>0.36 [-0.29, 1.02]</td>
</tr>
<tr>
<td>Velocity</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>BAN-exited girls</td>
<td>N=16</td>
<td>0.02 (+0.04) †</td>
<td>0.73 (+0.61) †</td>
<td></td>
</tr>
<tr>
<td>Matched girls</td>
<td>N=18</td>
<td>0.05 (+0.06) †</td>
<td>1.55 (+1.10) †</td>
<td></td>
</tr>
<tr>
<td>BAN-exited boys</td>
<td>N=23</td>
<td>0.02 (+0.04)</td>
<td>1.19 (+0.89)</td>
<td></td>
</tr>
<tr>
<td>Matched boys</td>
<td>N=21</td>
<td>0.03 (+0.05)</td>
<td>1.47 (+1.07)</td>
<td></td>
</tr>
</tbody>
</table>

† Significant difference (p<0.02).
CHAPTER VIII

SYNTHESIS

Summary of findings

The information presented in this dissertation contributes to the body of knowledge on the acceptability and feasibility of implementing the WHO HIV and infant feeding guidelines within the Malawian context by examining:

1) the use and acceptance of LNS as an breastmilk substitute;

2) the vulnerability of the non-breastfed child to seasonal fluctuations in food supply;

3) the factors that influence maternal acceptance of the WHO guidelines;

4) the social stigma and repercussions associated with following the guidelines;

5) the prevalence of dietary inadequacy among non-breastfed infants after nutritional supplementation has ceased;

6) the susceptibility of the non-breastfed child to growth faltering after nutritional supplementation has stopped;

Taken together, the results of this dissertation suggest the 2006 WHO HIV and infant feeding guidelines were accepted and feasible when supported within the context of the BAN Study. In this setting, the WHO guidelines were successfully implemented when mothers and infants were supported by consistent infant feeding counseling and provisions of LNS as a breastmilk substitute.
Public health and policy significance

Recent revisions to the WHO HIV and infant feeding guidelines recommend continued breastfeeding to 12 months coupled with the receipt of maternal or infant antiretroviral medications during the breastfeeding period (WHO, 2009); these recommendations will likely improve HIV-free survival to 12 months. The new guidelines encourage exclusive breastfeeding to 6 months and only differ in that they promote mixed feeding (breastmilk and complementary foods) between 6 and 12 months (i.e. postpone weaning to 12 months) in addition to the provision of ARVs to prevent the transmission of HIV from breastmilk. The infant feeding recommendations promoted by the BAN Study resemble the new WHO guidelines but instead of consuming a breastmilk substitute between 6 and 12 months, mothers will continue breastfeeding and wean at 12 months. After 12 months of age, non-breastfed children living in this environment will likely have nutrient needs that exceed what the traditional child diet can provide without breastmilk. PMTCT programs should therefore aim to provide nutritional supplementation between 12 and 24 months of age. More specifically, LNS was a culturally appropriate breastmilk substitute and could be safely used in this environmental context. The amount of LNS supplement during the 12-24 month period should be based upon the nutrient needs of the infant during this period when breastfeeding is not possible.
Public PMTCT programs:

Although the 2006 WHO antiretroviral therapy guidelines are still in effect within Malawi, the 2009 guidelines are scheduled to roll out starting mid-2011. When the new guidelines are implemented, PMTCT programs will update their recommendations to promote long-term antiretroviral therapy, exclusive breastfeeding to 6 months, and breastfeeding cessation at 12 months. PMTCT services are provided free of charge in conjunction with antenatal care programs at many government hospitals within Malawi.

For health workers implementing the WHO HIV and infant feeding guidelines we recommend providing intensive supportive counseling to HIV-infected mothers on how to prevent vertical transmission; obtaining knowledge and support will motivate mothers to accept and adhere to the WHO guidelines. We also recommend consistent infant feeding counseling sessions to teach mothers how to: perform exclusive breastfeeding, provide an adequate complementary diet from locally available foods, and equip mothers with a variety of weaning techniques to ensure successful breastfeeding cessation. The knowledge, skills, and social support provided to mothers will fuel their motivation, self-confidence, and ability to perform the guidelines thereby increasing acceptance and adherence.

In terms of finding an appropriate breastmilk substitute, LNS was culturally accepted within the Malawian context and was not stigmatized due to its previous use in the area rehabilitating malnourished children. LNS can be used effectively as a breastmilk substitute in this setting and is much safer than infant formula. We also
recommend health workers pay close attention to the diets of non-breastfeeding children during the hungry season and provide further supplementation if needed to ensure adequate nutrition.

LNS Research

The incorporation of LNS into the complementary diet promoted dietary adequacy among non-breastfed children. Mothers found multiple ways to feed LNS to their children, maximizing infant acceptance and consumption; some of these, such as dilution with water in a feeding bottle could increase risk of gastrointestinal infections, and should not be promoted. However, future feeding programs may yield better results if they advertise multiples ways to feed LNS (i.e. mixed into porridge, added to nsima or rice).

The majority of LNS research to date has documented the ability of this supplement class to rehabilitate severe acute malnutrition and more recently moderate malnutrition. There is limited research on the ability of LNS to prevent malnutrition and growth faltering post-intervention; one study followed Malawian infants for 36 months after exiting an LNS intervention and found those who had received 50g of LNS had a reduced risk of stunting (p<0.05), and less decline in mean WAZ (p<0.05) and LAZ (p=0.10) scores when compared to 25g of LNS or 71g CSB (Phuka et al., 2009). This dissertation illustrated that LNS provisions to 12 months likely protected non-breastfeeding infants from exhibiting significantly lower LAZ, WAZ, and WLZ scores in comparison to matched breastfed infants at 15-16mo and again at 17-18mo. However,
three months after LNS provisions stopped the velocity of child weight gain had significantly faltered and since weight gain precedes linear growth, length velocity would likely be affected within the upcoming months. Longer follow-up durations will hopefully shed light on these questions in the future.

**Future research**

The BAN Study provided us with a unique opportunity to study the non-breastfed child in the context of a PMTCT trial and assess dietary intakes with and without LNS provisions. In this ‘best-case scenario’ research setting, we found LNS was well received and incorporated into the infant complementary feeding diet; future studies must investigate the true effectiveness of LNS (i.e. acceptance, consumption) when distributed on a larger scale within national PMTCT programs. Stigma related to the WHO HIV and infant feeding guidelines was largely due to early breastfeeding cessation. It would therefore be of interest to see if the adoption of the 2009 guidelines (i.e. breastfeeding cessation at 12 months) results in less HIV stigma associated with guideline adherence.

Previous PMTCT trials conducted in sub-Saharan Africa have reported high infant mortality rates at 18 months and 24 months and suggested that this outcome was related to inadequate nutrition after early breastfeeding cessation. The BAN Study has only reported infant mortality by 6 months (1.6 per 100) but future papers will report mortality by 12 months. Uninfected infant participants in the ZEBS trial had a mortality rate of 9.4% by 12 months and 13.6% by 24 months; uninfected infant participants in the ZVITAMBO study had a mortality rate of 9.2% by 24 months. Of great interest are the
long term outcomes of infants after exiting the BAN Study. A large scale follow-up study would enable us to document infant health outcomes to 24 months and make comparisons with previous PMTCT trials that did not provide LNS as a breastmilk substitute, and investigate if the diet and growth patterns found within our small sub-sample were characteristic of the greater sample.
APPENDIX 1

Breastfeeding Cessation Counseling AID

From week 21 visit

Introduction

The purpose of this counselling script is to provide guiding information to counsellors for counselling mothers on early breastfeeding cessation.

Check the visit 12.00 baby DNA PCR results.

Start early breastfeeding cessation counselling at week 21 visit (visit 14.00) schedule for all clients whose babies were negative at visit 12.00.

For all mothers whose babies were positive at visit 12.00, encourage them to continue breastfeeding and begin to introduce complementary foods.

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 him/her sitting upright or semi-upright on your lap. Put a cloth underneath his/her 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 his/her own speed.
♦ A low-birth-weight baby starts to take the milk into his mouth with his tongue. A full term or older baby sucks the milk, spilling some of it.
♦ You will know the baby has had enough when he/she closes his/her mouth and does not take any more.
♦ If the baby does not drink very much, offer him/her more at the next feeding or feed him/her 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 his/her 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- child 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 he or she is not waking often to feed.
♦ When it is near the time to stop breastfeeding, carry or rock the baby to sleep if he or she wakes in the night.

**Try not to breastfeed the baby in order to sleep.**
♦ Instead, lay the baby down and pat his back gently and rhythmically to calm him or her and to ease him or her into sleep.
♦ Helping your baby fall asleep on his/her 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 he or she is cold or uncomfortable first, and take care of these needs, before feeding him/her.
Comfort the baby when he or she 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 2

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. Fill in the gaps*

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 s/he 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 he 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 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
- 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, 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 to eat as much as possible. Sometimes children have to be coaxed into eating
- You can ensure that child eats enough by feeding baby yourself or encouraging baby to eat; feeding baby from separate plate; and feeding baby before the rest of the family members
- Give child a variety of foods to prevent micronutrient deficiencies such as vit. 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 child may not eat adequate food.

**Guidelines on frequency, quantity and quality of complementary foods**

<table>
<thead>
<tr>
<th>Age</th>
<th>No of feeds per day</th>
<th>Quantity</th>
<th>Quality/Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>6 - 8 months</td>
<td>2 to 3 times per day</td>
<td>50 – 100 ml per feed</td>
<td>Enriched porridge with sugar, oil, pounded groundnuts in addition to Chiponde cha Mwana</td>
</tr>
<tr>
<td>9 - 11 months</td>
<td>3 to 4 times per day</td>
<td>100 to 150 ml per feed</td>
<td>Enriched, pounded, mashed or strained foods e.g. powder meats, vegetables and fruit juice or mashed fruit in addition to Chiponde cha Mwana</td>
</tr>
<tr>
<td>12 - 24 months</td>
<td>4 to 5 times per day</td>
<td>200 to 300 ml per feed</td>
<td>Enriched, chopped/mashed foods and snacks</td>
</tr>
</tbody>
</table>
Feeding frequency
- Babies need to be fed frequently because they have small stomachs (200ml) so they cannot eat much at one feeding—about 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 diarrhoea.
- 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 all the time.
  - Putting all faeces in a latrine/toilet.

Feeding during illness
- Sick children need more food and drink to fight infection.
- Illnesses which affect nutrition most include diarrhoea, 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 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 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 behaviours include active physical help and verbalisation during eating, role-playing and persistence but not forcing. The behaviours 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 3

Feasibility Study recruitment tool

Feasibility Study
(BAN sub-Study)

Who:
• Completed BAN Study
• Baby - 1yr & 3 months (15 months)

Contact:
• Bottom Hospital
  • Martin Tembo
  • Tasila Zulu
  • Chrissie Chilima
# APPENDIX 4

**Demographic Questionnaire for WOMEN**

BAN Sub-study: Feasibility of Replacement Feeding as an HIV Prevention Method

Version 1.0 (Dec 2007)

<table>
<thead>
<tr>
<th>Date</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Location</td>
<td>0-Bwaila --- 1-Area 25 --- 2-Kawale</td>
</tr>
<tr>
<td>Name of interviewer</td>
<td></td>
</tr>
<tr>
<td>ID code</td>
<td>IDIBAN _ _ IDICNT _ _</td>
</tr>
<tr>
<td>CTA enrollment ID</td>
<td>__ __ - __ __ __ __ __</td>
</tr>
<tr>
<td>BAN temporary ID</td>
<td>__ __ __ __</td>
</tr>
</tbody>
</table>

### DEMOGRAPHIC INFORMATION

1. Participant’s age: _______(years)

3. **What is your marital status?**
   - [1] Married
   - [2] Never married
   - [3] Separated
   - [4] Divorced
   - [6] Living with partner
   - [7] Other ________________________

4. **What is your tribe?**
   - [01] Chewa
   - [02] Tumbuka
   - [03] Yao
   - [04] Sena
   - [05] Lomwe
   - [06] Senga
   - [07] Ngoni
   - [08] Tonga
   - [09] Nkhone
   - [10] Lambia
   - [12] Shona (Zimbabwe)

5. **What is your religion?**
   - [01] Catholic
   - [02] Islam
   - [03] CCAP (Protestant?)
   - [04] Anglican
   - [05] Seventh Day Advent
   - [06] Seventh Day Baptist
   - [07] Pentecostal/Revivalist
   - [08] Traditional
   - [09] No Religion
   - [10] New Apostolic
   - [12] Jehovah’s Witness
   - [13] Evangelical
   - [14] African
[15] Bible Believer
[16] Living Waters
[17] Jesus Centered Church
[18] Salvation Pentecost
[19] Christ Citadel
[20] Baptist

[88] Other
(specify)________________________

[99] Don’t know

<table>
<thead>
<tr>
<th>6. Where were YOU born?</th>
<th>6.1 What region were YOU born in?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>[5] Zomba</td>
</tr>
<tr>
<td></td>
<td>[7] Nkotakota</td>
</tr>
<tr>
<td></td>
<td>[8] Ntcheu</td>
</tr>
<tr>
<td></td>
<td>[9] Nkhata Bay</td>
</tr>
<tr>
<td></td>
<td>[10] Mchinji</td>
</tr>
<tr>
<td></td>
<td>[12] Dedza</td>
</tr>
<tr>
<td></td>
<td>[13] Phalombe</td>
</tr>
<tr>
<td></td>
<td>[14] Kasungu</td>
</tr>
<tr>
<td></td>
<td>[15] Lusaka (Zambia)</td>
</tr>
<tr>
<td></td>
<td>[16] Machinga</td>
</tr>
<tr>
<td></td>
<td>[17] Mzimba</td>
</tr>
<tr>
<td></td>
<td>[18] Dowa</td>
</tr>
<tr>
<td></td>
<td>[19] Ntchisi</td>
</tr>
<tr>
<td></td>
<td>[20] Salima</td>
</tr>
<tr>
<td></td>
<td>[21] Chitunga</td>
</tr>
<tr>
<td></td>
<td>[22] Mwanza</td>
</tr>
<tr>
<td></td>
<td>[23] Nsanje</td>
</tr>
<tr>
<td></td>
<td>[24] Liwonde</td>
</tr>
<tr>
<td></td>
<td>[25] Rumpi</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>7. Where was your BABY born?</th>
<th>7.1 What region was BABY born in?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>[5] Zomba</td>
</tr>
<tr>
<td></td>
<td>[7] Ntcheu</td>
</tr>
<tr>
<td></td>
<td>[8] Mulanje</td>
</tr>
<tr>
<td></td>
<td>[9] Kasungu</td>
</tr>
<tr>
<td></td>
<td>[10] Machinga</td>
</tr>
<tr>
<td></td>
<td>[12] Dedza</td>
</tr>
<tr>
<td></td>
<td>[13] Dowa</td>
</tr>
<tr>
<td></td>
<td>[14] other____________________</td>
</tr>
</tbody>
</table>

**HOUSEHOLD MEMBERS**

8. How many adults older than 15yrs live in your home, including you? ___
9. How many children under 5 years (< 5yrs) old live in your home? ___
10. How many times have you been pregnant (gravidity)? ___
11. How many times have you given birth (parity)? ___
12. How many living children do you have? ___
13. How long have you lived in Lilongwe? ___ years ___ months

**HOUSEHOLD CHARACTERISTICS**
15. Does your home have electricity?  (1) YES   (2) NO
16. Does your home have a working fridge?  (1) YES   (2) NO

17. What was your main source of **drinking water** over the past month?
[01] Piped water in dwelling  
[02] Piped outside dwelling, personal  
[03] Communal standpipe  
[04] Personal handpump/borehole  
[05] Communal handpump/borehole  
[06] Protected spring  
[07] Personal unprotected well  
[08] Personal protected well  
[09] Communal protected well  
[10] Communal unprotected well  
[12] Lake/reservoir  
[88] Other (specify) ____________________

18. What kind of **sanitary facility** does your household use?
[01] Private flush toilet  
[02] Communal flush toilet  
[03] Private VIP latrine  
[04] Communal VIP latrine  
[05] Private traditional latrine with roof  
[06] Communal traditional latrine with roof  
[07] Private traditional latrine without roof  
[08] Communal traditional latrine without roof  
[09] Private Sanplat/Dome slab pit  
[10] Communal Sanplat/Dome slab pit  
[11] None  
[88] Other (specify) ____________________

19. The **roof** of the main dwelling of your household is predominantly made of what material?
[1] Grass  
[2] Iron sheets  
[3] Clay tiles  
[4] Concrete  
[5] Plastic sheeting  
[88] Other (specify) ____________________

20. The **floor** of the main dwelling of your household is predominantly made of what material?
[1] Sand  
[2] Smoothed mud  
[3] Smooth cement  
[88] Other (specify) ____________________

21. What are your sources of **lighting fuel**?  **Multiple responses**
[01] Collected firewood  
[02] Purchased firewood  
[03] Grass  
[04] Paraffin  
[05] Electricity  
[06] Gas  
[07] Battery/ Dry cell/Torch  
[08] Candles  
[88] Other (specify) ____________________

156
22. What are your sources of cooking fuel?  
   [01] Collected firewood  
   [02] Purchased firewood  
   [03] Paraffin  
   [04] Electricity  
   [05] Gas  
   [06] Charcoal  
   [07] Crop residue  
   [08] Saw dust  
   [09] Animal waste  
   [88] Other (specify)_______________

MATERNAL EDUCATION
23. What is the highest level of education you completed at school? (Circle response)
   [0] Standard 1 2 3 4 5 6 7 8
   [1] Secondary school – Form 1 2 3 4
   [3] Adult literacy only
   [4] Never attended school

24. How well can you read and write Chichewa?

25. How well can you read and write English?

26. What is your MAIN occupation?
   [01] Small holder farmer/subsistence farmer
   [02] Tenant farmer
   [03] Ganyu labour (agriculture)
   [04] Ganyu labour (non-agriculture)
   [05] Paid employment with salary
   [06] Self employed (non farming)
   [07] Fisherman
   [08] Teacher
   [09] Health worker
   [10] Field Assistant
   [12] No job
   [13] Schooling
   [88] Other (specify)_______________________

MALE PRIMARY PARTNER CHARACTERISTICS
27. Are you living together with the man who is responsible for this pregnancy?
   a. If you are living with a man, what is his tribe?
      [00] No man, no tribe  [06] Senga
      [01] Chewa  [07] Ngoni
      [02] Tumbuka  [08] Tonga
      [03] Yao  [09] Nkhonde
      [04] Sena  [10] Lambia
      [12] Shona (Zimbabwe)
      [88] Other (specify)_______________________
      [99] Don’t know
b. What is the highest grade level of this man? (Circle response)
[0] Standard 1 2 3 4 5 6 7 8
[1] Secondary school – Form 1 2 3 4
[3] Adult literacy only
[4] Never attended school
[5] Don’t know

c. What does this man do to earn a living?
[01] Small holder farmer / subsistence farmer
[02] Tenant farmer
[03] Ganyu labour (agriculture)
[04] Ganyu labour (non-agriculture)
[05] Paid employment with salary
[06] Self employed (non farming)
[07] Fisherman
[08] Teacher
[09] Health worker
[10] Field Assistant
[12] Don’t know
[13] Land Lord (land owner)
[15] Student
[88] Other
(specify)______________________

d. Where does this man work?
i. How many months does the man spend outside of Lilongwe in a year?
____ ____ months

FOOD SECURITY
31. Do you think your household is currently facing a food shortage?
(1) yes (2) no

34. Are you currently receiving any food aid? (1) yes (2) no
34.1 What is the source of the food aid? (Circle all that apply)
(1) NGO
(2) Church/place of worship
(3) Government
(4) Other (specify): _________________________________

34.2 How long do you think the food aid you received will last?
(1) days (2) weeks (3) months
(4) don’t know

Continue with the Individual Interview guide.
APPENDIX 5

CONTROL MOTHERS


Hi. My name is ________ and I am a staff member with the Feasibility Study. We have invited you here to have a private discussion on issues of infant feeding and care practices. We are specifically interested in hearing about how things are going for you at home feeding your infant, and life in general. Of course, everything you tell me will be kept confidential. I understand that your time is valuable. We really appreciate your time and participation. Do you have any questions? Okay…let’s start.

Introduction

Ndikufuna kuti tikambirane za mmene mumawadyesera ana anu. Tidziwe za mitundu ya zakudya imene mumawapatsera, komanso mmene mumawadyetsera, nthawi imene mumawanyambitsa zakudya zina, ndiponso ngati pali nkhawa yomwe mawana muli nayo pa umoyo wa mwana wanu.

1) Tsopano ndikufuna mundifotokozere za inu ndi banja lanu. Ndiye ndikufunsani mafunso okhudza inuyo ndi za umoyo wanu.

As you know, I am here to talk to you because we are trying to find out more about how infants are fed here in Malawi. We want to know 1) about the types of foods, 2) how you feed them, 3) when you introduce certain foods, and 4) any concerns you have about your child’s health.

1) Now that you are here, I would like for you to tell me a little bit about yourself and your family… so we are going to fill out a demographic questionnaire.

Skip to demographic questionnaire

Infant feeding advice – AT BIRTH

Tsopano tikamba pang’ono za zomwe zinachitika nthawi yomwe mwana wanu anabadwa.

Okay, now we will talk a little bit about what happened around the time of your baby’s birth.
Ndi uphungu womwe munalandila kuchokera kwa abale anu wokudza kadyetsedwe ka mwana?

What, if any, infant feeding advice did you receive from your family?

Nanga kwa amuna anu ndi achibale awo?

How about your husband and his family?

Ndi malangizo otani omwe munalandira kuchokera kwa anzanu ndi anhu ena m’dera lanu?

And what advice did you receive from your friends or others in your community?

Ngati munachilira ku chipatala munalandirako uthenga wina uliwonse kuchokera kwa a dotolo, anamwino kapena azamba okhudza za kadyetsedwe ka mwana?

If you gave birth at a hospital or health center, did you receive any information on infant feeding from doctors, nurses, or midwives?

Do you know what is EBF?

What advice did they give you?

TELL ME THE STORY….

DID ANYONE COUNSEL YOU ON EXCLUSIVE BREASTFEEDING? CAN YOU EXPLAIN TO ME WHAT THIS MEANS?

Infant Diet - The Early Months

0 MONTHS

Tsopano ndikufuna ndikufunseni za kadyedwe ka mwana wanu m’miyezi yoyambiri ra.

Okay, now I'd like to ask you some questions about your child’s diet in the early months.

Munayesera kumuyamwitsa mwana wanu atangobadwa kumene?

After your child was born did you try to breastfeed him?

Yes ____  No_____

Tandifotokozera nkhani yonse mmene munayambira kumuyamwitsa,….panatenga nthawi yavitali bwanji atanobadwa kemene kuti mumuyamwitse?

TELL ME THE STORY of how you began to breastfeed … like how soon after delivery did you start trying?

Did you practice exclusive breastfeeding?

What were your experiences with EBF?

1. If NOT – Mungandifotokozeleko nkhani yonse m’mene munasankhira
kusamuyamwitsa?

If NOT – Can you tell me the story of how you CHOSE NOT TO BREASTFEED?

   WHY did you choose not to breastfeed?
   WHAT foods?
   WHY did you choose those foods?

Mother’s Health  0-6 MONTHS

Pano tikambako za inuyo pang’ono…

Okay, now we want to focus on you a little…

Povamba - Mungandifokozeleko za umoyo wanu mwana wanu atango badwa….. Kenako m’mene umoyo wanu unalili miyezi yoyambilira mutangobeleka?

FIRST – tell me about your own health when the baby was born… And then how your health was in the first few months following your delivery. “Tell me about it… what happened?”

Breastfeeding Problems

Ndi zovuta zanji ngati zilipo zomwe munkakumana nazo pamene munkayamba kuyamwitsa mwana wanu?
What, if any, problems did you experience when starting to breastfeed your child?
   “Tell me about it… what happened”
   Dry breasts, Season, Lack of food

Pano tikamba zamavuto omwe munakumana nawo kufika miyezi 6. Munakumanapo ndi mavuto ena aliwONSE?
Okay, now let’s talk about any problems you faced up to 6 months. Did you have any problems?
   Probe: breast health, sores
   Probe: mother’s health

Food Introductions

Amavi ena amayamwitsa mwa kathithi.
Some mothers feed only breast milk to their baby and no teas or water (EBF).

Inuvo, ndi msinkhu wanji umene munayambitsa kumpatsa mwana wanu zakumwa zina ?
At what AGE did you first introduce any liquids (such as water, sugar water, milk, infant formula) to your baby?
   WHY did you choose that age?
   Tell me the story…. 
Tandifotokozeleni m’mene munayambo kumpatsa mwana wanu zakudya?
Tell me about when you first offered foods (phalas, etc) to baby?
   HOW old was he?
   WHAT foods?
   WHY did you choose that age?
   How did the baby respond?

Family Foods: Early MIXED Diet ➔ ~6 months

Okay, before we talked a little about the foods you first introduced to your child. When a child’s diet has both breast milk in it and food – we call this mixed feeding.

Ndi msinkhu wanji umene munayamba kasakaniza (zakudya ndi mkaka wa m’mawere)?
At what age did your child start eating a mixed diet (Food + Breast Milk)?
   What was in this diet?

Ndizakudya zanji zimene munkampatsa?
What foods did you first introduce to your child?
   Tell me about this…did you offer them both at the same time?
   How did you offer it? What quantity?
   And WHY these foods?

Chifukwa chani munasankha zakudya zimenezi?
What were the reasons for choosing these foods?

Mwazakudya zimenezi amakonda ziti kwambiri?
Which of these foods did they typically eat the most of?

Current Meal Practices

Ndi pa msinkhu wanji womwe munasintha kusiya kumuyamwitsa kwambiri ndi kumamupatsa zakudya zochuluka?
Okay, How old was your baby when they starting eating mostly food and less breast milk?

Mwana wanu amadya kangati tizakudya tina ndi tina mkati mwa chakudya cha m’mwawa ndi masana kapena chakudya cha masana ndi madzulo? Zakudya zanji?
How many times/day (in addition to breast milk) do you feed your child ‘snacks’ in between breakfast and lunch and dinner? What snacks?

Munkachikonza motani chakudyachi kuti mwana angathe kudya mosavuta?
How did you prepare the foods to make sure your child could eat them?
   Probe: did you pre-chew the food
   Probe: was it thin / thick – phala
   WHY?

Infant Feeding Beliefs

Ngati mayi ali ndi ana ena…
If the mother has other children …
Mwanayu mukumudzetsa chimodzimodzi mmene munkawadzera ana enawo, kapena mukusiyanitsa? (Why)
Are you feeding this baby in the same way as you have fed your other children?

Mumafuna mutamuyamwitsa kwa nthawi yayitali bwanji?
For how long would you like to breastfeed your baby in total?
  Why is this a good age?
  Tell me other reasons that breastfeeding is good….

**FOOD SECURITY (Kusowa Kwa zakudya)**

Many families have got problems to always have enough food for the family. So sometimes they go hungry without having enough food and sometimes missing meals.
  We call this a lack of General Foods – not just NSIMA!!
  IT MEANS a lack of RELISH, PORRIDGE, GREENS, MEATS, etc.

Tandifotokozeleni za mavuto a kupelewela kwa chakudya pakhomo panu….Kachulukidwe ndi kaonekedwe ka chakudyachi?
Tell me about any problems you have securing enough food in your home…. Both quantity and quality?

Mukuwona kuti ndi nthawi yayitali bwanji imene mwana angadalire mkaka wa mmaere okhaokha?
For how long, do you think, a baby is satisfied eating ONLY breast milk? Why is this age appropriate to stop BF?

**Infant Health Concerns ➔ 0-12 MONTHS**

Tsopano ndikufunsani zokhudza umoyo wanu ndi wa mwana kuchokera mutangochira.

Now I would like to ask you some questions about you & your baby’s health since the birth.

1. **Mungandiwuzeko za umoyo wa mwana wanu pa miyezi yoyambilira kuchokera pomwe anabadwa? (0-3 months)**
   Can you tell me about your infant’s health during the first few months after the birth?
   Probe: any sickness, growth, temperament
   ANY CONCERNS?
   Probe: “Tell me more about this concern you have….’ (are you at risk?)

2. **Mumatsata njira zanjii zosamalira mwana wanu akadwala? (help sick baby)**
   What methods do you use to take care of your baby when they are sick?
   Probe: WHAT do you feed them?

3. **Umoyo wake unali wotani mmene amakula? Munawonapo kusintha kulikonse?**
   As your baby got older, how was their health – did you notice any changes?
Probe: any concerns?
Growing? Active?
Any illness?

Mother’s Diet & Health ➔ 0-12 months

Tell me about your diet while you were breastfeeding…

Tandiuzeni za madyedwe anu pa nthawi anu pa nthawi imene mumayamwitsa?

Overall can you tell me about your health, and any events that have happened, during the past year?

Mwachidule mungandiuzezo za umoyo wanu ndi zina zomwe zakuwonekerani pa chaka chapitachi?

What concerns do you have for your own health?

Muli ndi nkhawa zanji pa umoyo wanu panopa?

Current Infant Diet ➔ 12 – 15 Months

Ok, now let us talk about how you feed your baby now that they are older…

Tsopano tikambirane za mmene mukumudyetsera mwana wanu pano mmene wakulamu.

1. What foods have you introduced to your baby in addition to the foods you told me before?

Ndizakudya zanji zomwe mukumupatsa powonjezera zomwe mwandiwuza zija?

2. How did you choose these foods?

Munasakha bwanji zakudya zimenezi?

   a. Tell me the story behind these foods…..

3. Typically, how would you categorize the foods your baby eats now?

Mungazigawe mmagulu otani zakudya zomwe akudyazi?

4. How many times a day does your baby eat?

Amadya kangati pa tsiku?

5. What foods do you most often feed your baby?

Ndzi zakudya zanji zomwe mumakonda kumpatsa nthawi zambiri?

6. Are there other foods that you would like to feed to your baby now?
Pali zakudya zina zomwe mungakonde kumpatsa mwanayu?
   a. If YES – what kinds of foods?

7. What are the best foods for a baby, to keep him healthy?

Ndi zakudya zanji zopereka thanzi kwa mwana?

8. What do you think makes _______ (name the food she mentioned) good for a baby?

Kodi mukuwona ngati chomwe chikupangitsa______ kukhala chabwino kwa mwana ndi chiyani?

**Infant Health : 12-15 MONTHS**

A. Do you have any concerns about your child’s health now, more recently?
   Muli ndi nkha wa iliyonse pa umoyo wa mwana wanu panopa?
   Nutrition, sickness

B. What do people in your community think of a woman when she doesn’t breastfeed her child?
   Anthu a ku dera kwanu amaganizira zotani mzimavi yemwe sakuyamwitsa mwana wake?
   Probe: HIV status, breast health problems
   Probe: Do people think that HIV is transmitted by breast milk?

C. Are you still breastfeeding? To what age are you planning to breastfeed?
   Mukuyamwitsabe ? Mukufuna mutamuyamwitsa kwa nthawi yaitali bwanji ?

D. What can happen if you stop your child breastfeeding before the time you wanted to?
   Chingachitike ndi chani mutasiya kumuyamwitsa mwana nthawi yomwe mumafuna kumusiitsa isanakwane ?

**Thank You**

Now, I want to thank you so much for your time. It is greatly appreciated. What you have told me will be so helpful to our research. Do you have any questions for me? If there is anything else that you feel that is important to our discussion, please feel free to contact me through Martin Tembo, the Nutrition Officer at Bwaila Hospital.

Hi. My name is _______ and I am a staff member with the Feasibility Study. We have invited you for this interview to have a private discussion on issues of replacement feeding acceptance and feasibility. We are specifically interested in hearing about how things are going for you at home feeding your infant, and life in general. Of course, everything you tell me will be kept confidential. I understand that your time is valuable. We really appreciate your time and participation. Do you have any questions?

Okay… let’s start.

Mulibwanji? Dzina langa ndine……………..ndipo ndikugwira ntchito mu kafukufuku wofuna kuona ngati nkotheka kumudyetisa mwana zakudya zina m’ malo mwa mkaka wa m’ mawere pamene mwasiya kumuyamwitsa. Takuitananinso kuti tikambirane nanu mwa chinsinsi za kafukufuku amene ndakufotokozera. Tiri ndichidwi kumva m’mene zinthu zikuyendera kunyumba pa nkhani ya kadyetsedwe ka mwana wanu komanso pakhomo panu. Zonse zimene tikambirane pano zikhala za chinsinsi. Nthawi ndi kutenga nawi mbali kwanu ndizofunikira kwambiri. Muli ndi funso liri lonse?

**Overall BAN Study**

As you know, I am here to talk to you because you have had some experiences that are important for us to understand about your time in the BAN project.

Ndimafuna kuti tikambirane chifukwa ndikudziwa kuti nthawi yomwe munali mu kafukufuku mwakhala mukukumana ndi zinthu zosiyanasivana zomwe tingafune kuzidziwa.

**Introduction**

Now that you are here, I would like you to tell me a little bit about yourself and your family… so we are going to fill out a demographic questionnaire.

Tsopano ndikufuna mundifotokozere za inu ndi banja lanu.

**Skip to demographic questionnaire**

**Joining the BAN Study**

So, can you tell me about your experience participating in the Ban study?

Mungandifotokozeleko zomwe munakumana nazo panthawi yomwe munali mu kafukufuku wa BAN?
Tell me how you decided to be in the BAN study – from the time you were in the antenatal clinic to when you joined the study – the whole story.

Mungandifotokozeleko m’mene munapangila chisankho chotenga nawo mbali mu kafukufuku wa BAN, kuyambila pomwe munabwera ku sikelo kwa nthawi yoyamba? (nkhani yonse)

How did your husband feel about you joining the BAN Study?

Amuna anu anamva bwanji pa nkhani yoti inu mutenge nawo mbali mu kafukufuku wa BAN?

What were your family’s thoughts about you participating in the BAN Study?

Nanga abale anu anali ndi maganizo otani pa nkhani yoti inu mutenge nawo mbali mu kafukufuku wa BAN?

What about your friends – what were their responses?

Nanga anzanu anamva bwanji?

| 0-6 months |

Okay, now I would like to talk to you about the infant feeding advice you received from the BAN Study.

Tsopano ndikufuna tikambirane za uphungu omwe munalandila ku kafukufuku pa zakadyetsedwe ka mwana.

In the BAN study, the nurses counseled several ways to feed your baby, is that right?

Mu kafukufuku wa BAN a namwino anakupatsani uphungu wa kadyetsedwe ka mwana wanu, si choncho?

Tell me what they told you about feeding your baby in the 1st 6 months of life.

Mungandifotokozeleko zomwe anakuwuzani za kadyetsedwe ka mwana wanu pa miyezi 6 yovambilira?

Breastfeeding

So the nurse asked you to exclusively breastfeed (kuyamwitsa mwakathithi) during the first 6 months….

Anamwino atakuuzani kuti muyamwitse mwakathithi kwa miyezi 6…….
What happened with you and the baby as you first tried to EBF?

Chinachitika ndi chiyani mutayesa kumuyamwitsa mwathithi kwa nthawi yoyamba?

Were you able to succeed in feeding only breast milk for the 1st 6 months?

Kodi munakwanitsa kumuyamwitsa mwana wanu mkaka wa m’mawe kwa miy 6?

Infant feeding advice

What infant feeding advice did you get from your family since your baby was born?

Ndi upungu wotani womwe munalandila kuchokera kwa abale anu wokudza kadyetsedwe ka mwana chibadwire mwanayu?

How was their advice different from the BAN nurses?

Kodi upunguwu unali wosiyana bwanji ndi umene a namwino anakupatsani?

Was there disagreement in your home about how to feed your baby - or was the decision all yours to make?

Kodi panali kusamvana kuli konse mnyumba mwana pa chisankho cha kadyetsedwe ka mwana wanu? Kapena chisankho chinali cha inu nokha?

Did anyone else, NOT in your family, talk to you about how to feed your baby?

Kodi pali munthu wina aliyense wosakhala m’bale wanu amene analankhulapo nanu pa zakadvede ka mwana wanu?

Infant health (0-12) [during BAN]

How was your infant’s health during the 1st 6 months when you were breastfeeding?

Kodi umoyo wa mwana wanu unali wotani pa miy 6 yoyambilira yomwe mumamuyamwitsa?

In general, did your baby’s health change after 6 months when you started feeding Plumpy nut?

Kodi umoyo wa mwana wanu unasintha nthawi yomwe munayamba kumudveltsa chiponde?

Mother’s Health (0-12) [during BAN]

Mutabeleka ndi mavuto anji omwe munali nawo?

After delivery, what problems did you have?

a. Tell me the story…. 
During the time you were breastfeeding (0-6m) - tell me about your own health?

Mungandifotozeleko m’mene umoyo wanu unalili nthawi yomwe mumamuyamwitsa mwana w reminded
wanu mwakathithi? Tandifotokozeleni za umoyo wanu?

Tell me about your overall diet during this breastfeeding (0-6m) time? What foods were you eating? Rations?

Mungandifotokozeleko m’mene mumadyera nthawi imeneyi? Ndizakudya zanji zomwe mumadya?

At what age did you start weaning the baby off the breast?

Ndi msinkhu wanji womwe munayamba kumusivitsa kuyamwa?

How was your health for the rest of the BAN Study when you were not breastfeeding (6-12 months)?

Kodi umoyo wanu unali wotani pa nthawi yomwe munali mu kafukufuku koma simumayamwitsa?

**Maternal Supplement Arm  {only 50% of mothers}**

Did you receive Chiponde for yourself after delivery?
If she DID receive it then answer the questions below.

….Ok, now lets talk about Plumpy Nut

When the BAN Study gave you Plumpy nut – Did you eat it?

Mutapatsidwa chiponde mumadya?

Yes  No

How much you were supposed to eat?

Mumayenera kudya chochuluka bwanji ?

Amount: __________   Yes  No

Probe: Did you like to eat it all, every day?

Mumakonda kudya chonse tsiku ndi tsiku?

Tell me if you think that Plumpy nut made a difference to your health? How?
Mungandiuze ko ngati chiponde chinasinthako chinachirichone pa umoyo wanu?

Were there ever any times that you could not eat all of the Plumpy Nut and others had some of your share?

Kodi ilipo nthawi yomwe simunadve chiponde chonse ndipo munagawana ndi anthu ena? Kodi zimachitika pafupi pafupi bwanji? Nanga m’mawagawira chochuluka bwanji? Ndipo m’magawira ndani?

**BAN Study Rations**

**FOOD SECURITY – Kusowa Kwa zakudya**

Many families have got problems to always have enough food for the family.
So sometimes they go hungry without having enough food and sometimes missing meals.
We call this a lack of General Foods – not just nsima


Did having Plumpy Nut for the baby decrease your family’s food security problems (chakudya chokwanira)?

Kulandira chiponde kunachepetsa mavuto a chakudya chokanira pa banja panu?

Did having the BAN maize rations decrease your family’s food security problem?

Kodi kulandira chimanga ku BAN kunachepetsa mavuto a chakudya chokwanira pa banja panu?

**6 – 12 Months**

Now we are going to talk about what happened during the time of the BAN Study when they asked you to stop breastfeeding and start feeding Plumpy Nut…

Panopa tikambirana za zomwe zinachitika nthawi yomwe munali mu kafukufuku wa BAN mutafunsidwa kusiya kumuyamwitsa mwana wanu ndi kuyamba kumudyetsa chiponde …

**Weaning (Kusiyitsa Kuyamwa)**

At 6 months of age, what advice did you receive from the nurse….

Pa miyezi 6 zakubadwa, a namwino anakupatsani malangizo anji…..
Can you tell me exactly how the nurse told you to stop breastfeeding and feed both Plumpy Nut and other foods?

Kodi mungandiwuzeko m’lene anamwino ananenera pa kaletsedwe kamwana kuyamwa ndi kuyamba kumudyetsha chiponde ndi zakudya zina...

Did you have any worries about stopping breastfeeding?

Munali ndi nkhawa ina iriyonse pa nkhani yomusiitsa mwana?

Tell me the story of how you tried to stop breastfeeding. Tell me exactly how you did it…

Kodi mungandifotokozeleko za m’lene zinalilili nthawi imene munayesa kusiyitsa mwana wanu kuyanwa? Tandiwuzeni m’lene munachitira...

How was your baby’s health during the weaning time?

Umoyo wa mwana wanu nthawi imene mumamusiyitsa kuyamwa unari otani?

And how was your health during this weaning time – like your breast health problems or other infections?

Nanga thanzi lanu linali lotani m’lene mumamusiyitsa mwana wanu kuyamwa – Bele lanu linali ndi vuto kapena nthenda iriyonse?

Do people in your community think that HIV is transmitted by breast milk?

Kodi anthu a m’dele lanu amaganiza kuti kachilombo ka HIV kungafalitsidwe kudzera mu mkaka wa m’mawele?

Tell me about any situations, if any, in which you felt you had to justify how you were feeding your baby ….

Tandiuzani za nthawi ina ili vonse imene munaona kuti anthu akukhala nanu mosiyana ndi nthawi zina chifukwa cha m’lene mumayamwitsira mwana wanu…

| Plumpy Nut (7-12 months) |

Ok, now lets talk about the Plumpy Nut that was given by the Study for baby…

Tsopano tiyeni tikambe za chiponde cha mwana chomwe mumapatsidwa ku kakafukufuku wa BAN…

What did you think about the Plumpy Nut?
Kodi munkachiwona bwanji chiponde?

Tell me **HOW** you fed Plumpy Nut to your baby?

Tandifotokozereni mmene mumamudyetsera mwana wanu chiponde. Mumamudyesa chiponde chokha chokha kapena mumaphatikiza ndi zakudya zina?

Tell me, did the baby like eating Plumpy Nut? How did they react when eating it? Tell me the stories…

Tandiuzani,, kodi mwana wanu ankakonda kudya chiponde? Pa nthawi yomwe akudya amatani?

While you were feeding baby Plumpy Nut, what foods/fluids did you feed the baby separately?

Ndizakudya/zakumwa zanjii zapadera zomwe mumampatsa mwana wanu pa nthawi imene mumamudyetsa chiponde?

What kind of issues arose with Plumpy Nut and sharing in your home? Were there any times when you did not have enough Plumpy Nut for baby?

Inalipo nthawi vina yomwe munalibe chiponde chokwanira cha mwana?

Tell me what happened?

Mungandifotokozele kuti chinachitika ndi chani?

If you ran out, what did you do?

Ngati palibe, munkachita chani?

How long were you without it?

Munakhala nthawi yayitali bwanji opanda chipondechi?

| **After EXITING the BAN Study** |

| **General** |

Ok now lets talk about how things have been going since you left the study when your baby was 12 months old….

Tsopano tiyeni tikambe m’mene zinthu zakhala zikuyendera chitulukileni mukafukufukulu wa BAN pamene mwana wanu anali ndi miyezi 12.

How has it been going (Pause) …. Have **you or your baby** had any problems? Tell Me…..
Zakhala zikuyenda bwanji? Inuyo kapena mwana wanu munayamba mwakhalapo ndi mabvuto ena aliwONSE?

When your baby was eating Plumpy Nut - along with the other family foods,- you told me that…..

M’mene mwana wanu amadya chiponde pandomzi ndi zakudya zina munandiuza kuti….

The baby liked eating it and their health was ______ (good/bad). So tell me - what happened when there was no more Plumpy Nut for baby? What happened in the first week?

Mwanayu ankachikonda ndipo thanzi linali ---------. Ndiye tandiwuzani chinkachitika ndi chiyani pamene panalibe chiponde cha mwanavyu? Chinachitika ndi chiyani sabata loyamba?

Your baby didn’t like to eat Plumpy nut. So tell me – what changed once you left the BAN Study at 12 months? (Probe: health got worse, ate more family foods)

Mwana wanu sankakonda chiponde. Tandiwuzani chinasintha ndi chiyani mutatuluka mukafukufuku patatha chaka?

How did you feed the baby **without** Plumpy nut? What did you replace it with?

Munkamudyetsa bwanji opanda chiponde? Munkamupatsa chiyani m’mallo mwa chiponde?

What foods did you feed your baby right after leaving BAN?

Kodi ndi zakudya zanji zomwe munkamudyetsa mwana wanu mutangotuluka kumene mukafukufuku wa BAN?

What methods did you use to feed your baby **without** Plumpy Nut?

Ndinjira zanji zomwe munkagwiritsa nchito pomudyetsa mwana wanu popanda chiponde?

Did your Baby accept these foods that you offered?

Kodi mwana wanu ankalola kudya zakudya zomwe mumamupatsa?

**Infant Health AFTER BAN**

So now we’re going to talk about your baby’s health after leaving the BAN Study.

Tsopano tikamba za umoyo wa mwana wanu mutatuluka mu kafukufuku wa BAN.

Tell me about your baby’s health during the 1st few months after you left the BAN study.
Mungandiuzeko m’mene umoyo wa mwana wanu unalili miyezi yoyamba mutangotuluka mu kafukufuku wa BAN?

Have there been any other changes?

Pali chilichonse chomwe chinasintha?

What concerns do you currently have for your child’s health now?

Ndi nkhawa zanji zomwe muli nazo pa umoyo wa mwana wanu panopa?

Has your baby been sick in the last few weeks? Can you tell me about it?

Kodi mwana wanu wakhala akudwala masabata apitawa? Mungandifotokazeleko?

What do you do when your baby gets sick?

Kodi mumachita chiyani mwana wanu akadwala?

| Infant Diet AFTER BAN |

Ok, lets talk about how you feed your baby now that he/she are older…

Pano tiyenzi tikambe za m’mene mumamudvetsera mwana wanu m’mene wakulamu….

How many times a day does your baby usually eat?

Kodi mwana wanu amadya kangati patsiku?

What foods do you most often feed your baby?

Nanga amadya zakudya za mtundu wanji?

1.
2.
3.

Do you think that these foods that you are giving baby are ok? Is the amount enough? Why?

Kodi mukuona ngati zakudya zomwe amadya mwana wanu ndi zabwino? Nanga ndizokwanira?

Are there other foods that you would like to feed to your baby now?

Kodi pali zakudya zina zomwe mungafune mutamudytetsa mwana wanu panopa?
What are the best foods for a baby, to keep him healthy?

Kodi zakudya zabwino zopatsa thanzi kwa mwana ndi ziti?

What do you think makes those foods good for a baby?

Kodi mukuganiza chimapangisa kuti zakudyazi zikhale zabwino ndi chiyani?

Food security

Who is responsible for providing food for you and your children? Probe for all:

Kodi amene ali ndi udindo opeza chakudya pa banja panu ndani?

What strategies is your household using to cope with the food shortage?

Ndi njira zanji zimene banja lanu limatsata pothana ndi kusowa kwa chakudya?

(DON’T READ) Probe respondent - Circle all that apply
(1) expected migration/plan to move away 
(2) consuming wild foods
(3) reducing number of meals 
(4) reducing work effort
(5) accepting food for work 
(6) begging
(7) exchanging or selling property to buy food
(8) doing extra work to be able to buy food
(9) getting money from relatives to buy food
(10) eating leafy vegetables only
(11) eating maize husks
(12) other (specify): ________________________________

Are there days in the last month when you did not have enough food for yourself or your children?

Pa mwezi wathawu alipo masiku ena omwe munalibe chakudya chokwanira cha inuyo ndi ana anu?

(1) Yes 
(2) No - If NO then skip to Next Question

29.1 How many days? ____________
Masiku angati?

29.2 What did you do? Especially for the baby?
Munachitapo chiyani?

Are there times of the year when you do not have enough food for yourself and your children?
Kodi ilipo nthawi ina pachaka yomwe mumakhala ndi chakudya chosakwanira cha inuyo ndi ana anu?

(1) Yes  (2) No

When? What do you do for food then? Probe: for the baby?

Ndi nthawi iti? Ndiye munachitapo chiyani pankhani ya chakudyavi?

**Thank You**

Now, I want to thank you so much for your time. What you have told me will be so helpful to the project, because we have had questions about how the BAN mothers and babies are doing after they exit the study. Do you have any questions for me?
# Baby’s Growth Record

Feasibility Study ID number: ____________

Infant Gender: ____________

Date of birth: ____________
Gestational age at birth: ____________
Single birth: Yes __ No __
Birth rank: ____________
Adverse events (dates): (death of parent, death of siblings <5 yrs)

<table>
<thead>
<tr>
<th>Date of visit</th>
<th>Age today (completed yrs/months/weeks)</th>
<th>Measurements</th>
<th>Observations</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Weight (kg)</td>
<td>Skin</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Length (cm)</td>
<td>Sickness:</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Edema:</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Average: _____</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Average: _____</td>
<td></td>
</tr>
</tbody>
</table>

177
REFERENCES FOR CHAPTERS I, II, III, IV, VIII


Murphy SP, Guenther PM, Kretsch MJ. Using the dietary reference intakes to assess intakes of groups: pitfalls to avoid. J Am Diet Assoc 2006;106:1550-1553.


