

Published in final edited form as:

AIDS Educ Prev. 2009 April; 21(2): 141–155. doi:10.1521/aeap.2009.21.2.141.

EVALUATING NURSES' IMPLEMENTATION OF AN INFANT-FEEDING COUNSELING PROTOCOL FOR HIV-INFECTED MOTHERS: THE BAN STUDY IN LILONGWE, MALAWI

Yvonne Owens Ferguson,

University of North Carolina at Chapel Hill

Eugenia Eng,

University of North Carolina at Chapel Hill

Margaret Bentley,

University of North Carolina at Chapel Hill

Margarete Sandelowski,

University of North Carolina at Chapel Hill

Allan Steckler,

University of North Carolina at Chapel Hill

Elizabeth Randall-David,

University of North Carolina at Chapel Hill

Ellen G. Piwoz.

Academy for Educational Development, Washington, DC

Cynthia Zulu,

UNC Project, Lilongwe, Malawi

Charles Chasela,

UNC Project, Lilongwe, Malawi

Alice Soko,

UNC Project, Lilongwe, Malawi

Martin Tembo,

UNC Project, Lilongwe, Malawi

Francis Martinson,

UNC Project, Lilongwe, Malawi

Beth Carlton Tohill,

U.S. Centers for Disease Control and Prevention, NE, Atlanta, Georgia, 30333, USA

Yusuf Ahmed,

U.S. Centers for Disease Control and Prevention, NE, Atlanta, Georgia, 30333, USA

Peter Kazembe,

Kamuzu Central Hospital, Lilongwe, Malawi

Denise J. Jamieson,

U.S. Centers for Disease Control and Prevention, NE, Atlanta, Georgia, 30333, USA

Charles van der Horst, and University of North Carolina at Chapel Hill

the UNC Project BAN Study Team

Abstract

A process evaluation of nurses' implementation of an infant-feeding counseling protocol was conducted for the Breastfeeding, Antiretroviral and Nutrition (BAN) Study, a prevention of mother-to-child transmission of HIV clinical trial in Lilongwe, Malawi. Six trained nurses counseled HIV-infected mothers to exclusively breastfeed for 24 weeks postpartum and to stop breastfeeding within an additional four weeks. Implementation data were collected via direct observations of 123 infant feeding counseling sessions (30 antenatal and 93 postnatal) and interviews with each nurse. Analysis included calculating a percent adherence to checklists and conducting a content analysis for the observation and interview data. Nurses were implementing the protocol at an average adherence level of 90% or above. Although not detailed in the protocol, nurses appropriately counseled mothers on their actual or intended formula milk usage after weaning. Results indicate that nurses implemented the protocol as designed. Results will help to interpret the BAN Study's outcomes.

Up to 42% of all HIV infected children less than two years of age contract the virus during the breastfeeding period (Breastfeeing and HIV Transmission Study Group, 2004). Among sub-Saharan Africa communities, the infant feeding information and advice nurses communicate influence mothers' infant feeding practices (Seidel, Sewpaul, & Dano, 2000; Semega-Janneh, Bohler, Holm, Matheson, & Holmboe-Ottesen, 2001; Piwoz, Iliff, et al., 2005).

International guidelines recommend that HIV-infected mothers exclusively breastfeed during an infant's first 6 months of life and stop breastfeeding once replacement feeding is acceptable, feasible, affordable, sustainable and safe (AFASS) (World Health Organization [WHO], 2001, 2006). When replacement feeding is AFASS, avoidance of all breastfeeding by HIVinfected mothers is recommended (WHO, 2001, 2006). Furthermore, guidelines recommend that mothers receive counseling about the risks and benefits of their infant-feeding options, as well as guidance and support in their infant feeding decisions (WHO, 2001, 2006). In accordance with the WHO (2001) guidance on infant feeding and formative research results focusing on infant feeding knowledge, attitudes, and behaviors in Malawi (Bentley et al., 2005; Corneli et al., 2007; Piwoz & Bentley, 2005), we developed an infant-feeding counseling protocol for nurses to implement as part of the Breastfeeding, Antiretroviral and Nutrition (BAN) Study. The BAN Study is an open-label clinical trial evaluating the safety and efficacy of antiretroviral and nutrition interventions to reduce maternal morbidity and MTCT among breastfeeding mothers in Lilongwe, Malawi (Galliard et al., 2004; van der Horst et al., 2009). The three main objectives of the BAN Study are to evaluate: (a) the benefit of nutritional supplementation given to women during breastfeeding; (b) the benefit and safety of antiretroviral medications given either to infants or to their mothers to prevent HIV transmission during breastfeeding; and (c) the feasibility of mothers exclusively breastfeeding their infant for 6 months, followed by early, rapid breastfeeding cessation (Bentley et al., 2005; Corneli et al., 2007).

Although infant feeding cultural norms in Malawi include prolonged breastfeeding up to 2 years and a median duration of exclusive breastfeeding of 2 months (National Statistical Office [Malawi] & ORC Macro, 2005), our formative research results suggested that HIV-infected mothers would adhere to the BAN Study infant-feeding recommendations if nurses explained why and how these practices would decrease the risk of mortality and HIV transmission to their infant (Piwoz et al., 2006). Evidence from a Zambian study, concluding that infant-feeding

counseling by trained nurses was associated with mothers exclusively breastfeeding for more than 2 months, support our formative findings (Piwoz et al., 2005).

In the context of prevention of mother-to-child transmission (PMTCT) clinical trials, with a nurse-delivered behavioral intervention component, nurses' implementation of the intervention is often not evaluated. Researchers agree that evaluating the process by which an intervention is implemented helps to inform study impact and outcome results (Corbett, Thompson, White, & Taylor, 1991; Dehar, Casswell, & Duignan, 1993; Israel et al., 1995; Linnan & Steckler, 2002; McGraw et al., 1994) and avoid intervention implementation failure (Basch, Sliepcevich, Gold, Duncan, & Kolbe, 1985). Knowing the content of infant-feeding information and quality of infant-feeding counseling nurses communicate to HIV-infected mothers is important in PMTCT of HIV during the postnatal period. We conducted a study to assess trained nurses' implementation adherence to an infant-feeding counseling protocol within the context of a PMTCT clinical trial in Lilongwe, Malawi.

METHODS

We developed an infant-feeding counseling protocol for nurses to implement during their counseling sessions with HIV-infected mothers enrolled in the BAN Study. The protocol, derived from the WHO Breastfeeding Counseling Training Manual (WHO/UNICEF, 1993; WHO/UNAIDS/UNICEF, 2000), and formative research results (Corneli et al., 2007; Piwoz et al., 2006) included both verbal and nonverbal counseling elements to be implemented at each counseling session. The nonverbal elements remained the same for each counseling session, but the verbal elements changed depending on the mother's pregnancy stage or their infant's age (i.e., visit type). The mother's visit type was categorized as antenatal, early postpartum (1st to 1sth week postpartum), mid-postpartum (21st, 24th and 2sth week postpartum), or late postpartum (32nd to 4sth week postpartum) visit.

Key nonverbal counseling elements included nodding, smiling, making eye contact with the mother, and sitting with a posture that showed an active interest in what the mother was saying. Implementing the nonverbal counseling elements helped the nurse to establish a rapport with the mother, listen to the mother's infant-feeding issues and display empathy (WHO/UNICEF, 1993).

MEASURES

The process evaluation components of fidelity, which is the extent to which the intervention was delivered as planned (Linnan & Steckler, 2002), and dose delivered, which is the number of intended units of each component delivered (Linnan & Steckler, 2002), were measured using a checklist tool we developed specifically for assessing a nurse's implementation adherence to the infant-feeding counseling protocol. This tool, called an implementation checklist, was tailored to the mother's visit type. Table 1 presents an example of the implementation checklist used during the mother's 1st to 18th week postpartum visit. Using these process evaluation components as a guide, we calculated the extent to which a nurse adhered to implementing the protocol as designed (i.e., implementation adherence percentage) for each completed implementation checklist.

SAMPLE

Out of 20 nurses working on the BAN Study, we selected a convenience sample of 6. This sample represented 30% of the total nurses working on the study. The 6 nurses were recruited by the nurse supervisor and team leaders. A nurse's prior participation in a weeklong BAN Study orientation and HIV and infant-feeding counseling training course were the only criteria necessary for inclusion in the study. Fifteen of the 20 nurses met this criterion. Of the 6 nurses

selected, all of them were married, were an average of 32 years old (range = 28–46 years old), averaged 6.8 years of nursing experience (range = 3–10 years), and worked for the BAN Study prior to enrollment of clinical trial participants, which began in March 2004. All nurses were fluent in English and Chichewa, Malawi's official languages (*World Encyclopedia*, 2005). These characteristics were similar to nurses not selected for the study. Participating nurses were assigned by the nurse supervisor and team leaders to a 2-week counseling room rotation for this study (versus their usual 1-week rotation in the counseling room), while the nurses not participating in this study were assigned to other BAN Study clinic duties.

Study participants also included 123 HIV-infected mothers who reported to the BAN Study clinic for their regularly scheduled antenatal through 48th week postpartum visit between November and December of 2005. Out of the 129 mothers recruited, 6 declined to participate and 123 accepted.

DATA COLLECTION

We used direct observations of infant-feeding counseling sessions between nurses and mothers, and interviews with nurses, to assess nurses' implementation adherence to the infant-feeding counseling protocol (Bentley, Boot, Gittelsohn, & Stallings, 1994; Patton, 1990; Walsh, Redman, Byrne, Melmeth, & Brinsmead, 2000). Five trained field investigators independently audio-recorded, wrote field notes, and completed an implementation checklist of each counseling session observed. After observing at least 20 of a nurse's counseling sessions, a field investigator conducted a 60-minute interview with the nurse.

Prior to data collection, all tools were pretested and an interrater reliability of 84.6%, slightly below our a priori criteria of 85.0%, for the implementation checklist was achieved.

DATA ANALYSIS

The data analyzed include the implementation checklists and the nurses' interview transcripts, with nurses as the unit of analysis. Employing content analysis techniques, we analyzed the implementation checklists and interview transcripts using a combination of case-oriented and variable-oriented approaches (Miles & Huberman, 1994). Counseling session transcripts and implementation checklist results were compared: as a whole by nurse (i.e., case); by mother's visit type (i.e., variable); and by key verbal and nonverbal counseling element (i.e., variable).

Implementation checklists were used as a quantitative tool to assess nurses' implementation adherence. An "implementation percent adherence" was calculated by adding the items implemented, dividing that number by the total number of checklist items and multiplying this number by 100. We established a 90% implementation adherence as an acceptable level a priori. The percent adherence was a weighted percentage, where verbal items contributed 80% and nonverbal items contributed 20%. We calculated an overall average implementation percentage for each nurse by visit type and by key verbal and nonverbal counseling element.

To analyze the nurse interview transcripts, we wrote a case summary of each transcript and noted important features (Sandelowski, 1995, 1996). Then, using AT-LAS.ti version 5.0 (Muhr, 2004), we coded each interview with codes derived from the interview guide questions and nurses' consistently mentioned ideas concerning their protocol implementation. Next, we conducted a content analysis and discerned reoccurring themes (Miles & Huberman, 1994; Ulin, Robinson & Tolley, 2004).

The institutional review boards at the U.S. Centers for Disease Control and Prevention, the University of North Carolina at Chapel Hill, and the National Health Science Research Committee in Malawi approved this study.

RESULTS

DIRECT OBSERVATIONS

We observed a total of 123 counseling sessions (30 antenatal, 33 early postpartum, 30 mid-postpartum, and 30 late postpartum sessions) among the 6 nurses (a minimum of 20 sessions observed per nurse). Implementation checklist findings revealed that all 6 nurses implemented the protocol at an acceptable level of 90% average implementation adherence or above. During every counseling session observed, nurses adhered to 100% of the nonverbal counseling elements. However, differences in nurses' average implementation adherence varied for the verbal counseling elements by the visit type.

Antenatal—All the nurses implemented 100% (30/30) of the verbal counseling elements during the antenatal visits (Table 2). Specifically, for the 30 antenatal sessions observed, all of the nurses advised the mother to give only breast milk and nothing else to their infant for the first 6 months of life, advised the mother on the advantages of giving only breast milk for 6 months to prevent HIV transmission to their infant, and advised mothers on the risks of mixed feeding and how it may increase the risk of HIV transmission to their infant (Table 3).

Table 4 provides a typical example of how the nurses assessed a mother's knowledge of exclusive breastfeeding. The nurse used repeating/reflecting back counseling techniques, asked questions, and employed active listening skills.

Early Postpartum—For the early postpartum counseling sessions, nurses' overall average implementation adherence was 95.7% (see Table 2) with a majority of the key counseling elements implemented at or above a 90% average implementation adherence (see Table 2). For example, nurses informed mothers about potential breast health issues in 91.0% (30/33) of the sessions observed but asked mothers directly if they had personally experienced any breast health issues in 66.6% (22/33) of the sessions observed (see Table 3).

Table 4 presents an excerpt of a nurse implementing the breast health-related counseling elements. During the exchange, the nurse described how poor attachment of the baby to the breast can lead to breast health problems and provided advice on how to treat this condition.

Mid-Postpartum—In the mid-postpartum counseling sessions, nurses consistently implemented the protocol with a 97.8% average implementation adherence (see Table 2). Nurses advised mothers on the importance of introducing and preparing locally available and affordable complementary foods in 100% (30/30) of the counseling sessions observed. However, nurses provided mothers with specific advice to comfort their infant after weaning in 86.6% (26/33) of the sessions observed (see Table 3).

During the mid-postpartum visits, mothers' responses related to actual or intended use of formula milk was a consistent theme after they reportedly stopped breastfeeding their infant at 6 months. Although not detailed in the BAN Study infant-feeding counseling protocol, nurses appropriately counseled mothers on formula milk use when the mother mentioned formula milk use after weaning their baby. Table 4 displays an example of how nurses counseled mothers, with much explanation and detail, about their intentions to feed their infant formula milk.

Late Postpartum—The average implementation adherence for the late postpartum sessions observed was 92.7% (see Table 2). The nurses advised mothers on the importance of giving their infant AFASS complementary foods in addition to the Chiponde (a locally produced fortified energy-dense breast milk replacement food, also known as "plumpy nut") provided by the BAN Study in 100% (30/30) of the late postpartum sessions observed. However, the

nurses asked the mothers if they had stopped breastfeeding completely in 73.3% (22/30) of the sessions observed and asked the mothers about the importance of stopping breastfeeding in 50.0% (15/30) of the sessions observed (Table 3).

INTERVIEWS

Interviews with the 6 nurses revealed their perceived barriers toward implementing the counseling protocol consistently and completely during every session and also provided suggestions on how to improve their protocol adherence.

Perceived Barriers—Although nurses reported that counseling mothers on exclusive breastfeeding was easy, they encountered some difficulty when counseling mothers on early breastfeeding cessation. Nurses expressed frustration when implementing this because they noticed that some mothers were not willing to stop breastfeeding at 6 months regardless of them counseling otherwise. One nurse with 5 years of nursing experience explained:

Our [Malawi] women are not used to stopping their infants from breastfeeding at six months. So to prepare these infants and mothers to stop breastfeeding at 6 months is not easy. I think it takes more time, more skills and a lot of knowledge to deliver this [information on breastfeeding cessation].

Nurses consistently identified the high patient-to-nurse ratio in the BAN Study clinic as another major barrier toward achieving complete implementation of the infant-feeding counseling protocol. On a typical work day, there are two nurses counseling patients and an average of 31 mothers and 16 infants waiting for counseling and other health care services (data not shown), accounting for approximately 15 mothers to be counseled by every nurse. Some nurses mentioned that the high number of mothers waiting in the clinic corridor for counseling overwhelmed them, resulting in incomplete implementation of the counseling protocol.

Nurses also expressed a need for additional training for complete implementation of the counseling protocol. One nurse with 8 years of nursing experience talked about why more training is important to her.

It's important for us to be trained more on this infant-feeding because it's so crucial. The way you deliver the message matters most because if we don't deliver the message properly, it will not work because the mothers will not understand what to do. Yes, it [improper messages to mothers] will kill our infants.

When describing their counseling training needs, nurses identified two categories of nurses working on the BAN Study: those who had participated in a formal, two or more weeklong infant-feeding counseling training course and those who participated in a weeklong HIV and infant-feeding counseling training course as part of their orientation to the overall BAN Study. One nurse with 5 years of nursing experience described the differences between her counseling training and that of formal counseling training:

From what I have observed, most nurses here in the BAN study have only done the BAN Study orientation counseling, not the formal full counseling training. So, I think we can learn a lot from the full formal training because we can be trained on more [counseling] skills that we do not know.

Suggestions for Implementation Improvement—Nurses' most common suggestion toward improving their adherence to the counseling protocol was to increase the number of nursing staff. Nurses believed that having more nurses on the BAN Study would decrease the workload and the high patient-to-nurse ratio, resulting in an increase in implementation adherence.

When discussing their implementation adherence to the complementary feeding counseling elements, nurses identified a gap between what is in the protocol and what mothers mention in their counseling sessions concerning formula milk. The protocol provides few details and no tools on how to counsel mothers on formula milk; thus, nurses suggested having more guidance during the mid- and late postpartum visits on probing mothers about their formula milk use and intentions. Based on the many women she had counseled who had fed, or intended to feed their infant formula milk, one nurse with 9 years of nursing experience explained:

I feel that the information [in the protocol] on complementary feeding is not enough. We find that some mothers who have enough food are not giving it to their babies correctly. For example, a mother might have formula milk and after I probe her [about her usage], you find out she is dissolving it wrong. She is giving this baby only water, not formula milk, and the baby may end up having diarrhea. So, I think at the 28th week postpartum visit there should be some information added to the protocol to remind us that we should probe the mother for her formula milk use.

Having a supervisor or evaluator monitor and observe their counseling sessions was also suggested as a method to help nurses improve their protocol implementation adherence.

DISCUSSION

We conducted a process evaluation to investigate nurses' implementation adherence to the BAN infant-feeding counseling protocol. Results from process data indicate that, based on this small convenience sample, nurses were implementing the infant-feeding counseling protocol at an overall average adherence level of 90% or above. These trained nurses' high implementation adherence to the protocol is contrary to previous reports from sub-Saharan Africa of poor infant-feeding counseling by trained counselors in South Africa (Chopra et al., 2002; Chopra, Doherty, Jackson, & Ashworth, 2005; Chopra & Rollins, 2008), Botswana (Programme Review Team et al., 2002), Kenya (Chopra & Rollins, 2008) and "satisfactory" in Zambia (Horizons Program, 2002).

There are several possible explanations for why nurses in this sample may have implemented the infant-feeding protocol with such high adherence. This process evaluation was part of the BAN Study, a clinical trial, which was conducted at one site in a controlled experimental study environment, whereas the studies that reported poor infant-feeding counseling among health providers were conducted in the context of countrywide pilot PMTCT programs (Chopra et al., 2005; Chopra & Rollins, 2007; Leshabari, Blystad, de Paoli, & Moland, 2007; Horizons Program, 2002; Programme Review Team et al., 2002). Another possible explanation for nurses' high implementation adherence was their prior participation in a brief HIV and infant-feeding counseling training workshop. Nurses' counseling training included was part of the BAN Study's week-long orientation training. In other studies examining infant-feeding counseling in the context of HIV, health providers received no or minimal training (Chopra et al., 2005; Chopra & Rollins, 2008; de Paoli, Manongi, & Klepp, 2002; Horizons Program, 2002; Programme Review Team et al., 2002).

Although the nurses' average implementation adherence was above 90%, our results identified inconsistencies in nurses' implementation of key counseling elements during the early and late postpartum visits. During the early postpartum visits, nurses did not consistently ask mothers if they had experienced any breast health issues. Although not asked directly, nurses may have closely observed the physical appearance of the mother's breasts during their breastfeeding demonstration. However, by not asking the mother directly if she had experienced any breast health issues, nurses may have missed opportunities to counsel and treat breast health problems, which have been linked to an increased risk of MTCT of HIV via breastfeeding (Ekpini et al.,

1997; John et al., 2001; John-Stewart et al., 2004; Ogundele & Coulter, 2003; Semba et al., 1999; WHO, 2004).

We observed that the late postpartum visits had the lowest overall average implementation adherence (92.7%). This reduction in percentage adherence was due to nurses not consistently asking mothers if they had stopped breastfeeding completely and not counseling them about the importance of stopping breastfeeding at 6 months to reduce the risk of HIV infection to their infant. Because these key counseling elements were also implemented during the midpostpartum visits, nurses may have assumed that mothers had stopped breastfeeding completely because they had started giving their infant other solid foods. However, because the infant-feeding norms in Malawi support giving infants solid foods while breastfeeding at 3 months (National Statistical Office [Malawi] & ORC Macro, 2005), it is imperative during the late postpartum counseling visits for nurses to ask the mother directly if she has stopped breastfeeding her infant completely and reiterate the importance of stopping breastfeeding completely to reduce the risk of HIV transmission to the infant during the postnatal period.

Mothers' actual and intended formula milk usage after stopping breastfeeding at 6 months was an unexpected finding. Although the observation data demonstrated nurses' excellent ability to counsel mothers on the proper preparation of formula milk, the interview data revealed that nurses wanted additional guidance on formula milk counseling and shed light on an important counseling element not thoroughly addressed in the current protocol.

This study has several limitations. One limitation is its focus on nurses delivering the counseling information and not on mothers receiving the information. The BAN Study impact evaluation is collecting data from the mothers on their actual infant-feeding practices (van der Horst, Jamieson, & Kazembe 2005). Thus, our study results can be used to complement the future impact and outcome evaluation results. The convenience sampling of nurses is also a limitation of this study in that it may have limited the transferability and applicability of these findings to other nursing populations. Selection bias may have occurred because the 6 participating nurses were not randomly selected.

Our use of direct observation data collection method is also a study limitation because of the potential for participants' reactivity owing to the field investigator's presence in the counseling room (Bentley et al., 1994; Curtis et al., 1993; Patton, 1990; Redman, Dickinson, Cockburn, Hennrikus, & Sanson-Fisher, 1989; Walsh et al., 2000). To address reactivity, the research design included observing many (at least 20) counseling sessions for each nurse to give the nurse and field investigator time to get used to each other's presence in the room and for the nurse to return to her habitual counseling behaviors (Patton, 1990).

Use of direct observation methods is also a strength of our study because it is an effective approach to assess program implementation (Patton, 1990; Walsh et al., 2000). A few researchers reported using this method to observe health provider's infant-feeding counseling behaviors (Chopra et al., 2005; Chopra & Rollins, 2008; Horizon Program, 2002). By using direct observation methods, we were able to observe the actual infant-feeding counseling behavior of the BAN Study nurses versus, as in previous studies, relying on their self-reported infant-feeding counseling behavior (Bradley & Meme, 1992; Davies-Adetugbo, 1996: de Paoli et al., 2002; Owoaje, Oyemade & Kolude, 2002)

Triangulation of data sources (e.g. counseling session transcripts, implementation checklists and interviews) was also a study strength because it allowed for an assessment of expected and unexpected occurrences and situations nurses encountered during their counseling sessions (Miles & Huberman, 1994).

CONCLUSION

The incorporation of a process evaluation study into the BAN Study clinical trial guarded against the implementation failure of the study's infant-feeding counseling protocol and will assist the coinvestigators with the interpretation of the BAN study's impact and outcome evaluation results (Israel et al., 1995; Linnan & Steckler, 2002). Findings also shed some light on nurses' adherence toward implementing WHO (2001, 2006) infant-feeding recommendations for HIV-infected women in resource-poor areas. Although this study took place within the context of a clinical trial, in a selected sample, the results can provide policymakers with an indication of how applicable the WHO (2001, 2006) policy recommendations concerning counseling and support are for trained nurses to implement in resource-poor areas. Lastly, our process evaluation findings suggest that even with a brief, week-long intensive training on HIV and infant-feeding counseling, it is possible for nurses to implement an infant-feeding counseling protocol with high adherence. This finding is important for public health practice because it suggests that as critical health service providers in PMTCT, nurses provide high quality infant-feeding counseling to HIV-infected mothers that is applicable to the local realities of the community.

Acknowledgments

This research was funded by the NIH/NICHD, National Research Service Award Minority Pre-doctoral Fellowship (F31 HD043705-03), Prevention Research Centers Special Interest Project SIP 13-01 U48-CCU409660-09 and SIP 26-04 U48-DP000059-01, Centers for Disease Control and Prevention, and was supported by the NIAID P30-AI50410 UNC Center for AIDS Research; DHHS/NIH/FIC 2-D43 Tw01039-06 AIDS International Training and Research Program and Abbott Laboratories, GlaxoSmith-Kline, Boehringer-Ingelheim, Roche Pharmaceuticals, and Bristol-Myers Squibb. The Call to Action PMTCT program has been supported by the Elizabeth Glaser Pediatric AIDS Foundation Call to Action Award and International Leadership Awards, UNICEF, World Food Programme, Malawi Ministry of Health, Johnson and Johnson and USAID. The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers For Disease Control and Prevention.

References

- Basch CE, Sliepcevich EM, Gold RS, Duncan DF, Kolbe LJ. Avoiding type III errors in health education program evaluations: A case study. Health Education Quarterly 1985;12(4):315–31. [PubMed: 4077544]
- Bentley, ME.; Boot, MT.; Gittelsohn, J.; Stallings, RY. The use of structured observations in the study of health behavior. Hague, The Netherlands: IRC International Water and Sanitation Centre; 1994.
- Bentley ME, Corneli AL, Piwoz E, Moses A, Nkhoma J, Tohill BC, et al. Perceptions of the role of maternal nutrition in HIV-positive breastfeeding women in Malawi. Journal of Nutrition 2005;135(4): 945–949. [PubMed: 15795467]
- Bradley JE, Meme J. Breastfeeding promotion in Kenya: Changes in health worker knowledge, attitudes and practices, 1982–89. Journal of Tropical Pediatrics 1992;38(5):228–234. [PubMed: 1433448]
- Breastfeeding and HIV International Transmission Study Group. Late postnatal transmission of HIV-1 in breast-fed children: An individual patient data meta-analysis. Journal of Infectious Disease 2004;189 (12):2154–2166.
- Chopra M, Doherty T, Jackson D, Ashworth A. Preventing HIV transmission to children: Quality of counselling of mothers in South Africa. Acta Paediatricia 2005;94(3):357–63.
- Chopra M, Piwoz E, Sengwana J, Schaay N, Dunnett L, Saders D. Effect of a mother-to-child HIV prevention programme on infant feeding and caring practices in South Africa. South African Medical Journal 2002;92(4):298–302. [PubMed: 12056362]
- Chopra M, Rollins N. Infant feeding in the time of HIV: Rapid assessment of infant feeding policy and programmes in four African countries scaling up Prevention of Mother to Child Transmission programmes. Archives of Disease in Childhood 2008;93:288–291. [PubMed: 17686796]

Corbett K, Thompson B, White N, Taylor R. Process evaluation in community intervention trial for smoking cessation (COMMIT). International Quarterly of Community Health Education 1991;11(3): 291–309.

- Corneli A, Piwoz E, Bentley ME, Moses A, Nkhoma JR, Tohill BC, et al. Involving communities in the design of clinical trial protocols: The BAN Study in Lilongwe, Malawi. Contemporary Clinical Trials 2007;28(1):59–67. [PubMed: 17000137]
- Curtis V, Cousens S, Mertens T, Traore E, Kanki B, Diallo I. Structured observations of hygiene behaviours in Burkina Faso: Validity, variability, and utility. Bulletin of the World Health Organization 1993;71(1):23–32. [PubMed: 8440034]
- Davies-Adetugbo AA. Promotion of breast feeding in the community: Impact of health education programme in rural communities in Nigeria. Journal of Diarrhoeal Disease Research 1996;14(1):5–11.
- Dehar MA, Casswell S, Duignan P. Formative and process evaluation of health promotion and disease prevention programs. Evaluation Review 1993;17(2):204–220.
- de Paoli MM, Manongi R, Klepp KI. Counsellors' perspectives on antenatal HIV testing and infant feeding dilemmas facing women with HIV in northern Tanzania. Reproductive Health Matters 2002;10(20):144–156. [PubMed: 12557653]
- Ekpini ER, Wiktor SZ, Satten GA, Adjorlolo-Johnson GT, Sibailly TS, Ou CY, et al. Late postnatal mother-to-child transmission of HIV-1 in Abidjan, Cote d'Ivoire. The Lancet 1997;349(9058):1054–1059.
- Gaillard P, Fowler MG, Dabis F, Coovadia H, Van Der Horst C, Van Rompay, et al. Use of antiretroviral drugs to prevent HIV-1 transmission through breastfeeding: From animal studies to randomized clinical trials. Journal of Acquired Immune Deficiency Syndrome 2004;35(2):178–87.
- Horizons Program. Ndola Demonstration Project: A midterm analysis of lessons learned. Nairobi, Kenya: Population Council; 2002.
- Israel BA, Cummings KM, Dignan MB, Heaney CA, Perales DP, Simons-Morton BG, et al. Evaluation of health education programs: current assessment and future directions. Health Education Quarterly 1995;22(3):364–389. [PubMed: 7591790]
- John GC, Nduati RW, Mbori-Ngacha DA, Richardson BA, Panteleeff D, Mwatha A, et al. Correlates of mother-to-child human immunodeficiency virus type 1 (HIV-1) transmission: Association with maternal plasma HIV-1 RNA load, genital HIV-1 DNA shedding, and breast infections. Journal of Infectious Disease 2001;183(2):206–212.
- John-Stewart G, Mbori-Ngacha D, Ekpini R, Janoff EN, Nkengasong J, Read JS, et al. Breastfeeding and transmission of HIV-1. Journal of Acquired Immune Deficiency Syndrome 2004;35(2):196–202.
- Leshabari SC, Blystad A, de Paoli M, Moland KM. HIV and infant feeding counselling: challenges faced by nurse-counsellors in northern Tanzania. Human Resources for Health 2007;5(18) 10.1186/1478-4491-5-18
- Linnan, L.; Steckler, A. Process evaluation for public health interventions and research: An overview. In: Steckler, A.; Linnan, L., editors. Process evaluation for public health interventions and research. San Francisco: Jossey-Bass; 2002. p. 1-23.
- McGraw SA, Stone EJ, Osganian SK, Elder JP, Perry CL, Johnson CC, et al. Design of process evaluation within the Child and Adolescent Trial for Cardiovascular Health (CATCH). Health Education Quarterly 1994;(Suppl 2):S5–S26. [PubMed: 8113062]
- Miles, MB.; Huberman, AM. An expanded sourcebook: Qualitative data analysis. Thousand Oaks, CA: Sage; 1994.
- Muhr, T. ATLAS.ti (Version 5.0) [Computer software]. Berlin: Scientific Software Development; 2004.
- National Statistical Office [Malawi] & ORC Macro. Malawi demographic and health survey 2004. Zomba, Malawi, Calverton, MD: Author; 2005.
- Ogundele MO, Coulter JB. HIV transmission through breastfeeding: problems and prevention. Annals of Tropical Paediatrics 2003;23(2):91–106. [PubMed: 12803739]
- Owoaje ET, Oyemade A, Kolude OO. Previous BFHI training and nurses' knowledge, attitudes and practices regarding exclusive breastfeeding. African Journal Medicine and Medical Sciences 2002;31 (2):137–40.
- Patton, MQ. Qualitative evaluation and research methods. 2. Newbury Park, CA: Sage; 1990.

Piwoz EG, Bentley ME. Women's voices, women's choices: the challenge of nutrition and HIV/AIDS. Journal of Nutrition 2005;135(4):933–937. [PubMed: 15795465]

- Piwoz E, Ferguson YO, Bentley M, Corneli AL, Moses A, Nkhoma J, Tohill BC, Adair L, Mtimuni B, Ahmed Y, Jamieson D, van der Horst C, Kazembe P. the UNC Project BAN Study Team. Differences between international recommendations on breastfeeding and HIV and health workers' attitudes and counseling practices in Lilongwe, Malawi. International Breastfeeding Journal 2006;1(2):1–8. [PubMed: 16722586]
- Piwoz EG, Iliff PJ, Tavengwa N, Gavin L, Marinda E, Lunney K, et al. An education and counseling program for preventing breastfeeding-associated HIV transmission in Zimbabwe: Design and impact on maternal knowledge and behavior. Journal of Nutrition 2005;135(4):950–955. [PubMed: 15795468]
- Programme Review Team, PMTCT Advisory Group, & Infant Feeding Study Group. Evaluation of a pilot programme and a follow-up study of infant feeding practices during the scaled-up programme in Botswana. Evaluation and Program Planning 2002;25:421–431.
- Redman S, Dickinson JA, Cockburn J, Hennrikus D, Sanson-Fisher RW. The assessment of reactivity in direct observation studies of doctor-patient interactions. Psychology and Health 1989;3:17–28.
- Sandelowski M. Qualitative analysis: What it is and how to begin. Research in Nursing and Health 1995;18(4):371–375. [PubMed: 7624531]
- Sandelowski M. One is the liveliest number: The case orientation of qualitative research. Research in Nursing and Health 1996;19(6):525–529. [PubMed: 8948406]
- Seidel G, Sewpaul V, Dano B. Experiences of breastfeeding and vulnerability among a group of HIV-positive women in Durban, South Africa. Health Policy and Planning 2000;15(1):24–33. [PubMed: 10731232]
- Semba RD, Kumwenda N, Hoover DR, Taha TE, Quinn TC, Mtimavalye L, et al. Human immunodeficiency virus load in breast milk, mastitis, and mother-to-child transmission of human immunodeficiency virus type 1. Journal of Infectious Disease 1999;180(1):93–98.
- Semega-Janneh IJ, Bohler E, Holm H, Matheson I, Holmboe-Ottesen G. Promoting breastfeeding in rural Gambia: Combining traditional and modern knowledge. Health Policy and Planning 2001;16(2):199–205. [PubMed: 11358922]
- Ulin, PR.; Robinson, ET.; Tolley, EE., editors. Qualitative methods in public health: A field guide for applied research. San Francisco: Jossey-Bass; 2004.
- van der Horst, C.; Jamieson, D.; Kazembe, P. HIV infection and breastfeeding: Interventions for maternal and infant health (UNC-CDC-Malawi: BAN Study). 2005.
- van der Horst CM, Hasela C, Ahmed Y, Hoffman I, Hosseinipour M, Knight R, Fiscus S, et al. Modifications of a large HIV prevention clinical trial to fit changing realities: A case study of the Breastfeeding, Antiretroviral, and Nutrition (BAN) Protocol in Lilongwe, Malawi. Contemporary Clinical Trials 2009;30(1):24–33. [PubMed: 18805510]
- Walsh RA, Redman S, Byrne JM, Melmeth A, Brinsmead MW. Process measures in an antenatal smoking cessation trial: Another part of the picture. Health Education Research 2000;15(4):469–483. [PubMed: 11066464]
- World Health Organization. New data on the prevention of mother-to-child transmission of HIV and their policy implications: Conclusions and recommendations. WHO Technical Consultation on Behalf of the UNFPA/UNICEF/WHO/UNAIDS Inter-Agency Task Team on mother-to-child transmission of HIV; Geneva. 11–13 October 2000; Geneva, Switzerland: Author; 2001.
- World Health Organization. HIV transmission through breastfeeding: A review of available evidence. Geneva, Switzerland: Author; 2004.
- World Health Organization. Consensus Statement; WHO HIV and Infant Feeding Technical Consultation Held on behalf of the Inter-agency Task Team (IATT) on Prevention of HIV Infections in Pregnant women, Mothers and their Infants; Geneva. October 25–27, 2006; Geneva, Switzerland: Author; 2006.
- World Health Organization./UNAIDS/UNICEF. Report No. WHO/FCH/CAH/00.3. Geneva, Switzerland: Author; 2000. HIV and infant feeding counselling: A training course.
- World Health Organization./UNICEF. Report No. WHO/CDR/93.4. Geneva, Switzerland: Author; 1993. *Breastfeeding counselling: A training* course.

World Encyclopedia. Malawi: 2005. Retrieved September 19, 2007 from www.encyclopedia.com/doc/1O142-Malawi.html

Appendix

The BAN Study Team at the University of North Carolina (UNC) at Chapel Hill, Centers for Disease Control and Prevention, Atlanta, GA, and the UNC Project team in Lilongwe include: Linda Adair, Yusuf Ahmed, Mounir Ait-Khaled, Sandra Albrecht, Shrikant Bangdiwala, Ronald Bayer, Margaret Bentley, Brian Bramson, Emily Bobrow, Nicola Boyle, Sal Butera, Charles Chasela, Charity Chavula, Joseph Chimerang'ambe, Maggie Chigwenembe, Maria Chikasema, Norah Chikhungu, David Chilongozi, Grace Chiudzu, Lenesi Chome, Anne Cole, Amanda Corbett, Amy Corneli, Ann Duerr, Henry Eliya, Sascha Ellington, Joseph Eron, Sherry Farr, Yvonne Owens Ferguson, Susan Fiscus, Shannon Galvin, Laura Guay, Chad Heilig, Irving Hoffman, Elizabeth Hooten, Mina Hosseinipour, Michael Hudgens, Stacy Hurst, Lisa Hyde, Denise Jamieson, George Joaki (deceased), David Jones, Zebrone Kacheche, Esmie Kamanga, Gift Kamanga, Coxcilly Kampani, Portia Kamthunzi, Deborah Kamwendo, Cecilia Kanyama, Angela Kashuba, Damson Kathyola, Dumbani Kayira, Peter Kazembe, Rodney Knight, Athena Kourtis, Robert Krysiak, Jacob Kumwenda, Edde Loeliger, Misheck Luhanga, Victor Madhlopa, Maganizo Majawa, Alice Maida, Cheryl Marcus, Francis Martinson, Navdeep Thoofer, Chrissie Matika (deceased), Douglas Mayers, Isabel Mayuni, Marita McDonough, Joyce Meme, Ceppie Merry, Khama Mita, Chimwemwe Mkomawanthu, Gertrude Mndala, Ibrahim Mndala, Agnes Moses, Albans Msika, Wezi Msungama, Beatrice Mtimuni, Jane Muita, Noel Mumba, Bonface Musis, Charles Mwansambo, Gerald Mwapasa, Jacqueline Nkhoma, Richard Pendame, Ellen Piwoz, Byron Raines, Zane Ramdas, John Rublein, Mairin Ryan, Ian Sanne, Christopher Sellers, Diane Shugars, Dorothy Sichali, Wendy Snowden, Alice Soko, Allison Spensley, Jean-Marc Steens, Gerald Tegha, Martin Tembo, Roshan Thomas, Hsiao-Chuan Tien, Beth Tohill, Charles van der Horst, Esther Waalberg, Jeffrey Wiener, and Cathy Wilfert, Patricia Wiyo, Onnocent Zgambo, and Chifundo Zimba.

TABLE 1Example of Implementation Checklist For Mother's 1st to 18th Week Post Partum Visit

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

Ferguson et al.

TABLE 2

Nurses' Average Implementation Adherence by Visit Type (%)

Nurse	Antenatal	Nurse Antenatal Early Postpartum Mid Postpartum Late Postpartum Average	Mid Postpartum	Late Postpartum	Average
1	100.0	95.8	100.0	100.0	6.86
2	100.0	100.0	100.0	91.6	6.76
8	100.0	95.6	96.2	90.0	95.4
4	100.0	89.6	95.4	98.0	95.7
5	100.0	96.2	95.2	82.0	93.3
9	100.0	96.5	100.0	95.0	8.76
Avg.	100.0	95.6	97.8	92.7	

Page 14

TABLE 3

Nurses' Percentage of Adherence of Key Verbal Counseling Elements Implemented by Visit Type

Visit (weeks) (total number of	Key Verbal Counseling Element	How Often Implemented	
observations)		N	%
Antenatal $(n = 30)$	Advised mother to give only breast milk to baby.	30	100.0
	Advised mother on the advantages of giving only breast milk.	30	100.0
	Advised mother on the risks of mixed feeding.	30	100.0
Early post partum $(n = 33)(1st to 18th week)$	Engaged mother to assess how well she understood the importance of giving only breast milk.	32	97.0
	Advised mother on the advantages of giving only breast milk.	33	100.0
	Advised mother on the risks of mixed feeding.	31	94.0
	Asked mother if she had experienced any breast health issues.	22	66.6
	Addressed mother's breast health issues.	30	91.0
	Asked mother to demonstrate her breastfeeding techniques	31	93.9
Mid post partum $(n = 30)(21st, 24th and 28th week)$	Explained to mother importance of early breastfeeding cessation at 6 months.	28	93.3
	Explained to mother that she should stop breastfeeding starting at week 21 and completely stop by week 24.	29	96.6
	Provided mother with specific advice to prepare the baby for breast-feeding cessation.	27	90.0
	Provided mother with specific advice to comfort infant after weaning.	26	86.6
	Advised mother on the importance of introducing complementary foods.	30	100.0
	Advised mother on how to prepare complementary foods.	30	100.0
	Advised mother to give spoonful of Chiponde* 3 times per day.	30	100.0
Late post partum $(n = 30)$ (32nd to 48th week)	Asked mother if she has stopped breastfeeding completely.	22	73.3
	Advised mother about the importance of stopping breastfeeding.	15	50.0
	Advised mother on importance of giving infant complementary foods in addition to Chiponde*.	30	100.0

^{*}Chiponde, commonly known as "plumpy nut," is a locally produced fortified energy-dense breast milk replacement food provided by the BAN Study to all infants postweaning of breastfeeding (van der Horst, Jamieson, & Kazembe, 2005).

TABLE 4

Examples of Nurses Using Infant Feeding Counseling Techniques by Visit Type

Visit type	Excerpt
Antenatal	Nurse: Before we start discussing much, I just want to remind you what is in the consent form which was read to you. In this study we will need all the mothers to exclusively breastfeed their babies, okay?
	Mother: Ummh [in agreement].
	Nurse: Now, when you hear the word exclusive breastfeeding what does it mean?
	Mother: It means breastfeeding the baby exclusively for six months.
	Nurse: Ummh [in agreement].
	Mother: Then stop the baby breastfeeding.
	Nurse: And stop the baby?
	Mother: Yes.
	Nurse: Thank you very much. That is very correct. I just want to add a little bit there. Exclusive breast-feeding means breastfeeding the baby frequently and it should only be breast milk without adding any other food or any drink but it should be only breast milk, okay? Even water or traditional drugs or any other drug which the doctor has not yet prescribed for the baby, okay?
Early post partum (1st to 18th week)	Nurse: Okay. Now, suppose you have cracked nipples. What are you supposed to do?
	Mother: I have never heard about what to do, but also, I have never seen such a case
	Nurse: You have never seen such a case? Have we not told you on what to do if you encounter such a problem during breastfeeding? Okay. So today we are also going to discuss on that one [cracked nipples] because while you are breastfeeding your baby you are bound to encounter some problems. The nipple can crack if the baby is poorly attached to the breast. If you have cracked nipples, chances are high that the baby can get infected with HIV because the baby could be suckling milk along with your blood. In addition to that, when the baby is not well attached to the breast, you could develop breast engorgement because the baby will be suckling less than expected. In which case, the baby will no be emptying all the milk from the breasts and then the milk does what?
	Mother: It forms mastitis right in the breast.
	Nurse: Mastitis. Then comes breast engorgement, right?
	Mother: Ummh [in agreement].
	Nurse: This engorgement can also facilitate the transmission of HIV infection. It is recommended that whenever you have breast engorgement you express milk from that breast onto what?
	Mother: A piece of cloth.
	Nurse: Yes, a piece of cloth. This relieves the pain in a way. It is also advisable to keep breastfeeding from the healthy breast and seek medical attention. If the breast had developed an abscess, it's also good that you do what?
	Mother: I report to the clinic.
	Nurse: Yes. Do you have any questions?
Mid post partum (21st, 24th and 28th week)	Nurse: Thank you very much for all the preparations you are doing after you stop breastfeeding. You mentioned that you are going to buy formula milk.
	Mother: Ummh [in agreement].
	Nurse: Let's talk about your emphasis on formula milk. For one to stop breastfeeding the baby, it doesn't require that person to have formula milk. No! No! What you find at home, any food available at home can do, okay?
	Mother: Ummh [in agreement].
	Nurse: You can depend on porridge. It is not a command or requirement for your baby to be given formula milk. Porridge is enough. Formula milk is expensive. At this age, the baby cannot get full with formula milk only I just want to encourage you to give your baby different foods but frequently. You should not rely on formula milk only. Have you eve given a baby formula milk?
	Mother: No, I have not.
	Nurse: When you have money and buy formula milk, for example, Lactogen milk, it has been written that it is for children from six months upwards.
	Mother: Ummh [in agreement].

Visit type	Excerpt
	Nurse: On the tin like this one [nurse showing example of Lactogen tin], there are a lot of instructions and many other things. They write the amount of water. For example, here it is written that for a bottle with 225 ml, you have to read that you have to boil the water first, okay?
	Mother: Yes.
	Nurse: And the water should be left to cool and you can use the bottle, that clean bottle. If the water should level at 225 ml you have to take nine spoons of Lactogen milk not less, because if you over dilute the formula milk the baby can get nothing from it to help the baby to grow healthy, okay?
	Mother: Ummh [in agreement].
	Nurse: I told you to measure nine spoons, right? Let me show you the spoon which is found in Lactogen milk. It looks like this [nurse showing the mother the measuring spoon]. You have to read what has been written on the tin. With the measure I told you and the level of water in the bottle, you should use nine spoons of formula milk. And take note that the measurements differ according to the type of Lactogen milk you have bought. Other types of Lactogen milk have instructions of taking 10 spoons of formula milk into 250 ml of water.
	Mother: Ummh [in agreement].
	Nurse: These are the difficulties of using formula milk because it requires one to know how much formula milk and water to mix together and read the instructions. Also, if you don't have any idea of what to do, it is very dangerous for the baby