What are the options?

Using formative research to adapt global recommendations on HIV and infant feeding to the local context

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Contents

Explanation of terms v

A. Introduction 1

B. General guidelines and steps for designing formative research 3

1. Define the scope of the research 5
2. Develop a conceptual model 5
3. Formulate research questions 6
4. Review available information 6
5. Identify study sites 6
6. Identify informants 7
7. Choose research methods 7
8. Determine study sample and sample size 8
9. Develop, test, and translate study forms 9
10. Design the analysis plan and database 10
11. Prepare and submit applications for review and approval of proposals 10
12. Recruit and train field investigators 10

C. Recommended topics and research methods for obtaining information 11

D. Analysing the findings 15

E. Disseminating the results 16

References 17

Annexes

1. Sources of information on HIV and infant feeding 19
2. Useful reading on formative research 20
3. Sample formative research design 21
4. Sample questions for formative research on HIV and infant feeding 25
5. Sample text for obtaining informed consent 37
6. Useful information on replacement feeding options 39

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Explanation of terms

Acquired immunodeficiency syndrome (AIDS): the active pathological condition that follows the earlier, non-symptomatic state of being HIV-positive.

Acceptable, feasible, affordable, sustainable and safe (AFASS): These terms refer to the conditions that should be in place for replacement feeding.

Artificial feeding: feeding with breast-milk substitutes.

Bottle-feeding: feeding from a bottle, whatever its content, which may be expressed breast milk, water, infant formula, or another food or liquid.

Breast-milk substitute: any food being marketed or otherwise represented as a partial or total replacement for breast milk, whether or not suitable for that purpose.

Cessation of breastfeeding: completely stopping breastfeeding, including suckling.

Commercial infant formula: a breast-milk substitute formulated industrially in accordance with applicable Codex Alimentarius standards to satisfy the nutritional requirements of infants during the first months of life up to the introduction of complementary foods.

Complementary feeding: the child receives both breast milk or a breast-milk substitute and solid (or semi-solid) food.

Complementary food: any food, whether manufactured or locally prepared, used as a complement to breast milk or to a breast-milk substitute.

Cup-feeding: being fed from or drinking from an open cup, irrespective of its content.

Exclusive breastfeeding: an infant receives only breast milk and no other liquids or solids, not even water, with the exception of drops or syrups consisting of vitamins, mineral supplements or medicines.

Human immunodeficiency virus (HIV): the virus that causes AIDS. In this document, the term HIV means HIV-1. Mother-to-child transmission of HIV-2 is rare.

HIV-negative: refers to people who have taken an HIV test and who know that they tested negative, or to young children who have tested negative and whose parents or guardians know the result.

HIV-positive: refers to people who have taken an HIV test and who know that they tested positive, or to young children who have tested positive and whose parents or guardians know the result.

HIV status unknown: refers to people who either have not taken an HIV test or do not know the result of a test they have taken.

HIV-infected: refers to people who are infected with HIV, whether or not they are aware of it.

HIV testing and counselling: testing for HIV status, preceded and followed by counselling. Testing should be voluntary and confidential, with fully informed consent. The expression encompasses the following terms: counselling and voluntary testing, voluntary counselling and testing, and voluntary and confidential counselling and testing. Counselling is a process, not a one-off event: for the HIV-positive client it should include life planning, and, if the client is pregnant or has recently given birth, it should include infant-feeding considerations.

Home-modified animal milk: a breast-milk substitute prepared at home from fresh or processed animal milk, suitably diluted with water and with the addition of sugar and micronutrients.

Infant: a person from birth to 12 months of age.

Infant feeding counselling: counselling on breastfeeding, on complementary feeding, and, for HIV-positive women, on HIV and infant feeding.

Mixed feeding: feeding both breast milk and other foods or liquids.

Mother-to-child transmission: transmission of HIV to a child from an HIV-infected woman during pregnancy, delivery or breastfeeding. The term is used in this document because the immediate source of the child's HIV infection is the mother. Use of the term mother-to-child transmission implies no blame, whether or not a woman is aware of her own infection status. A woman can contract HIV infection from unprotected sex with an infected partner, from receiving contaminated blood, from non-sterile instruments (as in the case of injecting drug users), or from contaminated medical procedures.

Programme: an organized set of activities designed to prevent transmission of HIV from mothers to their infants or young children.

Replacement feeding: feeding infants who are receiving no breast milk with a diet that provides the nutrients infants need until the age at which they can be fully fed on family foods. During the first six months of life replacement feeding should be with a suitable breast-milk substitute. After six months the suitable breast-milk substitute should be complemented with other foods.

'**Spillover':** a term used to designate the feeding behaviour of new mothers who either know that they are HIV-negative or are unaware of their HIV status – they do not breastfeed, or they breastfeed for a short time only, or they mix-feed, because of unfounded fears about HIV or of misinformation or of the ready availability of breast-milk substitutes.

A. Introduction

Mother-to-child transmission (MTCT) of HIV accounts for about 800,000 or 10% of all new HIV infections worldwide each year. Paediatric HIV infection causes premature death when antiretroviral (ARV) treatment is not available. In Africa, for example, 30 to 50% of all untreated HIV-positive children die before their first birthday and fewer than 30% survive beyond 5 years of age (Dray-Spira et al, 2000).

MTCT occurs during pregnancy, at the time of delivery, and after birth through breastfeeding, but HIV transmission is by no means universal. In the absence of interventions to prevent transmission, 5 to 10% of infants born to HIV-infected mothers are infected in-utero, 10 to 15% are infected during childbirth, and another 5 to 20% are infected through breastfeeding (De Cock et al, 2000).

Several conditions are known to increase the risk of HIV transmission during breastfeeding. These include the mother's immune status (Leroy et al, 2003; John et al, 2001) and blood viral load (Richardson et al, 2003; Semba et al, 1999); the duration of breastfeeding (Read et al, 2002); the presence of bleeding nipples (Embree et al, 2000; John et al, 2001), breast inflammation, mastitis, abscesses (Embree et al, 2000; John et al, 2001; Semba et al, 2001; Ekpini et al, 1997) or oral thrush in infants (Embree et al, 2000). Mixed feeding may also increase the risk of HIV transmission (Coutsoudis et al, 1999; 2001). Women who become infected with HIV while they are breastfeeding are also more likely to infect their infants during breastfeeding because of the higher viral load that occurs at this time (Dunn et al, 1992).

ARV prophylaxis given late in pregnancy and/or during labour and delivery reduces the risk of being born with HIV by about half (ranging from 37 to 63%) (Dabis et al, 1999; Guay et al, 1999; Shaffer et al, 1999; Wiktor et al, 1999; the Petra Study Team, 2002, Leroy et al, 2002). However, even with ARV prophylaxis, infants still risk becoming infected with HIV unless steps are taken to reduce postnatal exposure during breastfeeding (WHO, 2001).

The transmission of HIV, the virus causing AIDS, through breastfeeding has created a dilemma for public health programmes and for mothers and families affected by the disease. The benefits of breastfeeding for mother and infant have been well documented (WHO, 2002). The increased risks of infant morbidity and mortality associated with artificial feeding in resource poor settings are also well known (WHO, 2000).

Many documents have been written on HIV and infant feeding (see Annex 1). The UN agencies have published a policy statement (1997), Framework for Priority Action (2003), guidelines for decision-makers and for health-care managers and supervisors (originally published in 1998 and revised in 2003), and a training course on HIV and infant feeding counselling (2000). The most recent recommendations on HIV and infant feeding (WHO 2001; WHO/UNICEF/UNFPA/UNAIDS, 2003) state:

- When replacement feeding is acceptable, feasible, affordable, sustainable and safe, avoidance of all breastfeeding by HIV-positive mothers is recommended.
- Otherwise, exclusive breastfeeding is recommended during the first months of life.
- To minimize HIV transmission risk, breastfeeding should be discontinued as soon as feasible, taking into account local circumstances, the individual woman's situation and the risks of replacement feeding (including infections other than HIV and malnutrition).
- When HIV-positive mothers choose not to breastfeed from birth or stop breastfeeding later, they should be provided with specific guidance and support for at least the first 2 years of the child's life to ensure adequate replacement feeding. Programmes should strive to improve conditions that will make replacement feeding safer for HIV-positive mothers.
- HIV-positive mothers who breastfeed should be provided with specific guidance and support when they cease breastfeeding to avoid harmful nutritional and psychological consequences and to maintain breast health.
- All HIV-positive mothers should receive counselling, which includes provision of general information about the risks and benefits of various infant

feeding options, and specific guidance in selecting the option most likely to be suitable for their situation. Whatever a mother decides, she should be supported in her choice.

- Assessments should be conducted locally to identify the range of feeding options that are acceptable, feasible, affordable, sustainable and safe in a particular context.
- Information and education on prevention of HIV infection in infants and young children should be urgently directed to the general public, affected communities and families.

The purpose of this manual is to provide programme managers, researchers, and policy makers with basic guidance on how to conduct local assessments to establish the range of replacement feeding options and breast-milk feeding options that may be acceptable, feasible, affordable, sustainable and safe (AFASS) in different contexts.[1] Findings from local assessments may also be used to develop national policies, guidelines for health workers, materials for training of counsellors and behaviour change communications strategies to support safe infant feeding in programmes to prevent HIV infection in infants and young children.

The following feeding options, currently recommended for infant feeding by HIV-positive women, are explored:[2]

- Commercial infant formula
- Home-modified animal milk
- Exclusive breastfeeding
- Early breastfeeding cessation
- Wet-nursing by an HIV-negative woman
- Expressing and heat-treating breast milk

Additionally, issues related to complementary feeding, required for children 6 months and older with all the above options, are also explored.

The guidance is based on work already carried out to develop infant feeding recommendations for HIV-positive mothers in sub-Saharan Africa and Asia (1998–2002), as well as many years of experience developing infant feeding recommendations for the Integrated Management of Childhood Illness (IMCI) strategy. This experience strongly suggests that rapid formative research, using a combination of qualitative and quantitative methods along with dietary assessment, provides the information necessary for defining feeding recommendations that are acceptable, feasible, affordable, sustainable, and safe. Recommendations based on this approach are more likely to lead to sustained behaviour change and nutritional improvement in diverse populations (Dickin et al, 1997; Caulfield et al, 2000).

[1] For the purposes of this manual, exclusive breastfeeding in the first six months of life is always considered AFASS, but formative research may discover ways to find facilitating factors and overcome any existing obstacles to this practice. The AFASS of other breast-milk feeding options, such as wet-nursing or expressing and heat-treating of breast milk, may need to be explored.

[2] One recommended feeding option, the use of breast-milk banks, is not explored in this manual. This is because breast-milk banks should already be functioning according to recognized standards, including heat-treatment of donated milk, before considering this option locally. If these conditions are met, then questions related to AFASS of expressing and heat-treating milk and wet-nursing can be adapted to address issues related to feeding infants on breast milk from human milk banks.

B. General guidelines and steps for designing formative research

Formative research can be carried out at any point in the programme cycle. Findings can be used to design a new programme, or to improve the communications and strategies used by an existing one.

In this manual we consider two possibilities:

1. research carried out before introduction of interventions to prevent HIV infection in infants and young children; and
2. research carried out after interventions to prevent HIV infection in infants and young children[1] have been introduced.

This distinction is important for the design and structure of the formative research. In the first situation, researchers will not be able to identify HIV-positive mothers (because testing and counselling services are not yet in place) and interviews with people who do not yet know their HIV status will be carried out. The exploration of AFASS is theoretical and not based on actual decision-making among families affected with HIV. In this situation, interviews should be carefully handled to avoid misunderstanding and confusion since most of the feeding options being discussed are not recommended for women of unknown HIV status. Researchers should make sure that respondents do not leave the study with the impression that the feeding options discussed are being recommended for them.

In addition to these interviewing concerns, when formative research is done prior to the introduction of a programme to prevent HIV infection in infants and young children, referral services for study participants may not be available. Referral services are desirable because the formative research interviews and group discussions may raise sensitive questions or heighten personal concerns about HIV. Having information and services available may help to allay concerns and prevent risky behaviour.

If the study is being carried out once HIV testing and counselling and other services are already in place, then the formative research may be carried out among women and families who have already tested for HIV and are in the process of confronting decisions about infant feeding and child care. If concerns arise as a result of some of the research questions, there are already services in place where women or families can receive additional support. However, in these circumstances there is also a greater likelihood that feeding advice is already being disseminated through the programme, and care must be taken to avoid misunderstanding and confusion as a result of the new ideas that may be discussed during the formative research interviews.

We propose that the following steps be followed when designing the formative research.

1. Define the scope of the research – will the study address infant feeding options only, or will other HIV prevention interventions be examined?
2. Develop a theoretical or conceptual model that illustrates the conditions and people who are expected to influence infant feeding decisions and their acceptability, feasibility, affordability, sustainability, and safety.
3. Formulate the questions that will be answered through the formative research and the types of respondents who will answer them.
4. Review available information and related programme messages – are some feeding options already being promoted in programmes, or can some be eliminated based on existing data?
5. Identify study sites – what will be the coverage of the programme, and will there be significant differences in services, support, and the expected AFASS in different settings (e.g., urban versus rural areas)?
6. Identify the key informants – these are the people whose opinions, knowledge, attitudes, and practices matter for assessing the AFASS of different feeding options.
7. Choose the research methods – this should be a combination of methods that include at a minimum:

[1] Basic interventions include HIV testing and counselling, antiretroviral (ARV) prophylaxis, infant feeding counselling, modified obstetric practices, and community education and sensitisation about HIV/AIDS and mother-to-child transmission of HIV.

- in-depth interviews to ascertain knowledge, attitudes, and some behaviours
- observation of water, hygiene, and food safety conditions
- market surveys of feeding options' prices and best buys
- semi-structured dietary assessment for children < 18 months
- trials to assess the feasibility and acceptability of different options

8. Determine the study sample and sample size – how many informants will be approached within each group of respondents and with each of the research methods employed?
9. Develop, test, translate, and back-translate study forms, including:
   - Recruitment scripts
   - Informed consent
   - Question and observation guides/instruments
10. Design the analysis plan and database
11. Prepare and submit institutional review board (IRB) applications
12. Recruit and train field investigators

BOX 1: DEFINITIONS OF ACCEPTABLE, FEASIBLE, AFFORDABLE, SUSTAINABLE AND SAFE

These terms should be adapted in the light of local conditions and formative research. The following may serve as a starting point:

Acceptable: The mother perceives no barrier to replacement feeding. Barriers may have cultural or social reasons, or be due to fear of stigma or discrimination. According to this concept the mother is under no social or cultural pressure not to use replacement feeding; and she is supported by family and community in opting for replacement feeding, or she will be able to cope with pressure from family and friends to breastfeed, and she can deal with possible stigma attached to being seen with replacement food.

Feasible: The mother (or family) has adequate time, knowledge, skills and other resources to prepare the replacement food and feed the infant up to 12 times in 24 hours. According to this concept the mother can understand and follow the instructions for preparing infant formula, and with support from the family can prepare enough replacement feeds correctly every day, and at night, despite disruptions to preparation of family food or other work.

Affordable: The mother and family, with community or health-system support if necessary, can pay the cost of purchasing/producing, preparing and using replacement feeding, including all ingredients, fuel, clean water, soap and equipment, without compromising the health and nutrition of the family. This concept also includes access to medical care if necessary for diarrhoea and the cost of such care.

Sustainable: Availability of a continuous and uninterrupted supply and dependable system of distribution for all ingredients and products needed for safe replacement feeding, for as long as the infant needs it, up to one year of age or longer. According to this concept there is little risk that formula will ever be unavailable or inaccessible, and another person is available to feed the child in the mother's absence, and can prepare and give replacement feeds.

Safe: Replacement foods are correctly and hygienically prepared and stored, and fed in nutritionally adequate quantities, with clean hands and using clean utensils, preferably by cup. This concept means that the mother or caregiver:

- has access to a reliable supply of safe water (from a piped or protected-well source)
- prepares replacement feeds that are nutritionally sound and free of pathogens
- is able to wash hands and utensils thoroughly with soap, and to regularly boil the utensils to sterilize them
- can boil water for preparing each of the baby's feeds
- can store unprepared feeds in clean, covered containers and protect them from rodents, insects and other animals.

STEP 1

Define the scope of the research

The primary purpose of this manual is to provide guidance to researchers, guideline-developers, and/or programme managers on how to assess the current WHO recommended feeding options for HIV-positive women in order to refine and simplify the range of options offered within existing programmes. Additional information on how to conduct and analyse formative research is found in Annex 2.

For each option listed, the goal is to determine likely acceptability, feasibility, affordability, sustainability and safety (AFASS) of available options in different contexts addressed by the national or local programme to prevent HIV infection in infants and young children. These terms are defined in Box 1.

Methods and questions for capturing and understanding these concepts are also discussed in Section C.

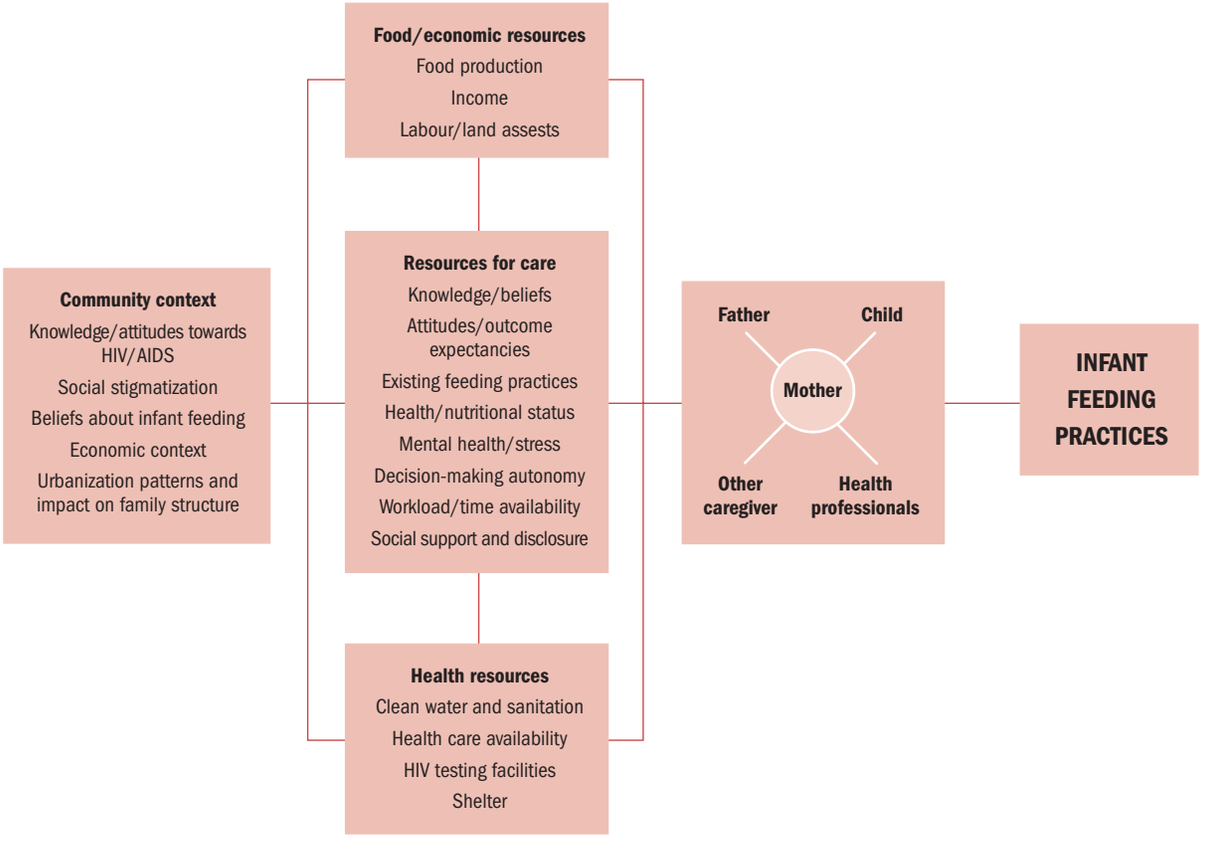
STEP 2

Develop a conceptual model

The conceptual model provides a theoretical framework to guide decision-making about the formative research design. It depicts the range of conditions that influence feeding decisions and their outcome (e.g., knowledge, perceptions, family influences, resources, environment, etc), and issues that need to be explored in order to define appropriate feeding options.

An illustrative framework based on the UNICEF Model of Care is shown in Figure 1. This framework depicts an ecological model, which assumes that feeding behaviours are influenced by interacting, intrapersonal, social and cultural, and physical environment variables. The boxes in this model cut-across the various aspects of acceptability, feasibility, affordability, sustainability, and safety described in Step 1. Individual studies should consider developing their location-specific models/frameworks.

Figure 1. Conceptual model: infant feeding in the context of HIV



Source: Engle PL, Menon P, Haddad L (1997). *Care and nutrition: Concepts and measurement*. IFPRI, Washington, D.C.

STEP 3

Formulate research questions

Once the conceptual model is defined, the next step is to formulate the questions to be answered through the formative research. Typical questions might include:

- What is the AFASS of each of the recommended feeding options for HIV-positive women and their families in the study population?
  - Which options should be discussed with HIV-positive mothers/families and whether any should be eliminated from counselling because of a clear lack of AFASS throughout the population?
  - Is there regional (e.g., rural/urban), cultural or other significant variation in conditions affecting AFASS of the feeding options in the population?
- What are the major constraints and facilitating factors for each feeding option?
  - What will be needed to overcome constraints to safe infant feeding in the first 6 months?
  - What will be needed to overcome constraints to safe infant feeding after 6 months?
- What training, IEC support, and other resources will be needed to ensure that health workers are able to counsel and support HIV-positive mothers about the locally appropriate feeding options, and can provide needed follow-up support?
- What training and support is needed to strengthen infant feeding counselling for HIV-negative women and women of unknown HIV status?
  - What can be done to avoid confusion in the general population about HIV and infant feeding (since feeding option messages are targeted to infected mothers only)?

Additional questions will emerge from the conceptual framework and discussions with formative research stakeholders.

STEP 4

Review available information

Existing information will help to guide and streamline the formative research. This information should be reviewed:

- **Epidemiologic information**: Socio-demographic data such as income, rural/urban populations, infant and child mortality rates; HIV prevalence rates by age, sex, and/or population group, uptake of HIV testing and counselling and ARV prophylaxis and treatment; prevalence of diarrhoea and other infectious diseases of infancy; access to safe water; and hygiene and sanitation.
- **Nutritional information**: prevalence and patterns of malnutrition, breastfeeding and complementary feeding patterns; dietary intake information; commonly available foods, prices, and seasonal influences; infant feeding related attitudes, beliefs and cultural practices.
- **HIV policies and guidelines** with special attention to HIV testing and counselling, prevention of HIV infection in infants and young children, and care and support for HIV-positive women and children.
- **Infant feeding and nutrition policies and guidelines** with special attention to breastfeeding and complementary feeding, nutritional management of childhood infections and severe malnutrition, and any existing policies or guidance related to infant feeding in the context of HIV.
- **The status of existing programmes that address infant feeding practices and their key messages**, including the Baby Friendly Hospital Initiative, IMCI, protein-energy malnutrition and feeding programmes for malnourished children, etc.
- **The experience of NGOs and other groups that might be working on issues related to HIV/MTCT and infant feeding**.

Existing information can be obtained from the National Assessment Tool for Infant and Young Child Feeding (WHO/LINKAGES, 2003) if an assessment has already been conducted, or from national experts in HIV, nutrition/infant feeding, anthropology, maternal child health, and agriculture/environment. Documents, such as policy documents and guidelines; national and regional HIV surveillance reports; nutrition surveys; demographic and health surveys (DHS); nutrition or HIV-related programme reports; NGO evaluations and programme documentation; and research reports (published and unpublished) should be located and obtained for the review.

STEP 5

Identify study sites

The formative research should be carried out in a population or populations that are representative – ethnically, linguistically, geographically/agronomically,

socially, and economically – of the area where counselling on infant feeding options will take place. Urban, peri-urban, and rural areas should be included if the programme is covering these types of districts because AFASS is likely to vary with changing urbanization, access to safe water, hygiene, commercial outlets, health services, and poverty levels.

Whenever possible, the sites should already have in place HIV testing and counselling and related support services. This is important, as mentioned previously, in order to allow for study of the infant feeding options in the context where actual decisions are being made, rather than in hypothetical circumstances. Conducting the research among women and men who have already been counselled and tested for HIV or at the least who know how HIV is prevented and transmitted can help to minimize any confusion that may arise as a result of new and possibly harmful or stress-inducing information.

STEP 6

Identify informants

Key informants for formative research on HIV and infant feeding options typically include:

- Pregnant women
- Mothers of young children (< 18 months)
- Fathers of young children (< 18 months)
- Health providers (traditional birth attendants, community health workers, midwives, medical officers, doctors, and other health workers providing HIV prevention and care services)
- Community leaders who deliver health related messages or influence local norms and practices, such as religious leaders and school teachers
- Elder family members (grandmothers, aunts who also influence decisions or participate in child care)

It is important to obtain information from a range of different informants who play a role in setting norms, providing advice and support, and influencing child-rearing behaviour. Findings obtained from different informants, or obtained from similar informants using different research methods (e.g., group discussions versus direct observation) are compared ("triangulated") to come up with a more complete understanding of local AFASS of the menu of feeding options.

STEP 7

Choose research methods

There is no blueprint for selecting the combination of methods to be used in a formative research study. The selection should be based on 1) available information and gaps to be filled with the research; 2) experience and skills of the investigating team; 3) social and cultural considerations; and 4) resources available (time, money, supporting materials).

In general, the following guidance is given to aid in selecting appropriate research methods:

a. **In-depth interviews** are useful for obtaining information on private issues, on actual feeding behaviours, and on reasons for them. In-depth interviews may employ different types of questions and different approaches for soliciting information.

In-depth interviews can be unstructured, semi-structured, or structured. The differences are in the degree of interviewer flexibility for directing the flow and content of the conversation. In an unstructured interview, the interviewer has a list of topics to be covered but the respondent largely determines the flow of the conversation. New topics may emerge and be explored further during the interview. Structured interviews typically involve a pre-tested question guide, with a set series or sequencing of topics and questions that are discussed with every respondent. Semi-structured interviews include a combination of sequenced questions and opportunities for more open discussion with respondents on the interview topics.

Unstructured, semi-structured, and structured interviews can include "open-ended", "closed-ended", and "mixed" questions (see Box 2), to gather descriptions; to find out how respondents organize information; or to understand the meaning of different concepts.

Different *approaches* to collecting information in in-depth interviews that are commonly used in formative studies include:

— direct enquiry about a topic or behaviour (e.g., feeding histories, 24-hour food recall, breast-feeding practices or weaning intentions);
— demonstration and observation of practices (e.g., food preparation, cup-feeding practices);
— free-listing, pile sorting, or ranking of issues, ideas, or objects/items (e.g., sorting of feeding options by respondents; categorizing items by perceived nutritional value).
— narrative scenarios (e.g., story completion to find out how respondents think others may feel or act about particular topics/behaviours);

BOX 2: EXAMPLES OF "CLOSED-ENDED", "OPEN-ENDED", AND "MIXED" QUESTIONS

"Closed-ended" questions:	How old was your son when you first fed him any liquid or solid food other than breast milk? (Record age in days or weeks)
	Have you ever given your baby commercial infant formula? (Yes or no)
"Open-ended" questions:	What concerns will an HIV-positive mother have if she is advised to stop breastfeeding when her baby is 6 months old?
"Mixed" questions:	Has anyone other than you ever breastfed your baby? (Yes or no). Why? What were the circumstances?
	Can you express and heat-treat your breast milk to feed it to your baby every day? (Yes or no). What makes you feel this way?

— actual testing of new behaviours and practices, with feedback on the results.

b. **Focus group discussions** are useful for obtaining information on norms, attitudes and beliefs. They may also be used to obtain information on sensitive topics of a hypothetical nature. For example, men may be more likely to talk about safer sex and condom use in group discussions rather than individual interviews. Grandmothers may more readily share their opinions about replacement feeding or wet-nursing in the context of a group discussion, rather than in a one-to-one interview when neither option has ever been practised.

Focus group discussions typically employ a structured or semi-structured question guide. Like the in-depth interview, different approaches for obtaining information may be used. Participants (normally 6–10 per group) may be asked direct questions; asked to free list or rank issues; to give feedback on new ideas; or to complete a story involving hypothetical characters faced with infant feeding decisions.

c. **Structured or semi-structured observations** are useful for obtaining information on physical environment, water sources and quality, food/milk formula preparation and safety, and household food availability. Observations of feeding practices, such as breastfeeding (positioning and attachment), milk expression, cup-feeding, infant formula preparation or storage and caretaker-infant interactions are important aspects of all formative research studies on the AFASS of feeding alternatives.

d. **Market surveys** are needed to determine the cost, distribution, and availability of the ingredients and commodities required by different feeding options. Information on products available at local kiosks or food stalls, public marketplaces, and commercial store outlets (e.g., supermarkets) should be recorded. Important data include brands, size, packaging, cost, expiry information, nutritional composition, seasonal availability/fluctuations, and restocking procedures, as appropriate.

e. **Dietary assessments** of feeding patterns for infants and young children are recommended if breastfeeding and food intake data are not available, if the goal is to design recommendations on replacement feeding options for children 6 months and older, and for complementary feeding recommendations. Often such recommendations already exist from work done to adapt the IMCI food box. If this is the case, then a simple, dietary history or modified 24-hour feeding recall (such as that included in Annex 4) can provide sufficient information for determining complementary feeding recommendations.

f. **Trials of new practices** can be carried out where appropriate (e.g., among HIV-positive mothers), by trying out the feeding option at home for a short period of time, and then reporting back on experience, including constraints and facilitating factors. This information is used to make informed decisions about the likelihood that different feeding alternatives (or specific aspects of them) will be adopted and consistently practised in a safe and appropriate manner.

STEP 8

Determine study sample and sample size

Formative research normally uses "purposive sampling", which means that the sample is relatively small and selected based on predetermined criteria and

study needs. A purposefully selected sample is not representative and study findings cannot be generalized to the entire population. However, the results provide valuable information about how people think and feel, and their reactions to new ideas and practices.

This approach is very different from other types of research, such as survey research, which uses large, randomly selected samples (i.e., selection is "by chance"). Random samples are used in surveys to measure characteristics and to make statements about their prevalence in larger, non-surveyed populations. In formative research, purposive sampling is used to study a focused set of issues in greater depth. The goal is to obtain qualitative information, such as why and how infant feeding is practised. Once these issues are understood, random sample surveys can be carried out to measure the occurrence ("how much") of these practices in the general population, if this type of data is desired.

In purposive sampling, the size of the sample depends on the size and diversity of the population area covered by the programme. It may also depend on the resources available for the research, including time, money, and human capacity.

As noted above, there will be several different types of respondents in any one formative study. For *each* population unit ("research site") with homogenous background characteristics believed to affect AFASS (e.g., a similar degree of urbanization; comparable socio-economic status; and similar agronomic, ethnic, linguistic characteristics), a *minimum* sample is as follows:

- 15 in-depth interviews with mothers of children < 18 months, including dietary assessments (5 interviews per 6-month age category; whenever possible it is best to interview mothers of known HIV-positive status)
- 15 structured observations of feeding practices, home hygiene, sanitation (may be done with the same or different families as the in-depth interviews)
- 15 trials of new practices, if deemed to be necessary (may be done with the same or different families as the in-depth interviews)
- 15 in-depth interviews with health providers (5 per provider category)
- 15 interviews or 2 focus group discussions each with other key informants (fathers, grandmothers, and others e.g., community leaders)
- 5 market surveys (covering different types of retail outlets)

The sample size can be increased if the information emerging from the interviews continues to be varied and different, and no clear-cut patterns or conclusions regarding AFASS can be established. Most formative research studies include more than one research site because programmes cover diverse populations, such as urban, peri-urban, and rural areas.

In terms of selecting the sample, interviewing respondents (women and men) who know their HIV-status is generally preferred because there are fewer concerns with introducing new ideas that could lead to harmful practices. However, when testing is newly introduced, the people who go for testing may be unusual – either more sick than the general population or more empowered and motivated to try new behaviours. If this is the case, then interviews and group discussions can be expanded to include women and others who have not tested for HIV. Whenever possible, it is best to choose respondents (who meet eligibility criteria) at random to avoid only talking with individuals with unusual circumstances. This may be done by conducting periodic counselling exit interviews or by choosing respondents from antenatal registration lists or from community programme rosters.

Interviews with health providers should include a variety of workers who come into contact with women during pregnancy and the postnatal period, and who provide advice and counselling about infant feeding. In established programmes it may be useful to interview the health workers who do HIV testing and counselling, and who provide other HIV prevention and care services.

STEP 9

Develop, test, and translate study forms

Study instruments include forms to screen and recruit research participants; to describe the study and obtain consent for participation; and to collect and record new information. All forms should be available in the local language (as well as an official language, e.g., English, if they are to be shared with others). If forms are translated from one language to another, back translation and checking are strongly recommended to ensure that concepts and important aspects of the study have not been changed.

Sample questions for the methods discussed above are found in Annex 3. Questions and approaches are determined based on the conceptual model about factors influencing the AFASS of the feeding options; the gaps that need to be filled through the research; and other programme-specific considerations. All

forms should be pre-tested prior to the start of the research study. Pre-testing involves administration or use of each form among 3–4 different respondents to check for interview flow, question clarity, and missing or inappropriate information.

STEP 10

Design the analysis plan and database

Formative research findings are analysed manually, using text-based coding software, and with dietary intake analysis programs. For studies that include many "closed-ended" and "mixed" questions, an EXCEL, EPI INFO, or other database can be established for ease of data tabulation.

During the fieldwork, all notes and completed interviews should be reviewed daily. As soon as is feasible, tape-recorded interviews and discussions should be transcribed and translated for review and processing. Interview data can be organized and written up as individual case reports, and matrices can be developed to compile information on each feeding option. Text-based data can be coded according to acceptability, feasibility, affordability, sustainability and safety for each option and then findings sorted accordingly, by respondent.

In the final analysis, recommendations about whether to include each option in local HIV and infant feeding counselling guidelines and protocol must be made. These recommendations should include supporting information on how the feeding option/practice can be promoted and supported in the programme area.

STEP 11

Prepare and submit applications for review and approval of proposals

Countries implementing and institutions funding research usually have institutional review boards (IRBs) that must approve protocols and procedures prior to the initiation of research. In some settings, IRB approval might be required even before doing the pilot testing. Countries may also have a national ethics research committee which needs to approve some research projects. Although preparation of the IRB application is here as step 11, the requirements for the application must be considered at the very beginning of the research process. The information described in steps 1–10 become part of the IRB application.

The amount and type of information required for the IRB application varies from board to board but almost certainly includes the objectives of the study; its expected benefits and any risks it poses; a description of the sample; consent forms; recruitment and consenting processes; illustrative study instruments; and a description of the analysis plan. Some IRB applications also require budget information.

During the formative research planning, teams should leave sufficient time for IRB review and reapplication if clarifications and changes are required. However, formative studies are often placed on an expedited review because they involve few or no risk to participants. Many journals now request that authors mention IRB approvals and describe the process used to obtain informed consent in articles submitted and accepted for publication.

STEP 12

Recruit and train field investigators

Ideally, field investigators will have previous qualitative research experience as well as background in HIV/AIDS and/or nutrition. A multi-disciplinary team is recommended. The training required will depend on previous experience and the depth and complexity of the formative study. At least two weeks of training, including classroom sessions and field practice, should be programmed.

Training should cover the following topics using principles of adult learning:

- background on HIV/AIDS in the study area
- overview of mother-to-child transmission of HIV, including local policies and programmes
- discussion on relevant international guidance and national policies on HIV and infant feeding
- background on formative research and its uses
- review of methods to be used
- discussion of the differences between qualitative and other research methods
- interview techniques and probing
- note-taking and record keeping
- the study design and objectives
- review of study instruments (including translations)
- class room and field practice
- review of field experience (adaptation of instruments if needed)
- analysing findings and disseminating results.

The initial training should be followed by continuous supervision and feedback during the research study to ensure the highest quality data and to identify and correct any study gaps or problems during study implementation.

C. Recommended topics and research methods for obtaining information

Matrices which list the priority topics related to each feeding option and the types of methods most useful for collecting this information are found in Tables 1 (breastfeeding options), 2 (replacement feeding options), and 3 (complementary feeding).

The priority topics cover these aspects of infant feeding:

- Knowledge, attitudes, and practices related to the feeding options
- Availability of materials (commodities, ingredients) and cost
- Nutritional considerations
- Constraints and facilitating factors for safe implementation

The emphasis given to each aspect of infant feeding can vary depending on the feeding option and pre-existing information:

- **For breastfeeding**, several issues should be explored. These include breastfeeding initiation and techniques; exclusivity of breastfeeding; expression and heat-treatment; wet-nursing; and issues around early cessation timing and methods. Greatest emphasis is given to knowledge, attitudes, and practices; constraints and facilitating factors; and opinions on AFASS for breast-milk feeding options.
- **For replacement feeding**, most questions pertain to availability and cost of preparing home and commercial infant formula; constraints and facilitating factors for safe implementation; and respondents' opinions on AFASS.
- **For complementary feeding after 6 months**, all topics need to be covered since appropriate complementary feeding involves safe preparation using locally available foods, which must be evaluated for acceptability, cost, and nutritional adequacy, unless specific feeding recommendations have already been developed through IMCI or other national nutrition programmes.

TABLE 1

Priority issues to explore related to breastfeeding options by method of data collection

Breastfeeding issues (BF)	In-depth interviews	Focus group discussions	Structured observations	Market surveys	Dietary assessments	Trials of new practices
– initiation	X	X			X	
– frequency	X				X	
– timing and duration of feeds			X		X	
– exclusivity	X	X	X		X	
– perceptions about milk quality, quantity	X					
– management of feeding problems	X					X
– introduction of other foods, liquids	X				X	
– constraints to optimal practice	X	X				X
– persons of influence	X	X				
– experience with previous children	X					
– infant behaviour and its influence on BF	X					
– age of BF cessation	X					
– reasons for stopping	X	X				
– opinions on stopping early	X	X				
– constraints, facilitating factors for stopping early	X	X				X
– strategies for stopping early	X	X				
– opinions on rapid and gradual weaning	X	X				X
– managing family and community reaction to new behaviours, stigma	X	X				X
– opinions on wet-nursing	X	X				X
– constraints and facilitating factors for wet-nursing	X	X				
– current, past wet-nursing experience, practice	X					
– managing family reactions to wet-nursing	X	X				X
– opinions on expressing and heat-treating breast milk (EHTBM)	X	X				X
– past experience with EHTBM	X					
– constraints, facilitating factors for EHTBM	X	X				X
– opinions on cup-feeding EHTBM	X	X				X
– experience cup-feeding EHTBM	X					X
– infant reaction to cup-feeding EHTBM	X		X			X
– availability, cost of fuel, time, supplies for EHTBM				X		
– managing family, community opinion	X	X				
– feelings about receiving counselling on HIV and infant feeding	X	X				
– opinions and experience with breastfeeding support groups	X	X				
– other concerns about HIV and infant feeding	X	X				X

TABLE 2

Priority issues to explore related to replacement feeding options by method of data collection

Replacement feeding issues (RF)	In-depth interviews	Focus group discussions	Structured observations	Market surveys	Dietary assessments	Trials of new practices
– general opinions about not breastfeeding	X	X				
– availability, cost of infant formula (commercial [CIF] or home-modified animal milk [HMAM])			X	X	X	
– availability, cost, use of goats, cows, other animals for milk	X		X	X	X	
– quality of animal milk sold locally (dilution, pasteurisation, etc)	X			X		
– sources, quality of water	X		X			
– water boiling, storage	X		X			
– CIF, HMAM preparation practices, safety (including dilution, mixing of ingredients)	X		X			X
– time to prepare, time to feed	X		X			X
– past experience with CIF, HMAM	X	X				
– frequency of feeding during day, night	X				X	
– understanding, feasibility of preparation instructions	X	X				X
– infant reaction to CIF/HMAM, including health/illness (if it is already an existing option)	X					X
– use of feeding bottles, cups for drinking fluids	X	X	X			
– opinions on cup-feeding	X	X				X
– availability, cost of micronutrient (MN) supplements	X		X	X		
– nutrient composition of MN supplements			X			
– opinions, past experience with MN supplements	X					
– infant reaction to MN supplements	X					X
– seasonal or monthly fluctuations in food, time, resource availability	X	X		X		
– ideas for supporting mothers with safe replacement feeding (e.g., peer support, individual support)	X	X				X
– other concerns about feeding CIF, HMAM	X	X				X

TABLE 3

Priority issues to explore related to complementary feeding options by method of data collection

Complementary feeding issues (CF)	In-depth interviews	Focus group discussions	Structured observations	Market surveys	Dietary assessments	Trials of new practices
– local foods given to young children as meals or snacks	X	X		X	X	
– local breast-milk substitutes, availability, cost	X			X	X	
– nutritional adequacy, density of CF diet					X	
– sources, quality of water			X			
– water boiling, storage	X		X			
– food preparation, hygiene, safety practices			X			X
– frequency of CF	X				X	
– quantity of food offered, consumed					X	
– indicators/cues for hunger, satiety	X	X				
– caregiver-infant interactions, responsive feeding			X			
– infant CF appetite, likes/dislikes	X					X
– use, cleanliness of feeding bottles	X		X			
– use of cup, separate plate for feeding	X		X		X	
– cost of local foods, best buys for infant nutrition				X		
– role of family, community members in feeding decisions	X	X				
– attitudes, practices re: feeding during illness	X	X			X	
– attitudes, practices re: feeding during convalescence	X	X			X	
– household food availability	X		X			
– opinions about new recipes, enriched CF	X	X				X
– opinions on increasing CF frequency, quantity	X	X				X
– opinions on use of breast-milk substitutes	X	X				X
– seasonal, monthly changes in food availability	X	X	X			
– other concerns about feeding CF	X	X				X

D. Analysing the findings

Analysis of qualitative research findings is an iterative process that begins in the field and continues throughout the study. During the fieldwork, notes and interviews must be regularly reviewed to ensure that all answers are complete and clearly reported. In some cases, investigators may wish to add questions if new topics emerge during the fieldwork. If interviews and focus group discussions are audio taped, then tapes should be reviewed and transcribed as quickly as possible.

If database programs are being used to store information, then entry should also take place as soon as possible. Studies should consider hiring experienced data entry clerks for this purpose.

Several rapid analysis methods are commonly employed in formative studies. These include simple tallying of responses for "closed-ended" questions; creating matrices to organize information on constraints and facilitating factors for safe implementation of each feeding option; and ranking of the AFASS of each replacement or breast-milk feeding option.

For ranking, one suggestion is to have one or more members of the study team review the available interview data and assign a value from 1 (low) to 3 (high) AFASS for each question shown in Table 4, for each feeding option. Each person completing the ranking exercise should work independently. After everyone completes the exercise, the entire group can convene to compare and synthesize their results, giving explanations for why each rating was given. The group can come up with final ratings for each AFASS dimension and feeding option, or take the median value from those who participated. Investigators can develop their own criteria for evaluating AFASS.

Investigators who are interested in more comprehensive analysis of their data should use text-based coding programs. These programs (e.g., NVIVO) allow for coding of answers to "open-ended" questions according to individual themes, or hierarchies of themes. Individual statements can be coded more than once. Most text-based coding programs allow for sorting and analysis of responses by other input characteristics.

For the type of study described here, coding the data according to the main dimensions of acceptability, feasibility, affordability, sustainability and safety will facilitate the process of drawing conclusions about the range of options to be supported in the programme. Coding according to the components of the underlying conceptual model may also be useful. An analysis that combines the ranking described in Table 4 with relevant quotes from interviews identified through text-based coding will be evidence-driven and compelling to decision-makers.

TABLE 4

Ranking AFASS for Feeding Option (specify) _____

1=low (poor rating)
2=medium
3=high (best rating)

Acceptability
- Cultural norms (conducive=3)
- Stigma (no=3)
- Discrimination (no=3)

Feasibility
- Time available (high=3)
- Other resources available, e.g., fuel, thermos flask, cup (high=3)
- Knowledge and attitudes (conducive=3)
- Skills teachable (easily=3)
- Impact on family (positive=3; negative=1)
- Impact on mother (positive=3; negative=1)

Affordability
- Cost affordable to family (yes=3)
- Cost affordable to health system (yes=3)

Sustainability
- Continuous/uninterrupted supply (yes=3)
- Dependable source (yes=3)

Safety
- Nutrition adequacy (high=3)
- Hygienic preparation (free of pathogens=3)
- Safe storage (yes=3)
- Hygienic feeding utensil (yes=3)

E. **Disseminating the results**

The findings from the formative research should be organized into a final report and dissemination presentation. The report should include the following chapters:

- Introduction/background (purpose of the research; conceptual model underpinning the design)
- Methodology and sample
- Data analysis approach
- Responsible organizations
- IRB and other approvals
- Findings related to each feeding option (knowledge, attitudes, practices; constraints and facilitating factors; etc.)
- Conclusions about the range of feeding options that are most likely to be AFASS and the rationale
- Other recommendations for local programmes to prevent HIV infection in infants and young children (related to options, training, communications, counselling and other support needed)

In addition to preparation of a full report, researchers are strongly encouraged to prepare a presentation of the study design and main findings to interested stakeholders and decision-makers. The presentation should highlight key findings and recommendations, using graphics, direct quotes, and other supporting visual materials (e.g., photographs), whenever possible.

As formative research is likely to be a new approach for many stakeholders, it is important to be prepared to answer questions about the design and to avoid the temptation to generalize formative research findings to larger populations. Remember that the study design and sampling strategy were purposive and not intended to represent the entire population.

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ANNEX 1

Sources of information on HIV and infant feeding

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ANNEX 2

Useful reading on formative research

There are hundreds of papers and publications on formative research for health programmes.

Manuals written prior to January 2000 were reviewed and summarized in an excellent resource book titled, *Qualitative research for improved health programmes: A guide to manuals for qualitative and participatory research on child health, nutrition, and reproductive health*.

This guide was prepared by Johns Hopkins University and the SARA Project of the Academy for Educational Development and can be downloaded from http://www.sara.aed.org/publications/cross_ cutting/qualitative.pdf.

The 200-page book contains descriptions of each manual; how it can be used; time requirements; methods and topics covered; and how to obtain copies of the complete manual.

Another new and extremely useful manual on qualitative research is Ulin PR, Robinson ET, Tolley EE, McNeill ET. *A Field Guide for Applied Research in Sexual and Reproductive Health*. Family Health International, 2002. This manual can be ordered through www.fhi.org.

The manual, *Designing by Dialogue: Consultative research to improve child feeding* by K Dickin, M Griffiths, and EG Piwoz contains the most detailed information on formative research related to infant and young child feeding. This manual and a companion training guide can be downloaded from http://www.sara.aed.org/publications/nutrition.

Other practice-oriented papers on qualitative research methods and analysis include:

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ANNEX 3

Sample formative research design

Note: Any recommendations in Annex 3 through 6 may not reflect the current guidelines on HIV and infant feeding. For the current guidelines, please refer to HIV and infant feeding: Guidelines for decision-makers, 2003.

Ndola (Zambia) Formative Research Study (LINKAGES/SARA/NFNC, December 1998)

This annex gives the overall design for a formative research study that was conducted in Ndola, Zambia. The conceptual model and specific research questions are not shown, but the design illustrates one way that the different methods were used to collect information on key feeding issues. This research study was rapid, requiring about 2.5 weeks of time in the field over a period of 2 months. Initial analysis was conducted in the field, and then between research activities. The study was conducted in one health district only. Larger studies covering more diverse populations would require additional time.

Research objective

To develop appropriate and feasible infant feeding recommendations for HIV-positive mothers and families living with HIV in Ndola District, Zambia.

Definition of terms

Appropriate – based on infant age, nutritional requirements, and locally available foods and milk alternatives.

Feasible – based on economic, social, and cultural considerations (facilitating factors and constraints), and on environmental considerations (following principles of safe and hygienic food preparation).

Research questions

What is the feasibility, acceptability, affordability and safety of WHO-recommended infant feeding options for HIV-positive mothers in Ndola peri-urban, high-density areas?

What training, information, education and communication (IEC), community sensitisation, and other support will be needed to introduce HIV testing and counselling and infant feeding counselling in the project area?

Research design

Research will be carried out in 3 phases.

- The **first phase** will be a review of existing information and an exploratory study to collect qualitative information on general HIV awareness issues; perceptions of transmission and risk; feeding practices among women with HIV; how feeding decisions are reached (in general); and community responses and resources for supporting women and families with HIV.

- The **second phase** will identify locally available replacement (or complementary) feeding alternatives (including costs, seasonal fluctuations) and environmental considerations that could facilitate or pose risks to safe and hygienic preparation of these foods and milks.

- The **third phase** will include household trials to test the feasibility and response to specific replacement feeding recommendations and/or practices for making breastfeeding safer for women with HIV. The findings of the trials will also be "checked" (tested) with additional groups (to be determined), but generally including other families, decision-makers, and stakeholders.

Each phase will be followed by a short period of analysis to guide the formulation of the objectives and content of the following phase. This is required to ensure that the research is locally relevant and responsive to the social, cultural, and economic needs and concerns of the Ndola women and families who will be served by the programme.

Research methods

Phase one will include **focus group discussions** with women (general population of women of childbearing age; pregnant women) and men, and **key informant interviews** with MCH providers and others who are providing services for women and families with HIV. Mothers with HIV should also be interviewed if a population can be identified. (The number of focus groups and the possibility of interviewing other community members at this stage should be discussed).

Phase two will include **community/household observations** and **food/milk availability assessments** (e.g., in markets, in households, of water and hygiene

considerations; to verify information collected at another time), and **key informant interviews** with maternal-child health (MCH) providers and mothers about appropriate complementary/replacement foods, preparation practices, and safety and hygiene issues. MCH case management practices (for children with diarrhoeal diseases) will also be explored. (**Twenty-four hour recall** studies may also be required, depending on the availability of existing information on feeding practices/diets of children in Ndola.).

Results from phases one and two will be analysed to develop a list of appropriate and feasible (defined above, including nutritional analysis) recommendations to be tested through either recipe or household trials (e.g., construction of a feeding assessment and counselling guide). Appropriate age-groupings for the trials will also be determined. It is likely that recommendations will be tested among pregnant women, and among mothers (and other care givers) of children < 4 months, 4–6 months, 6–12, > 12 months of age.

Phase three will include **household trials** to explore possible changes in current practices (possible issues include preparing and serving breast-milk alternatives; improving the quality of complementary foods; expressing and heat-treating breast milk; improving other feeding practices such as frequency, snack foods, active feeding; cleaning utensils, etc.). **In-depth interviews with health providers and community leaders** will also be carried out to obtain feedback on the trial results from other audiences.

It is important to note that the exploratory research may indicate that women with HIV will continue to breastfeed (by choice or necessity). If this is the case, the trials will be of improved complementary (rather than replacement) feeding practices, with testing of options for making breastfeeding safer (e.g., early cessation of breastfeeding, expressing, storing, heat-treating breast milk, etc.)

Research products

Phase One: Report on general HIV and infant feeding awareness issues and community services for women and families with HIV

Phase Two: Report on existing feeding and counselling practices, and a draft assessment and counselling guide with the list of feeding recommendations to be tested (see Designing by Dialogue) for appropriate age groups/audiences.

Phase Three: Report on the results of the trials and checking research with recommendations for the MCH/HIV testing and counselling programme.

Final Product: Infant feeding and related recommendations for the Ndola Demonstration Project.

Phase One

Focus Group Discussion Topics

General HIV awareness issues

- know what HIV is; names for disease
- know how disease is spread and what to do to prevent it
- know how to tell if someone has disease

HIV testing issues

- know about the HIV test
- ever had a test
- would they get tested if available (motivations for testing, not)
- who would make decision
- who would find out about the results (partner and confidant notification issues)
- what happens when the result is positive (what they do, how people react)
- probing on issues of stigmatisation and how positive results affect family, community, and other relations

General questions about HIV transmission

- how a mother could spread HIV to baby
- ever heard that HIV could be transmitted to babies through breastfeeding
- where they have heard about HIV transmission (media, family, health system, other infected people)

Understanding concepts of risk (using beans)

- illustration of risk (e.g., 10 people)
- risk of not breastfeeding (what happens)
- risk of becoming infected (what increases)
- perception of the risk of HIV through breastfeeding

Women who do not breastfeed

- are there women who do not breastfeed in the community
- why don't they breastfeed
- when do they stop breastfeeding early
- how do they feed their children
- what problems do they face (social, health, family)
- what do they or others think about mothers who do not breastfeed

Breastfeeding decisions

- would infected mother initiate breastfeeding (why, why not)
- how would she decide

- if she did not breastfeed what would she do (wet nurse, formula)
- where would she get the replacement feeding (formula, other milk)
- how would it be prepared, offered (water, cup vs. bottle)
- how could she afford it, who would buy it, how often, where
- time requirements, balanced with work
- how long would feed formula (months), how often
- what else would she give her baby, when start solid foods
- early weaning (cessation of breastfeeding) ideas (age, why)
- child development milestones and feeding changes
- perceptions of growth, relationship between food and growth
- what happens to the non-breastfed baby (sick/well, grow, healthy)
- common breastfeeding problems, how managed (e.g., cracked nipples, breast infections)

Key Informant Interview Topics

Community support for infected women, men, children

- services in the community (general, HIV-related)
- who uses them
- do infected women want to have more children
- what do they do when they become ill, who cares for their children, how are they cared for and fed
- what happens to orphans (who cares for them, how are they fed)
- support for breastfeeding in the community
- perception of the HIV problem by the community (is it perceived of and treated as an individual, family, or community problem)

Phase Two

Community Observations

General water, hygiene, sanitation issues

- water sources
- sanitation facilities
- presence of electricity, refrigeration
- cooking and prepared food storage practices and possibilities
- fuels used for cooking

Food/market assessments

- permanent and periodic food markets
- milk alternatives (prices, contents, size, availability)
- commercial foods available (infant foods, nutritious snack foods)
- vitamin/mineral supplements available (cost, where, how obtain, who uses, for children?)
- infant formula advertising practices
- costs of different alternatives (market, time)

Key Informant Interviews

Health provider practices (MCH)

- breastfeeding knowledge and counselling practices
- other feeding practices knowledge and practices
- knowledge of issues related to HIV and infant feeding
- if/how counsel mothers on HIV and infant feeding
- perception of problem of HIV
- current treatment of children who are not breastfed (is this encountered, what do they do)
- knowledge and treatment of diarrhoea (case management practices)

Health provider practices (maternity)

- training/knowledge about breastfeeding/infant feeding
- prenatal counselling about infant feeding (what, when, how often)
- where are women giving birth, who attends them (may need to explore baby-friendly hospital practices if women are giving birth in hospitals)
- does newborn breastfeed immediately, is it kept in physical contact with mother
- what do they do differently for HIV-positive mothers (are they identified)
- follow-up infant feeding counselling given (what, when, how often)
- questions/concerns raised by mothers about breastfeeding/infant feeding
- any commercial pressures for infant formula present
- referral for infected women to support groups
- referral for breastfeeding support groups

Mothers (with children of different ages)

- breastfeeding initiation, practices (demand feeding, how often, problems encountered, duration)
- age when other liquids introduced, other solids
- age when breastfeeding stops, or reasons for stopping
- other feeding decisions (frequency and timing, foods, recipes, fruits and snacks)
- who buys food, how obtained, how often
- active feeding and supervision
- how knows child has enough to eat
- what to do about fussy eaters and children without appetites
- who makes feeding decisions, sources of information on feeding
- experience feeding other children
- child development milestones and feeding changes

- perceptions of growth, relationship between food and growth
- participation in growth monitoring activities

24-hour recall (optional)
- rapid food analysis

Phase Three

Household Trials (up to 3 visits)

Feeding practice assessment
- 24-hour recall for target child
- active feeding (feeding style) questions
- feeding during, following illness
- concerns about child and feeding
- use of bottles, cups, other utensils for feeding

Household observation
- child's food preparation
- hygiene practices
- clean water (source, covered, boiled, etc.)
- fuel
- foods in home, vitamin-mineral supplements in home
- formula, other milks present
- mothers who are already practising replacement feeding (how they prepare)

Introduction of recommendation(s) from assessment and counselling guide, negotiation

Follow-up assessment, reactions, modifications, acceptability

Interviews with health providers, community leaders
- Reactions to recommended practices

ANNEX 4

Sample questions for formative research on HIV and infant feeding

The questions contained in the following pages have been used in formative research studies on HIV and infant feeding. The questions are provided as samples that researchers may adapt if the content addresses their research questions. These questions are illustrative and are not intended to represent a blueprint that must be followed by individual studies.

Most of the questions can be asked as open-ended, closed-ended (with fixed responses) or mixed (open and closed-ended questions) depending on the research design. Researchers should develop their own study forms, including information to identify and describe the respondents and other relevant background information.

Included in this annex are questions that have been used in:

- Focus group discussions
- In-depth interviews
- Market surveys
- Trials of improved practices

Although the questions contained in this annex relate primarily to infant feeding, most formative studies also examined other intervention issues, such as acceptability of HIV testing and counselling, HIV status disclosure and stigma, uptake and adherence to ARV prophylaxis, and maternal health and caring practices. Researchers can incorporate these topics in their studies, if this is part of their research plan, but questions on these interventions are not included here.

SAMPLE FOCUS GROUP DISCUSSION QUESTIONS

Ndola (Zambia) Formative Research Study (LINKAGES/SARA/NFNC, December 1998)

This study was done prior to the design of a PMTCT programme. The formative research included in-depth interviews, focus group discussions, market surveys, and trials of new practices. The purpose of the study was to narrow down the range of feasible and acceptable feeding options for HIV-positive mothers and to determine the training and communications needs for the programme.

Below is an outline of the topics and questions discussed in focus groups in this study. Each focus group consisted of 6-8 participants, including mothers with young children, fathers, and women who were members of an HIV-support group.

Although this study followed the questions noted below, it is possible to use narrative scenarios to collect the same information. In narrative scenarios, a story is created with fictitious characters that are confronted with decisions about HIV and infant feeding. The questions relate to the anticipated feelings and actions of the characters rather than participants' own experience or views.

Topics addressed through focus groups

Topic 1: HIV and mother-to-child transmission

Topic 2: Infant feeding practices and decision-making

Format

Introduce the moderator and note-taker. Explain that we are here to learn more about HIV and infant feeding and that we want to learn from them in order to better design antenatal care and reproductive health programmes for women and families. Explain the ground rules for the meeting - that the discussion will last 1 to 1.5 hours; that everything they say will remain confidential and their names will not be used when reporting on the findings. A tape recorder is used only to facilitate the recording and analysis of the discussion.

Materials

Discussion guides, notepads, pens, tape recorder, tapes, batteries, beans, index cards.

Discussion questions

Topic 1: HIV and mother-to-child transmission

1. General issues related to HIV/AIDS

- What do we know about HIV/AIDS?
- Who is affected by it?
- What is it called in this community? (Record names, relevant characteristics)

2. General issues related to transmission/spread of HIV/AIDS

- Who can tell us about how the disease known as HIV/AIDS is spread (in this community)? PROBE and note if mother-to-child transmission is mentioned.
- What do people do here to prevent getting infected?

3. Sources of information on HIV/AIDS

- Where have you heard about HIV transmission? PROBE on all sources (radio, family, health system, community organizations, family and friends)
- What do these sources say about HIV and how to prevent transmission of the virus?

4. Mother-to-child transmission issues

- Has anyone ever heard of a mother passing on HIV to her baby?
- How does this happen?
- *If breastfeeding is not mentioned above*, has anyone ever heard that HIV can be transmitted to babies through breastfeeding? (PROBE and record all answers)
- Do you think this problem (of HIV transmission through breastfeeding) is very common or is it rare in this community?
- In general, do you think all infected mothers pass on HIV to their babies or only some of them? (Use index cards or beans to illustrate numbers of mothers.) PROBE about characteristics of mothers who do/do not transmit.
- Consider a time when you are/were pregnant (or your wife was pregnant). If you got tested for HIV and found out you were HIV-positive (infected), what would you do?
- How would you feel about feeding your baby? What makes you feel this way?
- *If participants say they would* ***not*** *breastfeed*, discuss how they would feed their babies? With what? Who would assist? How would this decision be reached? What would happen?

5. Conclusion and wrap up

We have just discussed the risk of transmitting HIV through breastfeeding. In reality, not every infected woman will pass on the virus to her baby through breast milk. **Show index card with stick figures**. If there are 7 infected women, it is likely that 2–3 of them will pass on the HIV virus during pregnancy or at the time of delivery if special precautions are not taken (shade in 2 figures). In addition, one more baby will become infected through breastfeeding (shade in 1 figure), but the rest of the babies (3–4) will **not** get infected, even if breastfeeding is practiced (unshaded).

Topic 2: Infant feeding

1. Breastfeeding practices

- How long do mothers usually breastfeed their babies?
- When do they stop? Why?
- Are there other reasons for weaning a baby (earlier than usual)? PROBE for illness in the mother, HIV.
- Do you think that women who are infected with HIV should breastfeed their babies? Why? Why not?
- How would a woman make this decision? Who/what would influence her?

2. Alternatives to breastfeeding

- Are there women in this community who do not breastfeed? Why not? (Is HIV/AIDS mentioned)?
- How do these women feed their babies? (PROBE for wet-nursing practices, use of formula, or non-human milks)
- Are there babies in this community that were not ever breastfed? Why not? PROBE to see if orphans are mentioned; mothers with HIV/AIDS.
- What has happened to these non-breastfed babies? Are they healthy? Do they survive, grow and develop like other children? PROBE about psychological as well as health/nutritional needs of non-breastfed babies.

3. Attitudes about not breastfeeding

- What are the reasons a mother would not breastfeed her baby? PROBE about illness, separation, other reasons.

- What does the baby get fed to replace breastfeeding?
- Who feeds and cares for the baby?
- What services, if any, are available in the community to help families with this problem/ decision?
- What do people say or think about a woman who does not breastfeed (by choice or other necessity as mentioned above)?

4. Other feeding decisions

- At what age do mothers typically introduce other liquids to their babies?
- What liquids are given? How are they fed?
- Why are liquids introduced?
- At what age are solid foods first introduced to babies (use local names)?
- How do you know that a baby is ready for solid foods? PROBE for cues and milestones that are recognized (e.g., specific ages, teeth, sitting, crying, reaching for food, etc.)
- What are the first foods typically given to young babies? PROBE for name, ingredients, and consistency.
- How are these foods fed? PROBE for use of separate plate, cups, by hands, other utensils.
- During the day, how often do you prepare foods for your children (< 2 years old)?

5. Feeding style and responsive feeding

- How do mothers/care givers know how much food to give a baby (or how much a baby can eat at one sitting)? (PROBE for how a mother knows that the baby has eaten enough; are specific quantities recognized).
- How does a mother encourage her baby to eat more?
- What does it mean to you when a baby does not want to eat?
- What can be done in this circumstance? PROBE to see if they would go to the health clinic, participate in monitoring growth, consult others about the problem/who; suspect illness.
- What are the signs of a healthy baby? PROBE for descriptions related to growth, size, and demeanour.
- What can a woman do to ensure that she has a healthy baby (what are practices, things within her control)?

Zambia Exclusive Breastfeeding Study (Boston University/Lusaka District Health Management Team/AED, October 2000)

The Zambia Exclusive Breastfeeding Study (ZEBS) is a clinical trial to compare HIV-free survival in HIV-exposed infants who are exclusively breastfed and rapidly weaned at 4 months with those who are exclusively breastfed and weaned gradually. The study used focus group discussions to explore the feasibility of early, rapid breastfeeding cessation in order to develop the counselling programme for the study.

The focus groups were carried out with mothers, fathers, health providers and members of neighbourhood health committees.

Discussion questions

1. General MTCT

- Have you ever heard about transmission of HIV from mothers to babies?
- What have you heard?
- What about HIV transmission during breastfeeding?
- Do you think that all HIV-positive mothers who breastfeed will pass the virus/infect their babies?
- Is this a common problem in the community?
- How can it be prevented?

2. Exclusive breastfeeding and early breastfeeding cessation

- Explain the WHO recommendation for HIV-positive mothers about exclusive breastfeeding and early, rapid cessation. Explain the ZEBS study advice.
- Have you ever heard this advice before?
- What do you think about it? (Note that more specific questions are asked next.)
- What do you think about giving breast milk only for the first months of life and nothing else to reduce the chance that the baby will become infected with HIV?
- How about the idea of early and rapid breastfeeding cessation?
- What do people in the community think about women who abruptly wean?
- Would abrupt weaning be something that is easy or difficult for the mother/ family/others?
- What effects would it have on the mother? On the baby? On others in the family?
- How would early/rapid weaning be done?
- How long would it take to stop breastfeeding like this?
- What problems would a mother have if she suddenly stopped breastfeeding?

- What can she do about these problems?
- What about fathers and other family members, can they help mothers with this practice?
- What should the baby who is no longer breastfeeding be fed during the day/ at night?
- How can a mother who is not breastfeeding comfort her baby when he/she cries?
- What about a mother who does not stop breastfeeding, how does she feed her baby when she begins to introduce new foods?
- Is there anything else you would like to say or to suggest about what we have discussed today?
- Are there any questions you would like me to answer about this issue?

SAMPLE IN-DEPTH INTERVIEW QUESTIONS

This section contains excerpts from in-depth interviews from several formative research studies. Typically, each interview begins with collection of basic socio-demographic information (age, education, marital status, number of children, etc.). Below are some of the questions that pertain directly to infant feeding issues.

Ndola (Zambia) Formative Research Study (LINKAGES/SARA/NFNC, December 1998)

These questions were asked in in-depth interviews with mothers of unknown HIV status prior to the implementation of a PMTCT programme.

1. Breastfeeding practices and alternatives

- In this community, how long do mothers usually breastfeed their babies?
- What are the reasons women stop breastfeeding before this age?
- *Interviewer: is illness mentioned as a reason? (yes/no)*
- *Interviewer: is HIV/AIDS mentioned? (yes/no)*
- Are there women in this community who do not breastfeed (at all, from birth)?
- Why do women not breastfeed? What are the reasons?
- *Interviewer: is HIV/AIDS mentioned? (yes/no)*
- How do women who do not breastfeed feed their infants? What do they give them? PROBE for milk alternatives, foods and recipes, style of feeding (e.g., cup, bottle, plate, hand), who feeds them. List all that are mentioned.
- Is wet-nursing practiced here? (yes/no)
- *If yes*, who wet-nurses the baby? How does she decide who should do it?
- Do babies who are not breastfed have special needs? (yes/no)
- *If yes*, what are these needs? PROBE for psychological, caring needs in addition to feeding/ nutritional needs.
- What problems do babies who are *not* breastfed face? PROBE about health, growth, development problems.
- What problems do mothers who do *not* breastfeed face? PROBE about family, health worker reactions, what people say, types of stigmatisation.
- Are there many young children whose mothers have died in this community?
- What happens to young children when their mothers die? Who feeds and cares for them?
- What services/programmes/informal arrangements are available in the community for feeding and caring for orphans?

2. Other feeding decisions

- At what age do women typically introduce other liquids to their babies?
- What are these first liquids (e.g., water, tea, medicines)?
- Why do they give them?
- At what age do women introduce semi-solid food to babies?
- What are the first foods given? PROBE about food consistency; how fed (in cup, bottle, plate).
- How do you know a baby is ready for solid foods? PROBE for infant behaviour, development cues (e.g., cries, reaches for food, has teeth).

Malawi Safe Mother/Safe Baby Formative Research Study (University of North Carolina/ CDC/AED; June 2002)

The Malawi Safe Mother/Safe Baby formative research study was carried out to facilitate development of a clinical trial on nutrition and ARV therapy to prevent postnatal transmission of HIV. The formative research study included several types of respondents. Below are some of the questions asked in in-depth interviews with HIV-positive mothers about infant feeding. The narrative scenario approach was used, as shown below, but the technique was more effective when the same story and questions were asked in focus group discussions.

1. Infant feeding practices

- How did you feed your baby when he/she was born (e.g., first day to first week of life)?

- At what age did you first introduce any liquids (such as water, sugar water, milk, infant formula)? Why?
- At what age did you introduce semi-solid foods to your baby (such as mashed fruit, porridge)? Why?
- Are you feeding this baby in the same way as you have fed your other children, or are you feeding him or her differently? Why?
- How do you feed your baby when he or she is sick? (Probe specifically about feeding practices when baby has diarrhoea, a respiratory infection, and a loss of appetite).
- For how long would you like to breastfeed your baby?
- Why do you feel this way?

2. Attitudes about exclusive breastfeeding

- Have you heard the term "exclusive breastfeeding"?
- Describe what it means to you
- Do you think that breast milk alone is enough food for a baby during the first 6 months of life?
- What makes you feel that way?
- What problems do you think you might come across when trying to breastfeed exclusively? (PROBE for problems with the baby and the mother's health. PROBE about her husband's, her mother-in-law's, and her neighbours' opinions about her practice of exclusive breastfeeding. PROBE to see if she thinks she has enough milk.)
- What would you do to overcome these problems? (PROBE for each problem listed above.)
- Who has given you information about breastfeeding in the past? (PROBE about information from health care providers, mothers-in-law, husbands, neighbours, traditional birth attendants.)
- What were you told?

3. Narrative scenario on breastfeeding by HIV-positive mothers

Now I would like to tell you a story about Mary. Mary is 8 months pregnant with her second child and she has just learned that she is HIV positive. During counselling she learns that some mothers pass on HIV during pregnancy and childbirth. She also learns that some mothers may pass on HIV to their babies through breastfeeding. She asks the counsellor what she should do.

- What does the counsellor tell Mary?

The counsellor talks to Mary about two different infant feeding options and their advantages and disadvantages. One option is that she can feed her baby only on breast milk for the first 6 months of life, taking care to give nothing else because other fluids and solids may damage the baby's stomach and make it more likely for the baby to become infected with HIV. As another option, she can choose not to breastfeed at all, and feed her baby infant formula.

- What do you think Mary will decide to do?
- Why will she make this decision?
- What will influence her choice?
- Will she talk to anyone to help her with a decision? Who?
- What does Mary think are the advantages of breastfeeding for her baby?
- What about the disadvantages of breastfeeding?
- What does Mary think are the advantages of infant formula for her baby?
- What are the disadvantages?

After discussing the situation with her husband, Mary decides that she will breastfeed. Some weeks later, she gives birth to a baby girl, Sarah. Mary initiates breastfeeding immediately and her milk comes in right away. She is trying to breastfeed exclusively.

- Will Mary be able to breastfeed exclusively?
- What makes you feel that way?
- If Mary is not able to breastfeed exclusively what will happen? (PROBE on mixed feeding.)

OK, now the story continues. Sarah is now 6 months old. Mary returns to the health centre. She wants to talk to the counsellor about Sarah. Sarah appears healthy. Mary wants to know whether she should continue to breastfeed now that Sarah is old enough to eat porridge. The counsellor tells her that there is a small chance that her baby could still become infected with HIV if she continues to breastfeed. However, if she is not breastfeeding, Sarah will still need milk and other nutritious foods in order to grow and stay healthy. She explains that nutritious foods and infant milk are expensive and they must be prepared hygienically to avoid diarrhoea. When Mary returns home, she talks with her husband about what to do.

- What will Mary and her husband decide?
- Do you think that Mary should stop breastfeeding at 6 months?
- What makes you feel that way?

Let's imagine that Mary decides to stop breastfeeding now that Sarah is old enough for other foods.

- How will she stop breastfeeding? (PROBE about whether this will be rapid or gradual.)
- How will she feed Sarah if she stops breastfeeding completely? (PROBE about what foods will be given, who can help.)
- What will Mary say when people ask why she is no longer breastfeeding?

Now we have to end this story.

- Tell me, how do you think this story will end?
- What will happen to Mary?
- What will happen to Sarah?

Khayelitsha (South Africa) Formative Research Study (University of the Western Cape/SARA; September 1999)

This study was done after the introduction of a mother-to-child transmission prevention programme that provided ARV prophylaxis and free infant formula to HIV-positive mothers. The purpose of the study was to improve on existing infant feeding education and support and to get feedback from mothers on feeding recommendations and options. Mothers who were living in the study areas but not part of the programme were also interviewed to learn about feeding and caring practices in the study area.

The following questions were asked to obtain information on infant dietary intake and feeding practices and to assess household food availability, hygiene and sanitation environment.

Modified 24-hour food recall for infants with rapid analysis

1. Ask the respondent to tell you about what the baby ate yesterday.

Begin when the baby woke up, and continue throughout the day (mid-morning; mid-day; mid-afternoon; evening; etc.), including nighttime. PROBE about breastfeeding, other milks/liquids, porridge, relish (solids not just soup), snacks (bananas, fruit, buns), etc. Ask how much the child ate each time, and how the food/liquid was prepared (ingredients used), and how fed (cup, spoon, bottle, etc.)

Ask if yesterday was a normal day for the baby in terms of what s/he ate and how much? Why/why not?

2. Rapid analysis of 24-hour recall (completed by interviewer using the information obtained during the recall)

- How often did *baby* eat maize-meal (staple) food? (# times per 24-hours)
- Did the baby eat porridge? (yes/no)
- Did the porridge have sugar added? (yes/no)
- Was the porridge cooked with oil or margarine? (yes/no)
- Did the baby porridge include peanut butter? (yes/no)
- Did the baby eat *nestum* or *cerelac*? (yes/no)
- Did the baby eat (mashed) vegetables? (yes/no)
- Did the baby eat any fruits? (yes/no)
- Did the baby drink any infant formula? (yes/no)
- Did the baby drink cow's milk? (yes/no)
- Did the baby eat any eggs? (yes/no)
- Did the baby eat any meat or chicken? (yes/no)
- Does the child eat all that is served? (yes/no)

Time (approximate)	Food/milk/liquid ingredients (recipes)	Amount eaten & utensil used

3. Use of commercial infant formula

- Do you ever feed *baby* commercial infant formula?
- What kind (brand names)?
- How old was your baby when you gave him infant formula for the first time?
- How do you feed this (cup, bottle, both, other)?
- How often do you prepare infant formula each day?
- How much does the baby eat?
- What happens with the leftover formula (PROBE about storage, other uses)
- How often do you buy the infant formula?
- How much do you buy each time?
- What is the cost?
- Are there times when you do not have enough formula to feed the baby?
- What do you do when this happens?

Cooking demonstration for commercial infant formula

4. Demonstration of infant formula preparation (ask the respondent to show you how it is prepared)

- How much powder does she use? (Record amount.)
- What is used to measure the amount of powder?
- How much water?
- What is used to measure the amount of water?
- Was the water boiled (before or during preparation)?
- How long does it take to prepare (record minutes)?

5. Use of cow's milk, multivitamins, gripe water

- Do you ever feed cow's milk?
- What kind of milk have you used (full cream liquid, full cream powdered, fermented, other)?
- How old was your baby when you first gave this milk?
- How often do you feed your baby the cow's milk (either fresh or cooked in food)?
- How often do you buy the cow's milk?
- How much do you buy?
- What does it cost?
- When you give liquid cow's milk to your baby, how do you prepare it? (PROBE about water dilution, boiling.)
- Do you ever give *baby* Multi-vite?
- What multivitamin do you give and how often?
- What does it cost?
- Do you have any vitamins in the home today? (Ask to see and record formulation.)
- Do you ever give *baby* gripe water?
- Why do you use gripe water?
- How much do you give each time?

Observations and questions related to home hygiene, sanitation, and food availability

6. Hygiene-related questions and observations

- What is the source of drinking water in the home?
- Is water stored in the home?
- Is water stored in a covered container?
- What type of latrine is present?
- Note condition of the home (tidy, swept, well organized; untidy but generally clean; untidy and unclean).
- Does the home have soap for washing hands or dishes today?
- Is the kitchen area clean/untidy?
- Are animals seen roaming in the food preparation and eating areas?
- How are infant's utensils cleaned?
- What type of cooking stove is in the home?
- Does the house have electricity?
- Does the house have a refrigerator?

7. Inventory of foods and food sources

Does the home have any of the following (yes/no)? Note amounts present where applicable.

- Vegetable garden
- Chickens
- Goats
- Other animals
- Maize meal
- Rice
- Potato
- Bread
- Infant formula (specify brand)
- Other milk (specify brand)
- Commercial baby cereal (e.g., Cerelac)
- Commercial baby food (e.g., Purity)
- Other vegetables (specify)
- Eggs
- Peanut butter
- Maas (fermented milk)
- Bananas
- Other fruit (specify)
- Sugar
- Margarine
- Cooking oil
- Cooking fuel

8. Other questions about food security

- How often does respondent receive money for food, fuel, and related purchases (including infant formula)?
- Who is responsible for providing food for you and your children?
- Were there days in the last **month** when you did not have food for yourself or your children?
- How many? What do you do for food then?
- Are there times of the **year** when you do not have enough food for yourself and your children?
- When?
- What do you do for food then? Who do you turn to for assistance?
- Do you think your household is currently facing a food shortage?
- Are you currently receiving any food assistance (from NGO, government programmes)?

SAMPLE FORMAT FOR THE MARKET SURVEY

The purpose of the market survey is to record the availability and price of foods and ingredients that will be needed to safely implement the different feeding options. A simple format can be developed that records:

- Date of survey
- Name of the shop or retail outlet, location
- Name of item (including brand name)
- Size of item (weight or volume)
- Price of item
- Expiration date
- List of ingredients
- List of nutritional fortificants (vitamins, minerals)
- Description of packaging
- Other observations about the product
- Other observations about the shop/outlet (proximity to transport, population area, etc).

Researchers should visit outlets mentioned by respondents when asked about where they purchase food items. Data from different retail outlets can be compared or used to estimate average costs for different feeding options.

SAMPLE QUESTIONS FOR TRIALS OF IMPROVED PRACTICES

Trials of improved practices will involve explaining to respondents about the recommended practices; obtaining their initial reactions and their agreement to try one or more of them; and follow-up visits to obtain information on their experiences. Because of this process, three separate forms are needed:

- A narrative of the recommended practices that will be tested (not shown here)
- A first visit interview guide (see an example below)
- A follow-up visit interview guide (see an example below)

Trials of improved practices have been used to test recommendations on replacement feeding (e.g., commercial infant formula, home modified animal milk, cup feeding) and complementary feeding (e.g., enriched home prepared foods, nutritionally fortified sprinkles, biscuits, and spreads). Trials have been carried out with mothers and infant caregivers as well as with health providers who are involved in counselling women about infant feeding. When trials are conducted with women and caregivers, the recommendations are tailored to their circumstances. This way, respondents can actually test new practices and products and talk about their experiences.

For more information on how to do the trials, please consult:

Dickin K, Griffiths M, Piwoz EG. *Designing by Dialogue: Consultative research to improve child feeding*. Washington DC: Academy for Educational Development, 1997. (Available at www.sara/aed.org/publications/nutrition).

WHO. Integrated Management of Childhood Illness Adaptation Guide, Part 3, Study Protocols: D. Protocol for Adapting Feeding Recommendations. June, 1997.

Khayelitsha (South Africa) Formative Research Study (University of the Western Cape/SARA; September 1999)

This study was carried out in a community where a PMTCT Programme was providing ARV prophylaxis and free commercial infant formula to HIV-positive mothers. **Trials were carried out with HIV-positive mothers and with women who did not know their HIV status**.

The study developed simply-worded recommen-

dations for each of the following groups of respondents, based on WHO recommendations and guidance:

- Mothers with infants less than 6 months and not breastfeeding
- Mothers with infants less than 6 months and breastfeeding
- Mothers with infants 6 months or older

The recommendations were translated into local language.

First visit interview guide: interviewing the respondent about the recommendations

Introduction

Explain that one of the purposes of this visit is to find out her opinions about some issues and practices related to feeding her baby.

Explain that you would like to give her some information about infant feeding and ask her some questions. Tell her that there are no right or wrong answers. The most important thing is to find out what she thinks about these ideas and practices. We want to know if she thinks some suggestions are feasible (realistic) or difficult to follow.

Also tell her that we will ask her to try out some of the suggestions for a few days and then return to find out what she (and others in the household) think/learned, and if the baby liked or disliked them.

1. For mothers/caregivers of infants less than 6 months and NOT breastfeeding

Read the mother the recommendations for this group. After you read the recommendations, ask these questions to find out her opinions. Ask her to explain her reasons for each answer. Probe about her thoughts on feasibility and acceptability, including issues like time, resources, approval/disapproval of other family members, and the expected reaction of the baby to the new practices. Record responses verbatim (in mothers' own words).

Cup-feeding

- Do you think it is possible to feed a *newborn* baby from a cup (as described)?
- Why/why not? (Probe about time, infant's ability to sip it, etc.)
- Do you think it is possible to cup-feed a baby during the night? Why/why not?
- Would this be easy or difficult? Can you do it?
- If a baby is already using a feeding bottle, do you think it is possible to switch to cup-feeding and not use the bottle again?
- Why/why not?
- How would you do it?
- What problems would you have?

Formula preparation and feeding

- Do you think it is possible to prepare and feed a baby that is not breastfeeding infant formula 5–6 times/day?
- Why/Why not? (Probe about time, resources, infant needs, etc.)
- Do you think it is possible to feed a baby that is not breastfeeding 500 ml (newborn) in 24 hours?
- How about 900 ml of formula per day (for 5–6 months old)?
- Why/Why not? (Probe about time, resources, infant needs, etc.)
- Do you think it is possible for you to boil water for the baby's formula as described?
- How many times each day would you do it?
- Where would you keep the boiled water?
- Do you think it is possible for you to sterilize the baby's cup or eating utensils in boiled water?
- To clean with soap and running water?
- Why/why not? (Probe about water availability)
- Do you use any other sterilizing agents?

Cost and affordability

- Do you think it is possible (for you) to buy 3.0–3.5 kg (R 100) of infant formula for a baby each month (for a baby who is not breastfeeding)?
- How often would you buy it?
- Who would help you to pay for it?
- If you could not afford it, what would you do?
- Do you think it is possible to mix the formula correctly? (Probe about when it would be difficult to prepare it correctly, dilution.)
- Do you think it is possible for you to keep a 500 g tin of formula in the home?
- Will it be kept clean/safe from insects?
- Will it be shared with others?

Ask the caregiver to try the agreed-upon practice with you first. Encourage her and try and assist with any problems or questions she might have in implementing the practice. Record what advice you gave to persuade her to try these practices.

Ask the caregiver to try some of these recommended practices for a few days.

Negotiate with her about which ones will be possible, given the age of the baby, the resources available, and things she is NOT already doing:

- Cup-feed the baby during the day
- Cup-feed the baby during the night

- Stop using a feeding bottle
- Prepare and feed formula 5–6 times per day
- Feed about 100–200 ml/feed
- Boil water for at least 5 minutes and cool it as described
- Mix the formula properly (according to directions) every time it is prepared
- Mix the formula properly and fresh every time it is given (not storing it)

Record any comments/questions the caregiver has and note any special modifications she will make in the recommendations discussed. Ask the caregiver to try the agreed-upon practice with you first. Encourage her and try and assist with any problems or questions she might have in implementing the practice.

Make an appointment to return in 2–3 days to find out her reactions to these practices. Thank the respondent and end the interview.

2. For mothers/caregivers of infants less than 6 months and breastfeeding

After you read the recommendations, ask these questions to find out her opinions. Ask her to explain her reasons for each answer. Probe about her thoughts on feasibility and acceptability, including issues like time, resources, approval/disapproval of other family members, and the expected reaction of the baby to the new practices. Record responses verbatim (in mothers' own words).

Exclusive breastfeeding

- What does the mother think about exclusive breastfeeding for about 6 months?
- Is this something that is possible?
- Why/why not?
- Ask the mother what she thinks about breastfeeding on demand (every time the baby cries) and feeding with both breasts at each feed.
- Is this something that she does or could do easily?
- Why/why not?
- Can she breastfeed the baby 8–10 times per day or more?
- What does the mother think about not giving babies less than 6 months infant formula, porridge, Cerelac, or Nestum?
- Can it be stopped once it has already been introduced or is regularly given?
- Why/why not?
- What would happen if the baby continued to cry?

Managing breast problems

- What does the mother think about breast problems?
- Does she have them often?
- Could she express milk to relieve the problem?
- Would she seek medical attention and treatment for these problems?
- Why/why not?

Expressing breast milk

- What does the mother think about expressing breast milk into a cup and asking someone else to feed it while she is away from her baby?
- Is this possible/acceptable? Easy or difficult?
- What problems would be encountered?
- How could it be made easier?

Ask the caregiver to try some of these recommended practices for a few days.

Negotiate with her about which ones will be possible, given the age of the baby, the resources available, and things she is NOT already doing:

- Does the mother agree to breastfeed exclusively (on demand) without giving any other liquids, milks, or porridge/Cerelac/Nestum to her baby for a few days?
- Does she agree to **stop** feeding porridge (or other liquids, milks, cereals) to her baby and breastfeed more often?
- Does she agree to **reduce** the number of times or quantity of thin porridge, milk, Cerelac/Nestum, or other foods are given to her baby and breastfeed more often instead?
- Does she agree to express breast milk and feed it in a clean (sterilized) cup for her baby?

Record any comments/questions the caregiver has and note any special modifications she will make in the recommendations discussed. Ask the caregiver to try the agreed upon practice with you first. Encourage her and try and assist with any problems or questions she might have in implementing the practice.

Make an appointment to return in 2–3 days to find out her reactions to these practices. Thank the respondent and end the interview.

3. For mothers/caregivers of infants 6 months and older

After you read the recommendations, ask these questions to find out her opinions. Ask her to explain her reasons for each answer. Probe about her thoughts on feasibility and acceptability, including issues like time, resources, approval/disapproval of other family members, and the expected reaction of the baby to the new

practices. Record responses verbatim (in mothers' own words).

Feeding frequency

- Do you think it is possible for you to feed your baby 2–3 times (if 6–8 months), 3–4 times (if 9–11 months), or 4–5 times a day (if 12–23 months)?
- Why/why not?
- What would be needed?
- What snack foods would you give?

Food quantity and variety

- Do you think it is possible to feed your baby this much food at each sitting?
- Why/why not?
- What would make it possible?
- What would make it difficult?
- How would you encourage the baby to eat it all?
- Do you think it is possible to feed any special foods for her baby (e.g., enriched maize meal with sugar, margarine or oil, milk, mashed vegetables or other solid foods)?
- What recipe would you use?
- What would the baby like/dislike about this?
- Can you give snack foods like mashed fruit to the baby between meals?
- Why/why not?
- What fruits does s/he like?
- What is available?
- What would prevent you or the baby from eating them?
- How would you help him/her?

Hygiene

- Can you clean the baby's plate and other utensils in boiling water before using them?
- Soap and running water?
- Why/why not? (Probe about time, fuel, other concerns)
- What can you do to make sure that the baby's utensils are clean?

If the baby is not breastfed

- Can you give liquid or powdered milk to the baby every day?
- Why/why not?
- Who would you need to consult?
- What would make this easy/difficult?
- What can you do to make this feasible?

Feeding sick children

- When the baby is sick, can you continue to offer solid foods?
- What foods would you give?
- What problems would prevent the baby from eating?
- Can you give the baby more food, or more frequent meals, soon after recovery?
- Which would be easiest for you?
- Do you take your baby to get weighed at the health clinic every month?
- Why/why not?
- What can be done to make this feasible for you?

Ask the caregiver to try some of these recommended practices for a few days.

Negotiate with her about which ones will be possible, given the age of the baby, the resources available, and things she is NOT already doing:

- Does the caregiver agree to feed the baby more frequently (# times stated per above for the age of the child)?
- Does the caregiver agree to feed the child larger quantities (size per above)?
- Does the caregiver agree to feed the baby enriched, thick porridge or other special food (describe recipe)?
- Does the caregiver agree to feed mashed fruits and other snacks between meals?
- Does the caregiver agree to sterilize the feeding utensils or clean them with soap and running water (specify)?
- If the baby is currently sick, does the caregiver agree to feed the baby solid foods during/after illness or increase the amount of food given?

Record any comments/questions the caregiver has and note any special modifications she will make in the recommendations discussed. Ask the caregiver to try the agreed upon practice with you first. Encourage her and try and assist with any problems or questions she might have in implementing the practice.

Make an appointment to return in 2–3 days to find out her reactions to these practices. Thank the respondent and end the interview.

Follow-up interview guide

Respondents are visited on the scheduled day to get feedback on the new practices. These questions are asked:

- How is the baby doing today?
- Were you able to try the agreed-upon practices?
- Which ones could you try?
- Which ones were you unable to try?
- Why/why not able to try (note responses for each)?

- What did you like and dislike about each practice (note responses for each)?
- Did you modify/change the recommended practice(s) in any way?
- Why?
- How did you change it?
- How did the baby react to the new practice(s)?
- Did s/he like/dislike them?
- What did s/he do?
- Did anyone object to the new practice(s)?
- Who? Why?
- What did you do?
- Would you continue with the new practice(s) in the future?
- Why/why not?
- What would this require to continue?

ANNEX 5

Sample text for obtaining informed consent

Below is the text for obtaining consent from different types of formative research participants. Researchers are encouraged to develop their own forms, which take into consideration local research guidelines, requirements from donors, cultural considerations, as well as literacy levels of participants.

Ndola (Zambia) Formative Research Study (LINKAGES/SARA/NFNC, December 1998)

TBAS and other key informants

Purpose of the study The purpose of this study is to learn what you know and think about HIV/AIDS, mother-to-child transmission of the disease, and infant feeding practices. The information collected will be used to help develop programmes for improving health care and services in the community, particularly for women of reproductive age. You were selected to participate in this project because you are a birth attendant who delivers babies in the community.

Procedures If you agree to participate, you will be asked some general questions about your background, such as your age, number of years of schooling, and the deliveries that you perform. We will also ask specific questions about HIV/AIDS, mother-to-child transmission of the disease, and infant feeding practices. We want your opinion about different practices of women with young babies in the community. The interview will last about 45 minutes to one hour.

Risks and discomforts Many of the questions asked relate to the people you deliver and the types of problems they encounter during pregnancy and delivery. These questions do not have right or wrong answers and there are no risks in providing this information. You can refuse to answer any question or stop the interview at any time.

Benefits What we learn from the research will be used to develop a project in this community for improving maternal and infant nutrition and health. In the course of the interview, you may learn new information about infant and maternal health, HIV/AIDS, and related issues.

Confidentiality Your name will be recorded only to facilitate our conversation. It will not be reported in any project document. All your answers will be strictly confidential.

If you have any questions about the project please feel free to ask at this time.

Household trials

Purpose of the study The purpose of this study is to learn what you know and think about different infant feeding practices. The information collected will be used to help develop programmes for improving the health and nutrition of women and children in the community. You were selected to participate in this project because you have or care for a child under 2 years of age.

Procedures If you agree to participate, you will be asked some general questions about your background, such as your age, number of years of schooling, and the health and diet of your baby. We will ask you your opinion on different infant feeding practices. There are no right or wrong answers to these questions. We will also ask you to try some of these practices for a day or two and give us your feedback. We will visit you twice during this process. The first visit will take about 12 hours. The second visit will last about 45 minutes to one hour.

Risks and discomforts At the end of this visit we will ask you to try a few new practices. These may involve preparing new recipes that may require additional time or charcoal/fuel. The changes may make you, your baby, or other family members uncomfortable since they are new. You can refuse to answer any question or try any new practice, and you can stop the interview at any time.

Benefits What we learn from these interviews will be used to develop a project in this community for improving infant nutrition and health. In the course of the interview, you may learn new information about infant feeding and diet.

Confidentiality Your name will be recorded only to facilitate our conversation. It will not be reported

in any project document. All your answers will be strictly confidential.

If you have any questions about the project please feel free to ask at this time.

Health providers

Purpose of the study The purpose of this study is to learn what you know and think about different infant feeding practices. The information collected will be used to help develop programmes for improving the health and nutrition of women and children in the community. You were selected to participate in this project because you are a health worker in the project area.

Procedures If you agree to participate, you will be asked some general questions about your background, such as your age, number of years of schooling, and your opinions about different recommended feeding practices. The interview will last about 45 minutes to one hour.

Risks and discomforts Many of the questions asked relate to new practices or ideas about infant feeding. These questions often do not have right or wrong answers and no risk or discomfort is expected. You can refuse to answer any question or stop the interview at any time.

Benefits What we learn from the research will be used to develop a project in this community for improving counselling about infant feeding. In the course of the interview, you may learn new information about infant feeding and related issues.

Confidentiality Your name will be recorded only to facilitate our conversation. It will not be reported in any project related document. All your answers will be strictly confidential.

If you have any questions about the project please feel free to ask at this time.

ANNEX 6

Useful information on replacement feeding options

Commercial infant formula requirements in first 6 months

Month	500g tins needed per month	450g tins needed per month
First month	4 tins	5 tins
Second month	6 tins	6 tins
Third month	7 tins	8 tins
Fourth month	7 tins	8 tins
Fifth month	8 tins	8 tins
Sixth month	8 tins	9 tins

Mixing home-modified animal milk using different animal milks (by volume):

60 ml (One feeding for a 1 month old baby)			
Type of milk	**Milk**	**Water**	**Sugar**
Cow, goat or camel	40ml	20ml	4g
Sheep and buffalo	30ml	30ml	3g
Evaporated	16ml	44ml	4g
Powdered full-cream	5g	60ml	4g

90 ml (One feeding for a 2 month old baby)			
Type of milk	**Milk**	**Water**	**Sugar**
Cow, goat or camel	60ml	30ml	6g
Sheep and buffalo	45ml	45ml	5g
Evaporated	24ml	66ml	6g
Powdered full-cream	7.5 g	90ml	6g

120 ml (One feeding for a 3-4 month old baby)			
Type of milk	**Milk**	**Water**	**Sugar**
Cow, goat or camel	80ml	40ml	8g
Sheep and buffalo	60ml	60ml	6g
Evaporated	32ml	88ml	8g
Powdered full-cream	10g	120ml	8g

150 ml (One feeding for a 5-6 month old baby)			
Type of milk	**Milk**	**Water**	**Sugar**
Cow, goat or camel	100ml	50ml	10g
Sheep and buffalo	75ml	75ml	8g
Evaporated milk	40ml	110ml	10g
Powdered full-cream milk	12.5g	150ml	10g

Breast-milk substitute requirements after 6 months

Age	Average amount of milk per day
6–8 months	600 ml
9–11 months	550 ml
12–23 months	500 ml

Animal milks do not require dilution after 6 months. However, special preparation is still required for fresh and powdered milk:

- **Fresh animal's milk**: Boil the milk to kill any bacteria.
- **Powdered or evaporated milk**: Add clean water according to the directions on the tin in order to make full strength milk.
- **Processed/pasteurised or UHT milk**: No preparation needed

Complementary feeding

Age	Texture	Frequency	Amount at each meal
From 6 months	Soft porridge, well mashed vegetable, meat, fruit	2 times per day	2–3 tablespoonfuls
7–8 months	Mashed foods	3 times per day	Increasing gradually to $^{2}/_{3}$ of a 250 ml cup at each meal
9–11 months	Finely chopped or mashed foods, and foods that infant can pick up	3 meals plus 1 snack between meals	$^{3}/_{4}$ of a 250 ml cup/bowl
12–24 months	Family foods, chopped or mashed if necessary	3 meals plus 2 snacks between meals	A full 250 ml cup/bowl

Note: These amounts are in addition to milk feeds