

**BREASTFEEDING AND REPLACEMENT FEEDING PRACTICES
IN THE CONTEXT OF MOTHER-TO-CHILD TRANSMISSION OF HIV**

AN ASSESSMENT TOOL FOR RESEARCH

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1 Introduction

This tool provides guidance for researchers who seek to establish the nature of the association and levels of risk of transmission between patterns of infant feeding and mother-to-child transmission of HIV (MTCT). Such a tool has not yet been developed for MTCT although comparable tools have been used in other contexts, such as childhood diarrhoea. Many indicators, including those in Demographic and Health Studies, already exist. By drawing on these existing instruments and involving many investigators in the design of this tool, it is hoped that the data may be more consistently collected from study to study, allowing improved comparison across sites and meta/joint analyses of data sets.

This tool is designed to assess infant feeding patterns and their relation with MTCT. It is not intended to collect information on nutritional adequacy of infant feeding.

Rationale for the present emphasis on MTCT:

By the end of the year 2000, UNAIDS estimated that 1.3 million children were living with HIV/AIDS and that 4.3 million children had already died of the disease. In the year 2000 alone, it was also estimated that 600 000 children were infected with HIV and 500 000 died of HIV/AIDS.¹ Almost all HIV-infected children acquire HIV from their infected mother.

MTCT can occur during pregnancy, at the time of delivery, and after birth through breastfeeding. Based on a compilation of studies, it is estimated that MTCT rates, without any anti-retroviral intervention, range from 15 to 30% in the absence of breastfeeding, to 25 to 35% if there is breastfeeding through 6 months and to 30 to 45% if there is breastfeeding through 18 to 24 months.²

Table 1. Estimated risk and timing of mother-to-child transmission of HIV

Timing	Transmission rate (%)		
	No breastfeeding	Breastfeeding through 6 months	Breastfeeding through 18 to 24 months
During pregnancy	5 to 10	5 to 10	5 to 10
During labour	10 to 20	10 to 20	10 to 20
Through breastfeeding			
Early (first 2 months)		2 to 10	2 to 10
Late (after 2 months)		1 to 5	5 to 10
Overall	15 to 30	25 to 35	30 to 45

Source: De Cock KM et al. 2000.

2 Risk factors for MTCT through breastfeeding

- **Maternal viral load and CD4-CD8 counts**

High maternal viral load measured during pregnancy³ or after delivery⁴ and low CD4/CD8 ratio⁴ have been associated with an increased rate of MTCT through breastfeeding.

- **Duration of breast feeding**

The risk of HIV transmission through breastfeeding is greatest in early infancy (before 6 months of age), and persists as long as breastfeeding continues.^{5,6} Some studies found that longer duration of breastfeeding is associated with increased risk of MTCT.^{3,7,8}

- **Breast milk infectivity**

A randomised clinical trial in Nairobi suggested that the volume of milk ingested is an important factor in breast milk transmission of HIV.⁹

- **Infant oral thrush**

A study in Kenya found that infant oral thrush before 6 months of age is a risk factor for post-neonatal infection of children.⁸

- **Breast inflammation and pathology**

Some studies found that inflammatory conditions such as mastitis, assessed clinically^{3,10} or biologically (by measuring the sodium level in breast milk),⁴ fissures¹⁰ and breast abscesses³ increase the risk of MTCT through breastfeeding.

Poor breastfeeding technique (poor attachment) is a frequent cause of such conditions. A suggested mechanism for the associated increased risk of transmission is that inflammation-induced openings in the mammary epithelium, secondary to poor breast emptying and milk stasis, allow plasma constituents, including HIV, to enter the breast milk.¹¹ The elevation of sodium in breast milk is used as a proxy for assessment for sub-clinical mastitis. Other conditions associated with elevated breast milk sodium include pre-term delivery (elevated sodium in the first four weeks), low milk volume (< 400 ml/day), pregnancy while breastfeeding (during the first two months). Colostrum also has a high sodium concentration.

A retrospective study conducted in Malawi⁴ found that HIV-infected breastfeeding women with elevated breast milk sodium levels (>12 mmol/l) consistent with sub-clinical mastitis in early infancy (6 weeks post-partum) had higher concentrations of HIV in their breast milk and were more likely to have HIV-infected babies at 6 weeks and 12 months of age than women with normal breast milk sodium levels. Breast milk samples were obtained at one time point only and it is impossible to ascertain whether elevated breast milk sodium from a single sample is independently associated with breastfeeding-related HIV transmission or if it is a marker for systemic inflammation and/or poor immune status in the mother. A prospective study of HIV-infected mothers in Durban found that raised breast milk sodium:potassium ratios (>1) correlated highly with breast milk HIV viral load and frequently occurred unilaterally.

- **Infant feeding patterns and MTCT**

A study conducted in Durban, South Africa found evidence that non-exclusive breastfeeding may be an additional risk factor.¹² In this study, a group of infants exclusively breastfed for at least three months had a lower transmission risk at six months (19.4%) than did those who also received other fluids or foods together with breast milk (26.1%). The difference in the cumulative probability of infection remained significant at 15 months, being 24.7% among 3

months exclusively breastfed infants compared to 35.9% among non-exclusively breastfed infants.¹³

This analysis was performed on HIV-infected women and babies participating in a vitamin A supplementation trial. Women in this study received advice about infant feeding, but self-selected their feeding practices. Other risk factors for MTCT, such as maternal CD4/CD8 cell ratio, syphilis screening test results, and pre-term delivery were controlled for in the analysis. The morbidity (diarrhoea, lower respiratory tract infection, candidiasis) in children prior to detection of HIV was similar in infants who were exclusively breastfed and in infants who were mixed fed. This addresses some of the concerns raised about this observational study, in particular the issue of reverse causality, whereby a change in infant feeding pattern may result from an infection. HIV acquisition may be wrongly ascribed to the change in feeding pattern rather than to the underlying infection that could have facilitated the acquisition of HIV infection. It is plausible that primary HIV infection in children may be associated with signs and symptoms, and result in a change of feeding pattern to which the infant HIV's acquisition can be wrongly attributed.

Potential mechanisms that could explain a reduced risk of MTCT when children are exclusively breastfed include:¹⁴

- Reduction in dietary antigens and enteric pathogens that may maintain integrity of the intestinal mucosal barrier and limit inflammatory responses to the gut mucosa;
- Promotion of beneficial intestinal microflora that may increase resistance to infection and modulate the infant's immune response;
- Modulation of anti-microbial, anti-inflammatory and immuno-modulating properties of breast milk;
- Maintenance of mammary epithelial integrity that may reduce viral load in breast milk.

3 Rationale for developing an assessment tool to record infant feeding pattern in the context of MTCT

The development of this tool has been driven by the recognition that more information on risk factors for HIV transmission through breastfeeding is needed and to ensure that research groups use the same definitions and terms. The objective of this tool is, therefore, to standardise the core information that needs to be collected and to ensure comparability between studies.

Unfortunately, the South African study did not measure breast health and the Kenya and Malawi studies did not distinguish between exclusive and non-exclusive breastfeeding, which precludes an understanding of the relative contributions of these risk factors to overall risk of MTCT of HIV. In fact, nearly all studies of transmission through breastfeeding have used customary but now inadequate methodologies based on comparisons between ever and never breastfed infants, grouping all breastfed babies into a single category and not permitting assessment of the effects of different breastfeeding patterns (e.g., exclusive breastfeeding, breast and formula feeding, predominant breastfeeding with water supplements, formula feeding alone, etc) on the risk of MTCT.¹⁵ This tool provides guidance to users on how to collect information on breastfeeding and replacement feeding practices in the context of research related to MTCT of HIV. Use of the tool within MTCT intervention studies conducted in breastfeeding populations will allow researchers to quantify the risks of HIV transmission according to various feeding patterns after adjusting for potentially confounding variables.

4 Definitions of breastfeeding and replacement feeding terms

In 1991, the World Health Organization convened an informal meeting to establish definitions and indicators for assessing breastfeeding practices in household surveys.¹⁶ The main purpose of promoting the use of the indicators was to have a common set of measures to assess practices and monitor the progress of breastfeeding promotion programs. Several of the following definitions are taken from this document; others are taken from the documents entitled "International Code of Marketing of Breast-milk Substitutes", "Breastfeeding Counselling: a training course" and "HIV and Infant Feeding: guidelines for decision makers".^{17,18,19}

▪ **Breastfeeding**

"The child has received breast milk (direct from the breast or expressed)".¹⁶

Breastfeeding practices may be further described according to timing and frequency. In terms of timing, breastfeeding may be described as on-demand (by the child) or on schedule (determined by a schedule or work/separation demands of the mother).

• **Exclusive breastfeeding**

"The infant has received only breast milk from his/her mother or a wet nurse, or expressed breast milk and no other liquids, or solids with the exception of drops or syrups consisting of vitamins, mineral supplements, or medicines".¹⁶

A child may be exclusively breastfed with expressed human milk from his mother, a breast milk donor or from a milk bank.

• **Predominant breastfeeding**

"The infant's predominant source of nourishment has been breast milk. However the infant may also have received water or water-based drinks (sweetened or flavoured water, teas, infusions, etc.); fruit juice; Oral Rehydration Salts (ORS); drop and syrup forms of vitamins, minerals, and medicines; and folk fluids^a (in limited quantities). With the exception of fruit juice and sugar-water, no food based fluid is allowed under this definition."¹⁶

▪ **Breast milk substitute**

"Any food being marketed or otherwise presented as partial or total replacement from breast-milk, whether or not suitable for that purpose".¹⁷

• **Complementary feeding**

Any food, whether manufactured or locally prepared, suitable as a complement to breast milk or to infant formula, when either become insufficient to satisfy the nutritional requirements of the infant. Such food is commonly called "weaning food" or "breast-milk supplement".¹⁷

• **Partial breastfeeding**

Means giving a baby some breastfeeds, and some artificial feeds, either milk or cereal, or other food.¹⁹

^a Folk fluids are liquids used for non-nutritional purposes, oil to relieve constipation, tea for relief of colic etc.

- **Replacement feeding**

Means the process of feeding a child who is not receiving any breast milk with a diet that provides all the nutrients the child needs. During the first six months this should be with a suitable breast-milk substitute — commercial formula, or home-prepared formula with micronutrient supplements. After six months it should preferably be with a suitable breast-milk substitute, and complementary foods made from appropriately prepared and nutrient-enriched family foods, given three times a day. If suitable breast-milk substitutes are not available, appropriately prepared family foods should be further enriched and given five times a day.¹⁸

5 Breast and infant mouth pathologies

The following descriptions are taken from two WHO documents: the breastfeeding counselling training course¹⁹ and a document on causes and management of mastitis.²⁰

- **Full breasts**

Breasts that are hot, heavy, hard or lumpy, but with flowing breast milk. No fever is present in the mother. This condition is commonly experienced in the first days of breastfeeding, before the mother's milk supply has adjusted to the baby's needs and breastfeeding patterns.

- **Engorged breasts**

Breasts that are over-full, partly with milk and partly with increased tissue fluid and blood. As a result, milk flow is inhibited. Engorged breasts are often painful, shiny, and diffusely red. Nipples may be stretched tight and flat. The condition may be accompanied by fever lasting 24 hours or less in the mother.

- **Mastitis**

Mastitis is an inflammation of the breast. It is a condition that commonly results from inadequate or poor drainage of milk from the breast. Mastitis can be infective or non-infective in origin. Non-infective mastitis, which is most common, is usually the result of a blocked milk duct, which causes inflammation of the breast tissue. Mastitis frequently affects only one breast (whereas engorgement often occurs bilaterally) and is characterised by hard swelling, severe pain, fever (24 hours or longer) and localised redness around the affected area. Other causes include infrequent feeds or ineffective suckling; breast trauma and tissue damage; and pressure on the breasts from clothes, fingers or other sources which inhibit milk flow and cause milk stasis leading to breast tissue inflammation. Infective mastitis is the result of bacterial infection. Poor breast attachment causing nipple fissures is a common pathway to infectious mastitis.

- **Breast abscess**

This is a collection of pus in part of the breast. It results in painful swelling of the breast and usually requires a surgical incision for drainage.

- **Nipple fissure or crack**

It is characterised by pain during feeding and may or may not be associated with pus and/or bleeding.

- **Breast thrush**

Fungal infection characterised by breast pain between feeds, very sore nipples and itchy/flaky nipples

- **Infant oral thrush**

Fungal infection characterised by punctuate or diffuse erythema and white-beige pseudo-membranous plaques on the oral mucosa that remain when scraped and that may interfere with feeding.

- **Infant mouth ulcer**

Mouth ulcers may provide an entry point for HIV. In addition, painful ulcers may interfere with feeding.

6 Questions to assess infant feeding practices in the context of MTCT

The questions are grouped into six modules.

Module 1	Baseline
Module 2	Feeding practices
Module 3	Maternal health
Module 4	Breast health
Module 5	Infant health
Module 6	Cessation of breastfeeding

For each of these modules, we suggest core questions that should be part of all studies investigating the relationship between infant feeding patterns and MTCT. Core questions are marked with a bullet point. A few optional questions on infant feeding and MTCT are suggested. These are written in *italics*.

The questions are presented in a generic format, and should be integrated into a questionnaire according to the specific design of each study. The layout of the questionnaire is designed for use in either prospective or cross-sectional studies.

It is intended that mothers will answer these questions during interviews by trained field workers who are not necessarily health care workers. Once the questions are integrated into the final questionnaire, field workers must undergo training specific to the study, to ensure that they understand all the questions, will deliver them in a standardised way and are able to record answers adequately.

6.1 Module 1 - Baseline data (at recruitment and/or during first visit after birth)

While many of these questions will be site specific, it is recommended that interviewers collect the following information to allow adjustment during analysis and comparison between study populations:

Socio-demographic and socio-economic data

- Education of the mother (years of schooling)
- Age of mother
- Marital status
- Reproductive health history
- Number of people living in the household
- Number of deaths in the household (during the past 12 months, per age group, and relationship to the mother)

Maternal health status

- Viral load during pregnancy
- Symptoms or definitive diagnosis of tuberculosis
- Clinical stage of HIV
- Nutritional status (BMI)

Obstetric information

- Duration of labour
- Type of delivery (vaginal, elective caesarean section, emergency caesarean section)
- Episiotomy or tear requiring stitches
- Antiretrovirals given to mothers and child (time before and after delivery, and how long after delivery they were given)
- Birth weight

Optional questions that may be recorded

- *Contraceptive practices of the mother*
- *Malaria status of the mother*
- *Stool examination (parasites)*
- *Gestational age*
- *Vacuum, forceps delivery*
- *Infant presentation*

6.2 Module 2 - Feeding practices

The breastfeeding indicators developed in 1991 are based on information on feeding patterns in the 24-hours period preceding the enquiry, and therefore reflect current infant feeding status.¹⁶ In the present document, assessment of feeding practices is based on whether specific items have ever been consumed and how frequently (in terms of times/day) they were consumed during the recall period. The proposed approach tries not only to record current infant feeding status, but also to capture infant feeding history.

Available data and presumed biological mechanisms suggest that even small or infrequent deviations from exclusive breastfeeding may increase the risk of HIV transmission through damage to the integrity of the mucous membranes of the gut (caused by inflammation, allergic reaction, or introduction of infectious pathogens). At present, there is not enough information to determine how much deviation from exclusive breastfeeding, or how much exposure to allergenic or pathogenic foods and liquids, increases transmission risk. Data are also insufficient to determine whether certain deviations, such as the introduction of one or more category of food other than breast milk (e.g. water, non-human milk) might influence transmission. The present questionnaire will allow such information to be recorded and will allow estimates to be made of the amount of nutrition coming from breast milk (a proxy for volume of milk consumed), how it changes over time and whether it influences post-neonatal MTCT transmission.

As stated in the introduction, this questionnaire is designed to assess infant feeding patterns and their relation with MTCT. It is not intended to collect information on nutritional adequacy of infant feeding.

The consensus of experts and from pilot testing of the questionnaire was that the maximum recall period to obtain reasonably accurate qualitative data on infant feeding patterns would be one week. This will be complemented by quantitative data recording the frequency of items given in the past 24 hours and if possible the approximate volume.

The dynamics of infant feeding are complex. An infant can be exclusively breastfed for a period, receive other food due to a change in circumstances, and then return to exclusive breastfeeding. This complexity is difficult to capture unless there is a continuous assessment of the infant feeding patterns. Most studies will only be able to do a repeated cross-sectional assessment survey of infant feeding patterns. Some specific studies might use a prospective diary given to the mother to record information on a daily basis, as an aid to recall during the interview.

6.2.1 First week of life (first visit only)

The first week of life is of special interest because of its complex feeding patterns. It is a time when both mother and infant are more likely to be unwell following the delivery, with possible mother and infant separation influencing infant feeding patterns. While the mother is in the hospital, she receives and is likely to follow health workers advice on infant feeding. When she goes back home, the way she feeds the infant is based on her own beliefs and experience, the advice she received from the health worker, and the influence of her partner, family and community. There are special beliefs and practices concerning colostrum. Colostrum may or may not be given to the infant. Other traditional practices may influence the initial feeding of the infant, such as the offering of pre-lacteal feeds to the newborn. It is unclear whether different foods carry different transmission risks in the immature gut, compared with their use later in the child's life.

Recall period: questions related to this period can be asked till one month after birth.

- Did you ever breastfeed your infant? (yes) (no)

If no, there is no need to complete the entire questionnaire

- If yes, how soon after delivery was your infant first put to the breast? (in hours)
- Did your infant receive anything to eat/drink before he was first put to the breast? (yes) (no) (don't know)
- Did the infant receive oral polio vaccine during the first week of life? (yes) (no) (don't know)
- If yes, indicate the date (day, month, year)

The following table is designed to collect data on the type of food given before the infant was first put to the breast and if this was related to the mother's or infant's health. The same table also records all foods given to the infant during the first week of life and the reasons why they have been given. Probe all the items listed in the table.

Questions on reasons underlying actual infant feeding practices aim at ruling out reverse causality (see Section 6.3)

**Food items given before infant was put to the breast for the first time
and during the first week of life**

	Before any breast milk		Day 1		Day 2 to Day 7	
	Given	Reason	Given	Reason	Given	Reason
Breast milk						
Unsure if other food given						
Water or Glucose water						
Tea or Juice						
Formula						
Other milk						
Cereals or porridge (home prepared or commercial)						
Vegetables or fruits						
Other foods unspecified						
Other foods specified						
Pharmaceutical medicines						
Traditional medicines						

Reason: a = infant perceived unwell; b: mother unwell; c = infant and mother unwell; d = other reasons

Other food specified 1: _____

Other food specified 2: _____

Other food specified 3: _____

6.2.2 Follow-up visits - Food items given (all visits)

- Since the last visit, has the infant received oral polio vaccine? (yes) (no) (don't know)
- If yes, date of oral polio vaccine (day, month, year)
- Has the child received anything else other than breast milk since the last visit? (yes) (no) (don't know)

	6 days before yesterday						Yesterday
	Answer yes/no						Quantify number of breastfeeds
	6	5	4	3	2	1	
Date (day/month)							Number of breastfeeds
Breast milk during day							
Breast milk during night							
							Number of times the item was given
Unsure of other food given							
Water / Glucose water							
Tea / Juice							
Formula							
Other non maternal milk							
Cereals or porridge(home prepared or commercial)							
Mashed vegetables or fruits							
Other foods unspecified							
Other foods specified							
Pharmaceutical medicines							
Traditional medicines							

Other food specified 1: _____

Other food specified 2: _____

Other food specified 3: _____

- Was yesterday feeding pattern typical of the last week? (yes) (no) (don't know)
- Was the last week feeding pattern typical of the way the infant was fed since last visit? (yes) (no) (don't know)

Suggested questions to assess the validity of the answers, probing for information on infant feeding practices that are not otherwise reported.

- Have you been separated from the infant? (yes) (no)
- Does the infant sleep with you at night? (yes) (no)
- Does the infant breastfeed at night? (yes) (no)
- Do you ever put the baby to the breast (e.g. when going asleep, when your child is crying?) (yes) (no)

6.2.3 Notes to further explain the previous tables

Yesterday (during the past 24 hours): From the time the mother woke up yesterday until the time she woke up today.

6 days before yesterday: The 6 periods of 24 hours prior to the time described as "yesterday", and using the same definition of a day.

Breast milk during day: any breast milk given between the time the mother woke up in the morning till the time she went to bed in the evening of the same day.

Breast milk during night: any breast milk given between the time the mother went to bed in the evening and the time she woke up in the morning the following day.

Breastfeed: defined as a suckling episode that lasts two minutes or longer, with each episode separated by 30 minutes or more.

Other food: any food item that is not listed. For example, the following items should be recorded under other food: tea with milk, folk fluids.

Pharmaceutical medicines: they include liquid medicines, liquid vitamins or minerals, gripe water

Other non-human milk: includes fresh animal milk, tinned or powdered milk, fermented or sour milk, yoghurt, cheese, other fermented, home-made infant milk formula, and all other milk from a cow or other animal.

Specific studies might document:

- *Beliefs and practices concerning the consumption of colostrum;*
- *Quality of the water given to the infant, either alone, with glucose, to dilute juices, to prepare food: piped water, water from a well/bore hole, stream, rain from a tank, bought from distributed containers; whether and how the water was treated (boiled, chemicals...);*
- *More details on the different food items introduced;*
- *Reasons other than those related to maternal and infant health underlying actual infant feeding practices.*
- ***Unit per feed during the last 24 hours:*** *Only for studies recording the amount of food consumed. For these studies, a measuring unit (based on a widely used volume) can be defined (e.g. 25 ml) and a cup graduated per unit. The amount of each item given can be assessed by referring to this standardised cup that can be shown to the mother.*
- *Some studies might document the utensils used to feed the infant (bottle with a teat, cup with a spout, cup, cup with a spoon...), their condition, and the way the utensils are cleaned.*
- *Some studies might document the use of pacifiers / dummies.*

6.2.4 Wet-nursing practices (all visits)

- Has anyone else (beside yourself) ever breastfed this infant since last visit? (yes)(no) (don't know)

If no, go to the next module.

- Number of days on which this occurred? (days)
- Why did the other person breastfeed your infant? (*Ask the question and tick only the answers given. Do not prompt, except to ask "Are there any other reasons?"*)
 - Mother ill/weak
 - Breast or nipple difficulty
 - Not enough milk
 - Work
 - Had to go out/be separated from infant
 - Advised by husband
 - Advised by other family member
 - Did not want to infect infant with HIV
 - Other (specify)
- Who beside the mother has breastfed this infant? (*Ask the question and tick only the answers given. Do not prompt.*)
 - Sister
 - Mother
 - Other family member
 - Neighbour
 - Other (specify)

6.2.5 Expressed milk (all visits)

- Have you ever expressed your breast milk since last visit? (yes) (no)
- Number of days on which this occurred since last visit? (days)
- Have you given the expressed breast milk to the infant since last visit? (yes) (no)
- Number of days on which this occurred since last visit? (days)
- Have you heat treated your breast milk since last visit? (yes) (no)
- Number of days on which this occurred since last visit? (days)
- Why did you express milk? (*Ask the question and tick only the answers given. Do not prompt, except to ask "Are there any other reasons?"*)
 - To relieve breast pain/engorgement
 - To relieve pain due to cracked nipples
 - Thought milk was bad/unsafe/contaminated
 - To heat-treat before feeding
 - Had to be separated from infant
 - To wean/stop breastfeeding
 - Other (specify)
 - Infant unable to suckle on breast due to illness).

Specific studies might document the way the milk was expressed, the way it was stored and the way it was given to the infant.

Some studies might document the utensils used to feed the infant (bottle with a teat, cup with a spout, cup, cup with a spoon...), their condition, and the way the utensils are cleaned.

Some studies might document the use of the pacifiers / dummies.

6.3 Module 3 - Maternal Health (all visits)

The aim of documenting maternal health in the context of this questionnaire is to rule out reverse causality. A sick mother might change her infant's feeding behaviour due to her disease, e.g. switching from feeding her infant with breast milk to other foods. The maternal illness might be the direct cause of increased transmission through breast milk (for example if this results in an increased viral load in the breast milk). Infant HIV infection possibly occurring around this time could be wrongly attributed to the change in his infant feeding pattern.

- Since your last visit, have you ever been sick? (yes) (no) (don't know)

For each event of sickness, record the following:

- Specify what sickness
- Did you seek treatment for this condition at the health centre?
- Have you consulted a doctor? (yes) (no)
- Have you been admitted to Hospital? (yes) (no)
- What date did the disease start? (day, month, year)
- What date did the disease finish? (day, month, year)
- Did you change the way you fed your child during that time? (yes) (no)
- What did you do differently? (*Ask the question and tick only the answers given.*)
 - Stopped breastfeeding
 - Stopped non-human milks
 - Stopped other liquids
 - Stopped solid foods
 - Began giving non-human milks
 - Began giving other liquids
 - Began giving solid foods

6.4 Module 4 - Breast health and breastfeeding related difficulties (all visits)

Questions are formulated in a way that they can be asked by a trained field worker without health care experience.

- Since your last visit have you experienced any difficulty with your breast or with breastfeeding health problem? (yes) (no)
- What breast health difficulties have you experienced?
 - episode 1: (started: day/mon/yea) (finished: day/mon/yea)
 - episode 2: (started: day/mon/yea) (finished: day/mon/yea)
 - episode 3: (started: day/mon/yea) (finished: day/mon/yea)

For each episode, fill a separate form, qualify the type of breast health problem, the type of pain if any and if the infant received milk from the affected breast or not.

Appearance of the breast:

- Was the breast enlarged? (yes) (no)
- If yes, was the enlargement in one breast or both? (one breast) (both breasts)
- Was the skin of the breast red/hot generalised (or discoloured/shiny)? (no)(yes, localised)(yes,
- Was there an abscess on the breast? (yes) (no)

Appearance of the nipple

- Was the skin of the nipple broken (cracked)? (yes) (no)
- If yes, was there pus? (yes) (no)
- Or bleeding? (yes) (no)
- Was the skin of the nipple flaking? (yes) (no)

Pain

- Was there pain during that episode? (no) (yes, mild to moderate) (yes, severe)
- Was there any itching? (yes) (no)
- Was the pain affecting the nipple during feeding? (yes) (no)
- Was the pain superficial or deep in the breast during feeding? (yes, superficial) (yes, deep) (no)
- Was the breast pain persisting between feeds? (yes) (no)

Fever

- Did you have any fever during this episode? (yes) (no)

Longitudinal study

- Was the infant fed from the affected breast? (yes) (no)
- Date breastfeeding was stopped from affected breast (day/mon/yea)
- Date breastfeeding was resumed from affected breast (day/mon/yea)

Cross-sectional study

- Was breastfeeding stopped from the affected breast during the episode? (yes) (no)
- Was breastfeeding stopped during some or all of the episode? (some) (all)
- Did the infant receive breast milk from the affected breast during the episode? (yes) (no)
- Did the Infant receive breast milk from the affected breast during some of the episode? (yes) (no)
- In a longitudinal study, ask about all events since the last visit. In a cross sectional study, ask about breast health pathology since the infant was born.

- Since last visit, have you experienced any difficulties breastfeeding your infant? (yes) (no)

If yes, can you describe what type of difficulties? (*Ask the question and tick only the answers given. Do not prompt, except to ask "Is there any other reason?"*)

- Mother was sick (specify)
 - Infant breastfed too often
 - Infant was not able to suckle
 - Mother thought she did not have enough milk
 - Infant had lesions or thrush in the mouth
 - Infant had difficulty latching on
 - Infant had difficulty breathing
 - Infant had other sickness/health problem (specify)
 - Other (specify)
- What did you do? (*Ask the question and tick only the answers given. Do not prompt, except to ask "Is there any other reason?"*)
 - Nothing, I continued breastfeeding
 - I gave infant other milk/food/liquids
 - I expressed milk from the affected breast
 - I consulted a health care provider (specify)
 - I consulted other person
 - I changed breastfeeding position
 - I took medicine (specify)
 - Other (specify)

Some studies might:

- *Employ trained health care workers who have followed the WHO breastfeeding training course to conduct these surveys;¹⁹*
- *Refer mothers with suspected breast pathology to trained study health staff (nurses or doctors) to ascertain the diagnosis;*
- *Collect breast milk samples to investigate more specifically signs of sub-clinical mastitis and other biological and immunological factors related to post-natal transmission of HIV;*
- *Record breastfeeding techniques after observing a breastfeeding session.*

All studies should identify a referral system so that a field worker can refer any mother with a current breast health problem for treatment.

6.5 Module 5 - Infant Health (all visits)

- Infant weight (in g) (grammes)

Has the infant shown any of the following signs since the last visit?

- Mouth sores? (yes) (no)
 - If yes, were they painful or not? (yes) (no)
 - How many times since last visit? (times)
 - Date when event(s) occurred (day/mon/yea)

 - Sore with white patches on the inside of the mouth which remained when scraped (oral thrush) (yes) (no)
 - How many times since last visit? (times)
 - Date when event(s) occurred (day/mon/yea)

 - Fast or difficult breathing ? (yes) (no)
 - How many times since last visit? (times)
 - Date when event(s) occurred (day/mon/yea)

 - Fever? (yes) (no)
 - How many times since last visit? (times)
 - Date when event(s) occurred (day/mon/yea)

 - Diarrhoea? (yes) (no)
 - How many times since last visit? (times)
 - Date when event(s) occurred (day/mon/yea)

 - Other problem (specify)
 - Did you consult a health care worker ?
 - If yes, specify:
 - Did your infant receive any treatment?
 - If yes, specify:
 - Was your infant admitted to Hospital?
- For each event, specify dates when started and stopped (longitudinal study only).
 - Did you change the way you fed your infant when this occurred?
 - What did you do differently? (*Ask the question and tick only the answers given*)
 - Stopped breastfeeding
 - Stopped non-human milks
 - Stopped other liquids
 - Stopped solid foods
 - Began giving non-human milks
 - Began giving other liquids
 - Began giving solid foods

In a longitudinal study, ask all events since the last visit. In a cross sectional survey, ask the list of infant health problems since birth.

Some studies may use verbal autopsy methods) to assess causes of infant deaths .

6.6 Module 6 – Cessation of breastfeeding

If the mother has not reported any breastfeeding in the last few days, ask:

- Have you completely stopped breastfeeding your infant every day and every night? (yes) (no)
- How old was your infant when you completely stopped breastfeeding him every day and every night? (age in months)
- Do you still put your child to the breast occasionally (less than once per day and night, e.g. when your child starts crying)? (yes) (no)
- How long did it take for you to completely stop breastfeeding your infant from the day you decided and began to stop to the day he or she no longer suckled from your breasts? (number of days)

Some studies may consider adding the following questions:

- *Why did you stop breastfeeding your infant? (Ask the question and tick only the answers given. Do not prompt, except to ask "Are there any other reasons?")*
 - *Infant old enough*
 - *Infant no longer wanted to breastfeed*
 - *To encourage infant to eat solid food*
 - *Pregnancy*
 - *Fear of transmitting HIV*
 - *Mother can afford replacement feeding*
 - *Advised by health provider*
 - *Advised by husband or partner*
 - *Resumption of sexual relationship*
 - *Advised by other person*
 - *Separation from infant due to work*
 - *Separation from infant for other reasons*
 - *Mother too sick to breastfeed*
 - *Infant too sick to breastfeed*
 - *Infant not growing well*
 - *Other reason (specify)*
- *How did you stop breastfeeding your infant? (Ask the question and tick only the answers given. Do not prompt, except to ask "Are there any other reasons?")*
 - *Put something on breast*
 - *Sent infant to relative or friend or neighbour*
 - *Took medicine to stop milk*
 - *Gave infant other milk or food*
 - *Gave infant a feeding bottle*
 - *Did nothing special*
 - *Other method (describe)*
- *Did you encounter any problems when you stopped?* (yes, no)

- *What problems did you encounter when you stopped breastfeeding your infant? (Ask the question and tick only the answers given. Do not prompt, except to ask "Is there any other reason?")*
- *Infant cried or unhappy*
- *Breast pain*
- *Breast engorgement*
- *Mother became ill*
- *Infant became ill*
- *Disapproval by partner or family or neighbours*
- *Disapproval by health worker*
- *No food or milk to feed the infant*
- *Other problems (specify)*

7 Recommended timings to apply the questionnaire

The questionnaire should, as a minimum, be first applied 4 weeks - 6 weeks after birth, when the infant is due to visit the health centre for HIV testing. However, it is recommended to conduct interviews at two-week intervals in the first two months of life, where this is acceptable and feasible. Then the questionnaire should be applied every month for the first 6 months, and every 3 months after 6 months of age.

8 Recommended timings for infant testing

The minimum timing for infant PCR HIV testing is:

- Birth - During the first 48 hours (in-utero transmission)
- 6 weeks (in-utero, intra-partum, and early post-partum transmission)
- 3 months (post-partum transmission)
- 6 months (post-partum transmission)
- 12 months (post-partum transmission)
- 18 months (post-partum transmission)
- 24 months (post-partum transmission)

9 Recommendations for presenting data

9.1 Infant feeding categories and outline of analysis

Data can be grouped under categories described in Table 2 (if you accept my comment on Page 14, change this reference to Table 4). Infant feeding patterns can be reported according to when different food items were first introduced. These categories represent a progression through the stages of introducing new risks, such as allergens or contaminants, into the infant feed. For example the addition of fruit juices or water to the infant's diet when s/he is receiving complementary foods is possibly of less relevance and interest than the addition of water or juices when the infant otherwise receives only breast milk.

Infants receiving all breast milk from a wet nurse should be excluded from the analysis.

The age categories for classifying infant feeding practices to study the risk of HIV transmission, based on the changing maturity of the infant's gut, are the following: 1st week, 1w-2m, 2m-4m, 4m-6m, 6-12m, 12-18m, 18m or more.

When describing infant diet during the previous 24 hours, feeding patterns should be defined according to the estimated amount of total intake coming from breast milk. These patterns vary from a) all intake coming from breast milk (exclusive breastfeeding), b) breast milk accounting for 90% or more, c) 50 to 89 %, d) 10 to 49 %, e) 1-9%, and f) no breast milk at all.

The data collected on infant feeding will allow analysis to examine:

- How the incidence of infection evolves according to the amount of breast milk ingested;
- If exclusive breastfeeding carries a lower risk of transmission compared with partial breastfeeding;
- If this is confirmed, what type (non-human milk, water with or without glucose, complementary food, pharmaceutical medicines, or traditional medicines) and extent of departure from exclusive breastfeeding (quantity and age when first introduced) increases the risk of transmission;)
- The impact of other postnatal risk factors on the rate of transmission, such as breast and infant oral pathology. Adjustment for these factors could be made when assessing the impact of the different feeding patterns.
- Possible reverse causality. Exploring whether a change in infant feeding pattern, for example from exclusive to partial breastfeeding, results in an increased risk of HIV transmission or if HIV transmission and early symptoms of HIV infection result in a change in feeding pattern is extremely important in MTCT studies. However, this question is difficult to answer objectively on the basis of observational or self-reported data. To address this limitation, we have included questions to ascertain whether any changes in infant feeding pattern were preceded by any infant or maternal morbidity.

The present tool is based on incomplete knowledge and the optimum definitions and categorisation of feeding patterns for MTCT research will evolve as more information becomes available. Investigators are encouraged to explore and report on the risk of postnatal HIV transmission according to variations in the definitions of the categories presented here. For example, comparisons in the risk of transmission, according to whether exclusive breastfeeding did, or did not, include pharmaceutical medicines, could be undertaken.

Some categories of infant feeding patterns of special interest could be:

- Exclusive breastfeeding not allowing even pharmaceutical medicines (+/- oral polio vaccine)
- Exclusive breastfeeding allowing of pharmaceutical medicines (+/- oral polio vaccine)
- Predominant breastfeeding (allowing water, water based drinks and juices)

As a second step, regression models for survival data could be fitted to the transmission data, using time varying co-variants to allow the impact of infant feeding patterns to be assessed while at the same time taking into account their correlation structure.

Table 2: Categories of infant feeding exposures for analysis (if you adopt my numbering this is now Table 4)

Breast milk and approximate proportion of nutrition received	Type of other feeds						Medicines	
	None	Formula	Other Non-human milk ^a	Water with or without glucose or sugar	Complementary feeds ^b	Oral vaccine and medicines ^c	Traditional medications	
No BM	X	RF	RF	RF	RF			
BM < 10% nutrition	X	PBF	PBF	PBF	PBF			
BM 10%-50% nutrition	X	PBF	PBF	PBF	PBF			
BM 50%-90% nutrition	X	PBF	PBF	PBF	PBF			
BM > 90% nutrition	X	PBF	PBF	PBF	PBF			
100% BM	EBF					EBF		

EBF: Exclusive BreastFeeding; **PBF:** Partial BreastFeeding; **RF:** Replacement feeding

^a This includes animal milks other than formula. Types of milks can be subdivided.

^b This includes any other non-milk liquids, such as fruit juices, solids and semi-solid foods. Can be subdivided according to types of complementary feeds given.

^c Includes limited amounts of prescribed pharmaceutical medications and products.

9.2 Breast conditions

Data collected on signs of breast health can be grouped into the categories of breast conditions described in Table 5. It is of special importance for the analysis to differentiate whether the infant received breast milk from the affected breast during the event or not.

Table 3: Breast condition

Condition	Appearance	Pain	Skin inflammation	Itch	Fever
Full breasts	Enlarged breasts bilateral	No or Mild	No	No	No
Engorged breasts	Enlarged breasts bilateral	Mild During between feeds, often relieved during feeds as milk is removed	Generalised	No	+/-
Mastitis	Enlarged breasts	Severe During and between the feeds	Localised to affected area	No	Yes
Breast abscess	Localised	Severe During and between the feeds	Localised to affected area	No	Yes
Nipple fissure or crack	Sore/wound on the nipple	Localised to affected area During the feeds	Localised to affected area	No	No
Nipple eczema	Flaky nipple	Itching	Localised to affected area	No	No
Breast thrush	Flaky nipple	During and between the feeds, with or without itching	Localised to affected area	Yes	No

10 References

1. UNAIDS/WHO. AIDS epidemic update: December 2000. 2000.
2. De Cock KM, Fowler MG, Mercier E, et al. Prevention of mother-to-child HIV transmission in resource-poor countries - Translating research into policy and practice. *JAMA* 2000;**283**(9):1175-1182.
3. John GC, Nduati RW, MboriNgacha DA, et al. Correlates of mother-to-child human immunodeficiency virus type 1 (HIV-1) transmission: Association with maternal plasma HIV-1 RNA load, genital HIV-1 DNA shedding, and breast infections. *J Infec Dis* 2001;**183**(2):206-212.
4. Semba RD, Kumwenda N, Hoover DR, et al. Human immunodeficiency virus load in breast milk, mastitis, and mother- to-child transmission of human immunodeficiency virus type 1. *J Infect Dis* 1999;**180**(1):93-8.
5. Miotti PG, Taha TE, Kumwenda NI, et al. HIV transmission through breastfeeding: a study in Malawi. *Jama* 1999;**282**(8):744-9.
6. Nduati R, John G, MboriNgacha D, et al. Effect of breastfeeding and formula feeding on transmission of HIV-1 - A randomized clinical trial. *JAMA* 2000;**283**(9):1167-1174.
7. Leroy V, Newell ML, Dabis F, et al. International multicentre pooled analysis of late postnatal mother-to-child transmission of HIV-1 infection. Ghent International Working Group on Mother-to-Child Transmission of HIV. *Lancet* 1998;**352**(9128):597-600.
8. Embree JE, Njenga S, Datta P, et al. Risk factors for postnatal mother-child transmission of HIV-1. *Aids* 2000;**14**(16):2535-2541.
9. Richardson B, John G, Hughes J, Nduati R, Mbori Ngacha D, Kreiss J. Breast milk infectivity of HIV-1 infected mothers. 13th International AIDS Conference 2000, Durban, South Africa.
10. Ekpini ER, Wiktor SZ, Satten GA, et al. Late postnatal mother-to-child transmission of HIV-1 in Abidjan, Cote d'Ivoire. *Lancet* 1997;**349**(9058):1054-9.
11. Filteau SM, Lietz G, Mulokozi G, Bilotta S, Henry CJ, Tomkins AM. Milk cytokines and subclinical breast inflammation in Tanzanian women: effects of dietary red palm oil or sunflower oil supplementation. *Immunology* 1999;**97**(4):595-600.
12. Coutsooudis A, Pillay K, Spooner E, Kuhn L, Coovadia HM. Influence of infant-feeding patterns on early mother-to-child transmission of HIV-1 in Durban, South Africa: a prospective cohort study. South African Vitamin A Study Group. *Lancet* 1999;**354**(9177):471-6.
13. Coutsooudis A, Pillay K, Kuhn L, Spooner E, Tsai WY, Coovadia HM. Method of feeding and transmission of HIV-1 from mothers to children by 15 months of age: prospective cohort study from Durban, South Africa. *Aids* 2001;**15**(3):379-387.
14. Smith MM, Kuhn L. Exclusive breast-feeding: Does it have the potential to reduce breast-feeding transmission of HIV-1? *Nutr Rev* 2000;**58**(11):333-340.
15. Preble E, Piwoz E. HIV and infant feeding: a Chronology and Research and Policy Advances and their Implications for Programs. *Academy for Educational Development, Washington D.C.* 1998.
16. WHO. Indicators for assessing breastfeeding practices. 1991. WHO/CDD/SER/91.4
17. WHO. 1981. International Code of Marketing of Breast-milk Substitutes. http://www.who.int/nut/documents/code_english.PDF
18. WHO/UNICEF/UNAIDS. HIV and Infant Feeding: guidelines for decision makers. 1998:WHO/FRH/NUT/CHD/98.1.

19. WHO. Breastfeeding counselling: a training course. Geneva, WHO/UNICEF, (WHO/CDR/93.3,4,5 and 6) 1993.
20. WHO. Mastitis - Causes and management. Geneva, WHO, 2000 (WHO/FCH/CAH.00.13) 2000.

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