Local Monitoring and Evaluation of the Integrated Prevention of Mother to Child HIV Transmission in Low-income Countries
## Acronyms

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>ANC</td>
<td>Antenatal care</td>
</tr>
<tr>
<td>ARV</td>
<td>Anti-Retrovirals</td>
</tr>
<tr>
<td>BCG</td>
<td>Bacillus Calmette &amp; Guerin</td>
</tr>
<tr>
<td>BMS</td>
<td>Breast-Milk Substitutes</td>
</tr>
<tr>
<td>C/E</td>
<td>Cost Effective</td>
</tr>
<tr>
<td>DALY</td>
<td>Disability-Adjusted Life-Years</td>
</tr>
<tr>
<td>DPT</td>
<td>Diphtheria Pertussis Tetanus</td>
</tr>
<tr>
<td>EPI</td>
<td>Expanded Program of Immunization</td>
</tr>
<tr>
<td>FBC</td>
<td>Full Blood Count</td>
</tr>
<tr>
<td>FP</td>
<td>Family Planning</td>
</tr>
<tr>
<td>HIV</td>
<td>Human Immunodeficiency Virus</td>
</tr>
<tr>
<td>IMCI</td>
<td>Integrated Management of Childhood Illnesses</td>
</tr>
<tr>
<td>IMR</td>
<td>Infant Mortality Rate</td>
</tr>
<tr>
<td>MCH</td>
<td>Mother-Child Health</td>
</tr>
<tr>
<td>M&amp;E</td>
<td>Monitoring and Evaluation</td>
</tr>
<tr>
<td>MIS</td>
<td>Management Information System</td>
</tr>
<tr>
<td>NVP</td>
<td>Nevirapine</td>
</tr>
<tr>
<td>MTCT</td>
<td>Mother to Child Transmission</td>
</tr>
<tr>
<td>OI</td>
<td>Opportunistic infections</td>
</tr>
<tr>
<td>PMTCT</td>
<td>Prevention of mother to child transmission</td>
</tr>
<tr>
<td>PLWAs</td>
<td>People living with HIV</td>
</tr>
<tr>
<td>RF</td>
<td>Replacement feeding</td>
</tr>
<tr>
<td>STD</td>
<td>Sexually Transmitted Diseases</td>
</tr>
<tr>
<td>VCT</td>
<td>Voluntary Counselling and Testing</td>
</tr>
<tr>
<td>ZDV</td>
<td>Zidovudine</td>
</tr>
</tbody>
</table>
Table of Contents

1. **Introduction** 6
   1.1. Background to Prevention of Mother to Child Transmission of HIV ....................... 6
   1.2. Background to Monitoring and Evaluation (M&E) of Integrated Prevention of MTCT 7

2. **Conceptual Framework for Monitoring and Evaluating PMTCT** 8
   2.1. Management of routine implementation through local monitoring: ....................... 8
   2.2. Demonstrate benefits and costs through core evaluation: ....................................... 9
   2.3. Address Unresolved issues through extended evaluation: ....................................... 9

3. **Selecting PMTCT interventions to monitor and evaluate** 12
   3.1. PMTC: A cascade of interventions ........................................................................... 12
   3.2. Selecting tracer interventions .................................................................................. 13

4. **Conditions Necessary for Moving from Efficacy to Effectiveness in PMTCT** 14
   4.1. Conditions for Effectiveness .................................................................................. 14
   4.2. Selecting Effectiveness Indicators .......................................................................... 15
   4.3. Minimum list of indicators to monitor and evaluate effectiveness: ....................... 18
   4.4. Assessing the quality of counselling ....................................................................... 20

5. **Monitoring and Evaluating Costs and Financing** 21
   5.1. Costs, Cost Effectiveness and Financial sustainability ............................................. 22
   5.2. Cost and Financing indicators .................................................................................. 22
   5.2.1. Cost indicators .................................................................................................... 22
   5.2.2. Financing indicators ........................................................................................... 24

6. **Analysing effectiveness and cost indicators** 25
   6.1.1. Monitoring effectiveness of a given tracer intervention....................................... 27
   6.1.2. Using monitoring for problem solving ................................................................. 28
   6.1.3. Learning from successes ..................................................................................... 29
   6.2. Evaluation: Assessing the successes and problems for decision making ............. 29
   6.2.1. Aggregating monitoring data .............................................................................. 29

7. **Evaluation of impact** 32
   7.1. Impact evaluation design .......................................................................................... 32
Local Monitoring and Evaluation of the Integrated Prevention of Mother to Child Transmission of HIV in Low-income Countries

7.1.1. Selecting a stratified sample ...............................................................................33
7.1.2. Comparison groups ............................................................................................35
7.2. Impact of pilot projects on HIV transmission from mothers to infants ...............36
7.3. Impact of pilot projects on Infant Mortality .............................................................38
7.4. Social consequences of HIV testing .................................................................40
    7.4.1. Measuring positive and negative life events ..................................................40
    7.4.2. Evaluation of attitudes to VCT in the general population ...............................42
7.5. Consequences of infant feeding counselling in the context of HIV .......................42
    7.5.1. Social Risk of Replacement Feeding .............................................................42
    7.5.2. Replacement Feeding “Spillover” to HIV-Uninfected Women .......................43

8. Management Information Systems for M&E ..........................................................45
    8.1.1. Service Provision Data ...................................................................................45
    8.1.2. Resources Management Data .........................................................................48
    8.1.3. Measuring indicators ......................................................................................49

9. Extended Evaluation Topics ......................................................................................51
    9.1. Impact on Child Mortality ..................................................................................51
    9.2. Impact of infant feeding counselling ...................................................................51
        9.2.1. Strengthening of breastfeeding practices ...............................................51
        9.2.2. Child Growth ..........................................................................................52
        9.2.3. Birth Intervals ........................................................................................53
        9.2.4. Other evaluation issues related to infant feeding ........................................54
        9.2.5. Additional references on Infant Feeding ....................................................55
    9.3. Cost-Effectiveness and Cost-Benefit of the Intervention Program .....................55
    9.4. Evaluation of Voluntary Counselling and testing ............................................57
        9.4.1. Rapid Testing for HIV Antibody ...............................................................57
        9.4.2. Comparative evaluation of different methods of counselling .....................58
        9.4.3. Recommended further reading ..................................................................58
    9.5. Adherence to Antiretroviral Therapy ..................................................................59
    9.6. Referral to support services ..............................................................................59
    9.7. Incidence of HIV Infection among Women during Lactation ............................60
        9.7.1. Question: What is the rate of HIV infection acquired during lactation? ......60

Annex 1: Tools for Evaluation of counselling ..................................................................62

Annex 2: Verbal autopsy questionnaire .........................................................................66
Table of figures/tables

Figure 1. Diagrammatic presentation of M&E conceptual framework .......................................................... 10

Figure 2. An example M&E of PMTCT ........................................................................................................ 11

Table 1. How to integrate PMTCT activities within WHO recommended schedule for MCH ................. 12

Table 2. Examples of Tracers to assess the performance of the package to prevent MCT ......................... 13

Table 3: Effectiveness indicators for activities to strengthen primary prevention and family planning services, and provide prenatal VCT ................................................................. 15

Table 4: Effectiveness indicators for obstetrical care .............................................................................. 16

Table 5: Effectiveness indicators of post-partum care ........................................................................... 17

Table 6: Key conditions for effectiveness of PMTC ................................................................................. 18

Table 7: Minimum list of indicators ......................................................................................................... 19

Table 8. Cost Indicators for Monitoring the Costs ..................................................................................... 23

Figure 3. Contributors to additional costs of PMTCT ............................................................................. 2

Figure 4: Plotting M&E indicators ......................................................................................................... 26

Figure 5. Plotting the different dimensions of effectiveness for a given intervention .............................. 27

Figure 6. Comparing effectiveness of VCT over time .......................................................................... 27

Table 9. Monitoring as a problem-solving tool to implement the Prevention of Mother to Child Transmission activities ........................................................................................................ 28

Table 10: Pregnancy and delivery data form retained at health facility or by the mother ..................... 45

Table 11: Child follow-up data form retained at health facility or by the mother .................................. 45

Table 12: Data sources for measuring effectiveness indicators .............................................................. 50
1. Introduction

1.1. Background to Prevention of Mother to Child Transmission of HIV

Preventing HIV infection among new-borns requires a continuum of appropriate care for both the child and the woman from the period before the pregnancy to several years after the birth of the child.

The Prevention of Mother to Child Transmission (PMTCT) includes:

- prevention of HIV infection in mothers;
- prevention of unwanted pregnancies; and
- prevention of HIV transmission to the infant by the HIV-infected mother;

Key cost-effective interventions can be provided for each step in the context of pregnancy.

Prevention of HIV infection in pregnant/childbearing age women includes with promotion of safe sexual behaviour and condom promotion, and STD treatment.

Prevention of unwanted pregnancies includes Family Planning and abortion where legal and desired

Prevention of the transmission of HIV through pregnancy and breast-feeding includes:

- STD screening and treatment
- prophylactic treatment by antiretrovirals
- avoidance of unnecessary invasive obstetrical procedures
- alternatives to prolonged breastfeeding

However, these interventions cannot be implemented in a vacuum. To be offered these interventions, women need to have access to adequate antenatal, delivery and post-natal care which includes:

- early access to Antenatal care (ANC before 34-36 weeks of pregnancy)
- voluntary counselling and testing (VCT)
- minimum package of ANC including screening and treatment of STD (to reduce both sexual and MTCT HIV transmission) and anaemia and vitamin supplementation
- delivery care by a skilled attendant including obstetric practices which may reduce the risk of transmission
- counselling on infant feeding and caring practices, and support for choice.

In addition, it is an ethical imperative if VCT is promoted to ensure that women who are diagnosed HIV-infected have access to long term care and support. Care should also be viewed as an additional opportunity for primary HIV prevention through helping people living with AIDS/HIV (PLWA) to adopt safer sexual behaviours. The follow up of the mother and child and support to HIV affected families includes:

- psycho-social care for the mother and the child;
- medical care of the mother and the child; and
- social support to HIV affected families.
1.2. **Background to Monitoring and Evaluation (M&E) of Integrated Prevention of MTCT**

Many countries are implementing pilot programs which are aimed at demonstrating the feasibility and effectiveness of integrating activities to prevent mother-to-child transmission of HIV in routine Mother-Child Health (MCH) services in developing countries. The main questions to be answered by the pilot projects are the following:

- Can the interventions be made effective if implemented in a routine setting?
  - Does the intervention reach the participants?
  - Does the intervention benefit the participants?
  - Does routine implementation lead to a significant impact on MTCT?
  - Do beneficiaries suffer any negative impacts from the intervention e.g. from replacement feeding?
- Is the routine integration of the intervention into MCH activities cost effective? affordable and financially viable at clinic and household level?
- What are the key conditions and appropriate operational strategies necessary for PMTCT effectiveness in a routine setting?

M&E aims at answering these questions. This document has been designed to support local managers and planners in monitoring and evaluating their activities in PMTCT. Some of the questions listed above need to be addressed not only during the pilot phase of integrating PMTCT, but also on the long run when the activities will be scaled up. The document is therefore also meant to provide a framework and suggested process for assessing performance of PMTCT implementation when the latter is offered as an integrated part of routine MCH services. The document includes guidelines for:

- Locally monitoring the progress in implementation, identifying problems, troubleshooting and adapting implementation strategies (Local Managers);
- Evaluating the effectiveness, impact, cost effectiveness and financial sustainability of the intervention in the pilot projects (Planners at National Level); and
- Conducting applied research to address unresolved issues, test strategies for optimising the effectiveness, impact, cost-effectiveness and financial sustainability and minimising the risks of the intervention program. (Planners at National Level).

This purpose will be accomplished by providing guidance on how to:

- Chose indicators for monitoring, evaluation and operations research
- Establish methodologies to analyse and use the information.
- Establish standards for information systems
2. Conceptual Framework for Monitoring and Evaluating PMTCT

Monitoring and evaluation activities support implementation of the program in that:

i. They are systematic ways of learning from experience and using the lessons learned to improve health activities and promote better planning.

ii. They can provide information support for local management and strategy, policy and program formulation and budgeting, and program delivery through various services and institutions.

It is essential to perceive monitoring and evaluation as decision-oriented tool, and to link the process closely with decision-making, whether at the operational or policy level. The process of carrying out monitoring and evaluation can be just as important as the conclusions drawn, since involvement in the process often induces a better understanding of the activities being assessed, and a more constructive approach to their implementation and to any future action required.

Therefore, all actors who hold part of the response to potential implementation problems have to be involved in the monitoring and evaluation process. This may include:

- grass-root community and civil society representatives
- representatives of community and women’s organisations, NGOs
- users’ representatives: PLWAs, mother support’s groups
- local decision-makers: local governors, Health Committees members
- local health managers: nurses, midwives, social workers, lab technician, counsellors, nutritionists, doctors etc
- supervisors and health planners

An ongoing local monitoring and trouble-shooting approach to programme implementation will ensure that the feasibility of intervention will be assessed. In this regard, health staff and local managers would routinely monitor the implementation of the key interventions in order to adapt strategies to deal with any identified implementation problems (Monitoring).

The outcomes of the implementation would then be evaluated, taking into account effectiveness, impact, cost effectiveness and financial sustainability (Core evaluation).

When necessary, additional evaluation activities would be carried out to gain insight into unresolved issues, test approaches to address these issues and obstacles to implementation. This would need to be adapted to the local context (Extended evaluation).

2.1. Management of routine implementation through local monitoring:

In each health facility offering the PMTCT intervention, local managers (e.g. nurses and physicians) and other stakeholders (e.g. including representatives of PLWAs, local leaders, mother support groups) will analyse the information they collect routinely for clinical and administrative management in order to get an idea on:

• whether the conditions for routine implementation are in place
• whether the implementation of the intervention is progressing,
• what are the key problems in the implementation to trigger corrective management action

Local monitoring indicators are mainly process indicators. However, when aggregated and analysed
as a whole, they should provide a valid picture of the progress towards effectiveness. These indicators are measured mainly with information collected for clinical and administrative management.

2.2. Demonstrate benefits and costs through core evaluation:

Planners will verify in a valid and reliable way whether:

- the intervention is successful in preventing MTCT
- the intervention reaches the beneficiaries
- it benefits the target population
- it harms the participants and/or non participants living in the area
- at what cost for the health care system and the beneficiaries
- it is affordable and financially viable

This approach would help assess the effectiveness, impact, cost effectiveness and financial viability of activities implemented. It will also help programmes come up with recommendations for policy and program improvement.

Core evaluation indicators include the aggregated monitoring indicators as well as the process and outcome indicators which cannot be collected as part of the routine clinical and administrative management and, therefore, require special studies to either validate or complement the monitoring data routinely collected.

The minimum core evaluation process will involve:

1. Interim Analysis of Aggregated Monitoring Data, synthesising local monitoring data from each clinic
2. Collection and analysis of additional data which cannot be collected validly through the clinical and administrative management process, using special studies: i.e., quality of counselling, client satisfaction, assessment of client provider interaction;
3. Assessment of impact on final outcomes (specific mortality, HIV transmission rates) on a sub-sample of women-index child couples chosen randomly among the enrolees of the MCH clinics providing the intervention.
4. Validation of data collected through routine monitoring, through careful individual follow-up of the sub-sample used for impact evaluation.

2.3. Address Unresolved issues through extended evaluation:

Planners and external evaluators will help local managers to get insights on specific issues and test the outcomes of different approaches to address unresolved issues, foreseen obstacles and major constraints.

Extended evaluation will provide answers to unresolved questions concerning different approaches to e.g. testing, counselling, replacement feeding, adherence to ARV, equity etc
Figure 1. Diagrammatic presentation of M&E conceptual framework

1.1.1.1.1 Extended Evaluation (in some pilot project)
- Applied Research
  - Using data collected on specific samples
  - Responding to specific concerns and unresolved issues

Core Evaluation (in each pilot project)
- Regular analyses of monitoring data and data collected on a sub-sample of population and enrollees

ON TOP OF LOCAL MONITORING:

- Synthesis of Local Monitoring indicators (Process evaluation)
- Measurement of Outcome and key Indicators (Impact evaluation)

Local Monitoring:
(in each MCH clinic)

- Continuous Monitoring of coverage with and quality of Services,

Using data collected for clinical and administrative management for all enrollees
Local Monitoring

During the first monitoring session after 3 months of implementation, the health staff identifies that:
- only 40% of the pregnant women receive iron and folic acid. As a result a large number of HIV+ women have an Hb less than 8 and cannot initiate the ARV treatment.
- their MCH center experiences shortages in BMS for children of HIV+ mothers about 20% of the time. Discussions between health staff, PLWAs and mother support groups show that in some cases BMS donated for MTCT was given to HIV-negative mothers “because they were poor and had not enough milk”

For the next period, the health staff decides:
- to put a particular emphasis on getting the pregnant women to actually take at least one month of iron/folic acid
- to keep BMS in the pharmacy and deliver it only with prescription

Core Evaluation

The project has now been in place for 18 months and enrolled 200 women whose children are 6 months or more. Together with external evaluators, the managers of the pilot project, decides that it is now possible to conduct an evaluation which can show whether the goal of reducing MTCT in the women covered by the intervention has been achieved without doing harm. For example, if one of the goal was to reduce the risk of MTCT to below 15%, in depth analysis of data collected from a sub-sample of mother-child pairs can show if the goal has been achieved. Policy and Program Recommendations for expansion of the program to other sites are then elaborated.

Extended Evaluation

Local managers have a major concern: the cost of individual pre-test counselling. To address the problem they will propose group counselling in one of the pilot clinic. Then they will assess the differences between individual and group pre-test counselling regarding acceptance rate, quality and costs. A specific applied research protocol is designed to compare the (cost)-effectiveness of the two strategies.
3. Selecting PMTCT interventions to monitor and evaluate

3.1. PMTC: A cascade of interventions

The prevention of mother-to-child transmission can be considered as a cascade of programme components or phases of the intervention as follows:
- Introduction of primary HIV prevention activities and Voluntary HIV Counselling and Testing services during antenatal care
- Improvement of basic obstetrical care including offer of antiretrovirals to HIV+ pregnant women and adequate delivery practices
- Infant feeding counselling during ANC
- Post-partum care including support to infant feeding, growth monitoring, family planning services and screening of HIV infection in children
- Long term support to HIV-infected mothers and their families.

Each phase will consist of several activities. Table 1 for example describes the frequency, timing and quality of MCH services recommended by WHO. The schedule provides a basis for monitoring and evaluating the activities. Some of these activities will be done at the level of MCH services (as in Table 1) but others will be done at community level (i.e communication programmes), or at the level of other health, social services or NGOs (i.e. long term care).

| Table 1. How to integrate PMTCT activities within WHO recommended schedule for MCH |
|---|---|
| When? | What happens in terms of intervention? |
| Antenatal visit 1 between 16 and 34 week: | - HIV/STD counselling  
- Promotion of condom use  
- HIV testing  
- Syphilis screening  
- anaemia prophylaxis by iron folic acid |
| Antenatal visit 2 Two weeks after the antenatal visit 1, between 18 and 36 weeks | - syphilis treatment  
- confirmation of HIV+ tests  
- post-test counselling  
- consent for ARV treatment for HIV+ women  
- HIV+ women referred to support groups and services  
- Promotion for exclusive breast-feeding to all HIV- pregnant women  
- Infant feeding counselling for HIV+ women |
| Antenatal visit 2 or 34-36 weeks | - individual counselling  
- initiation of ARV treatment (if recommended regimen includes a pre-natal component)  
- Counselling and Testing of partner |
| Labour/Delivery | - Intra-partum ARV component  
- Avoidance of unnecessary invasive procedures  
- Universal precautions |
| Immediate post-partum | - Support to infant feeding (as per choices of the mother)  
- BCG, Polio 0  
- family planning, promotion of condom use |
| According to EPI schedule | - DPT1, DPT2, DPT3, measles (hep B)  
- support to adequate feeding and infant caring practices  
- growth monitoring  
- referral to support groups and care services |
| As needed for illness | - treatment of infections  
- nutritional and caring counselling |
| According to HIV screening schedule (e.g. Elisa at 12 and 18 months of age) | - HIV testing of the baby  
- Referral for paediatric care if child HIV+ |
3.2. Selecting tracer interventions

The large range of interventions in the Prevention of Mother to Child HIV Transmission Package is a challenge to monitor. Monitoring and evaluating all the interventions might be too cumbersome for peripheral staff. Managers will have to choose the components which are most representative. In this case, tracer interventions can be used - the trends of the tracer reflecting the trends of the key components of the intervention. The tracer interventions chosen should be closely allied to the primary outcome being measured. Immunisation program effectiveness, for example, is usually considered a good indicator of primary health care effectiveness (Schimouchi et. al., 1994). These tracers aim at reflecting the overall package although they do not include all of its components.

The criteria for choosing tracers should include:

- The importance of the given intervention for the overall success of the program: VCT, for example, is the cornerstone of MTCT prevention program and should therefore be included in the tracers
- The expected difficulties for successful implementation of a given component: infant feeding counselling is, for example, one of the most challenging component to implement together with activities to minimize the risks of replacement feeding.
- The possibility of measuring their effectiveness in a valid, reliable and interpretable way, i.e. the possibility to identify indicators easy to measure and providing reliable information: while reliable indicators to measure changes in sexual behaviors are difficult to identify, information regarding the consumption of STD drugs is easy to collect.

Table 2 shows potential tracers by phase of the intervention. For each of these tracers, specific monitoring, operations research and evaluation indicators will be developed.

Table 2. Examples of Tracers to assess the performance of the package to prevent MCT

<table>
<thead>
<tr>
<th>Interventions</th>
<th>Primary HIV prevention &amp; VCT</th>
<th>Obstetrical care</th>
<th>Post-partum child care</th>
<th>Mother and Family care</th>
</tr>
</thead>
<tbody>
<tr>
<td>VCT of pregnant women</td>
<td>Anaemia prophylaxis</td>
<td>Infant feeding counselling</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acceptance raising</td>
<td>Vitamin supplementation</td>
<td>Growth monitoring</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Condom Distribution</td>
<td>Tetanus toxoid immunisation</td>
<td>EPI</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Routine STD diagnosis and treatment in pregnant women</td>
<td>ARV treatment</td>
<td>Micronutrient supplementation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Support to share test result with partner or other family members</td>
<td>Safe delivery</td>
<td>Integrated Management of the ill child*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Condom promotion among partners</td>
<td>Universal Precautions</td>
<td>Support to feeding practices</td>
<td></td>
<td></td>
</tr>
<tr>
<td>VCT of partners</td>
<td>Caesarean section</td>
<td>Distribution of breastmilk substitutes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Promotion of safe sexual behaviour, Development of youth friendly services</td>
<td>Vaginal Cleansing</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Peer education and support</td>
<td>Avoidance of routine episiotomy</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Avoidance of artificial ROM</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Voluntary abortion</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tracer</td>
<td>Anaemia prophylaxis</td>
<td>Integrated Management of the ill child</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Voluntary Testing and counselling</td>
<td>ARV treatment</td>
<td>Support to household feeding practices</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Condom distribution</td>
<td>Avoidance of Episiotomy</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>STD treatment</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>* The strategy of Integrated Management of Childhood Illness (IMCI) aims to reduce child mortality and morbidity in developing countries by combining improved management of common childhood illnesses with proper nutrition and immunization. The strategy includes interventions to improve skills of health workers, the health system, and family and community practices.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
4. Conditions Necessary for Moving from Efficacy to Effectiveness in PMTCT

For children of HIV+ mothers to benefit from PMTCT, managers have to ensure that several critical conditions are met. Only then will the PMTCT efficacy (its capacity to reduce the problem in ideal conditions) translate into a fully effective, efficient and financially sustainable program.

4.1. Conditions for Effectiveness

To be effective, a program has to fulfil the following conditions:

**Availability** of key resources is a necessary condition for an operational intervention. An uninterrupted supply of HIV tests, ZDV and laboratory supplies must be guaranteed. This requires either procurement through the usual channels of drug supply or the establishment of a parallel system (e.g., when funding for ZDV is channelled through an organisation such as the Red Cross in Thailand).

**Physical and financial accessibility** is also an issue. Women have to be able to get to the place where testing, counselling and treatment by ZDV is offered. For example, requesting all pregnant women to go to the district hospital outpatient ward for the first and second antenatal visit can increase the difficulty of seeking care, as the amount of travel time and cost of transportation increase. The costs for the family should not be an obstacle for women to access the intervention. For example, women may chose to breastfeed only because the costs of infant formula are too high.

**Initial use** of services must also be ensured. When utilisation of antenatal care is low, specific strategies have to be designed to increase it. This may include community-based problem solving and monitoring, education or social mobilisation initiatives. When utilisation is high, specific attention should be given to ensure that voluntariness of VCT is clearly understood to avoid that fear or discriminatory attitudes lead women not to attend antenatal clinics anymore.

**Continuity** of care and adherence is one, if not the most important, issue the system must address successfully. First, women need to return to obtain the result of their HIV test. Then they need to go back for each of the important subsequent steps. Finally, they need to comply with their treatment. Specific strategies can be implemented to fulfil each of these critical steps.

**Quality** of the services provided is a major element of the final effectiveness of the intervention. Standard procedures have to be well designed and they have to be followed. Personnel must be positive, empathetic and compassionate. The criteria for counselling quality must be met.

Operational strategies for putting conditions in place are most often specific to each country. Both indicators of monitoring and evaluation have to measure how these local strategies ensure these conditions are met.

---


---

Local Monitoring and Evaluation of the Integrated Prevention of Mother to Child Transmission of HIV in Low-income Countries
Capacity to conduct the program including adequate funding, availability of trained personnel, adequacy of space to carry out activities will be prerequisites to fulfil the conditions listed above and is a critical condition for sustainability.

4.2. Selecting Effectiveness Indicators

To chose which dimensions of effectiveness (see section 4.1) of which tracer interventions (see section 3.2) are important to monitor, it is useful to draw a table crossing chosen tracer interventions and dimensions of effectiveness. Tables 3,4,5 give examples of indicators for each dimension of effectiveness of PMTC interventions.

Table 3: Effectiveness indicators for activities to strengthen primary prevention and family planning services, and provide prenatal VCT

<table>
<thead>
<tr>
<th></th>
<th>Primary HIV prevention</th>
<th>Family Planning</th>
<th>VCT</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Target Population</strong></td>
<td>Sexually active population living in the geographical area covered by the pilot project</td>
<td>Childbearing age women</td>
<td>Pregnant Women</td>
</tr>
</tbody>
</table>
| **Availability of Resource** | % of the people living in a neighbourhood where the availability of condoms and IEC material is constant | Availability of contraceptives (e.g., pill, IUD) | % of time with no shortages of HIV rapid test
|                          | % of time with no shortages of STD drugs                                                |                                                      | ratio of available HIV test kits to the # of women tested
|
| **Access**               | % of the people having access to condom distribution or sale                            | % of target population living less than two hours away from a facility offering family planning services | % of women living at a specified acceptable distance (in terms of Km, time and cost) from facility in which VCT is available |
|                          | % of people living less than 5 km from a health centre where STD treatment is available. |                                                      |                                                                     |
| **Initial Use**          | % of people declaring having used condoms over the previous year                       | % of childbearing age women using one modern method of contraception | % of women having delivered over the period considered, coming for a first antenatal visit, for whom a pre-test proposing voluntary testing was conducted |
|                          | % of childbearing age women using one modern method of contraception                   |                                                      |                                                                     |
| **Continuity**           | % of STD patients having benefited from a full treatment according to national standards of care. | % of childbearing age women visiting FP services once a year | % of women having received counselling who were tested for HIV
|                          | % of childbearing age women visiting FP services once a year                            |                                                      | % of women having been tested who benefited from post-test counselling at appropriate timing |
| **Quality**              | % of STD patients whose partner has been treated                                       | % of childbearing age women who received Family Planning counselling of adequate quality | % of women who benefited from counselling by a trained counsellor
|                          | % of childbearing age women who received Family Planning counselling of adequate quality |                                                      | % of women who were satisfied of the VCT and provided correct information
|                          |                                                                                        |                                                      | % of partners testing before birth
|                          |                                                                                        |                                                      | % of partners testing at 6 months
| **Impact**               | HIV prevalence among pregnant women\(^1\)                                              | Fertility rate / Birth spacing                       | Frequency of Stigma                                                   |

1. Numbers of HIV seropositive women who did not receive the pilot project interventions because they were not tested for HIV may be estimated from existing sentinel serosurveillance or through anonymous unlinked surveys conducted specifically for the pilot project (see Population Surveys section under Impact Evaluation).

3. Adapted from indicator of frequency of stock-outs of commodities, in Handbook of Indicators for Family Planning Program Evaluation, p. 73, The Evaluation Project, USAID.

4. Adapted from indicators of commodities and logistics, in Handbook of Indicators for Family Planning Program Evaluation, The Evaluation Project, USAID.
Table 4: Effectiveness indicators for obstetrical care

<table>
<thead>
<tr>
<th>Intervention</th>
<th>ANC</th>
<th>ARV treatment</th>
<th>Safe Delivery</th>
</tr>
</thead>
<tbody>
<tr>
<td>Target Population</td>
<td>Pregnant Women</td>
<td>Pregnant women with HIV</td>
<td></td>
</tr>
<tr>
<td>Availability</td>
<td>% of time with no shortages of iron folac acid</td>
<td>% of time with no shortage of ZDV (^3)</td>
<td>% of time with the presence of a skilled attendant and no shortage of methyl-ergometrin and oxytocin, gloves and chlorhexidine</td>
</tr>
<tr>
<td>Accessibility</td>
<td>% of women having delivered over the period considered, living at a specified acceptable distance (in terms of Km, time and cost) from facility in which VCT/ARV/RF is available</td>
<td>% of women having delivered over the period considered, who initiated the ARV treatment</td>
<td>% of HIV + women having delivered over the period considered with a skilled attendant</td>
</tr>
<tr>
<td>Initial Use</td>
<td>% of women having delivered over the period considered, having attended at least one antenatal visit(^1)</td>
<td>% of HIV+ women having delivered over the period considered, who initiated the ARV treatment</td>
<td>% of HIV + women having delivered over the period considered with a skilled attendant</td>
</tr>
<tr>
<td>Timing and Compliance Coverage</td>
<td>% of women having delivered over the period considered benefiting from at least four antenatal visits, one in the 8th month</td>
<td>% of HIV+ women having complied to the ARV treatment during the two weeks preceding delivery</td>
<td>% of HIV+ women having delivered over the period considered, with a skilled attendant, who benefited from one postnatal visit with FP</td>
</tr>
<tr>
<td>Quality</td>
<td>Among women having delivered over the period considered</td>
<td>% of women having delivered over the period considered who got an Hb test</td>
<td>% of HIV+ mothers having delivered over the period considered without RPM or Episiotomy</td>
</tr>
<tr>
<td></td>
<td>% who got TT2</td>
<td>% who got Syphilis testing</td>
<td></td>
</tr>
<tr>
<td></td>
<td>% who got iron/folates (^2)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Impact Measures</td>
<td>Birth Weight</td>
<td>HIV transmission rate</td>
<td>Maternal and neonatal mortality</td>
</tr>
</tbody>
</table>

1. This indicator has been extensively tested and is used in countrywide USAID-sponsored Demographic Health Surveys.
2. Based on WHO Standards for Prenatal Care in Developing Countries
3. Adapted from indicator of frequency of stock-outs of commodities, in Handbook of Indicators for Family Planning Program Evaluation, p. 73, The Evaluation Project, USAID.
4. Adapted from indicators of commodities and logistics, in Handbook of Indicators for Family Planning Program Evaluation, The Evaluation Project, USAID.
5. Definition: \((A - B) + C?D\), where A, B, C, and D are defined as described below:

\(A\) = Number of antenatal (neonatal) ARV courses available at the beginning of the period.
\(B\) = Number of antenatal (neonatal) ARV courses distributed to patients during the period.
\(C\) = Number of antenatal (neonatal) ARV courses delivered to the clinic during the period.
\(D\) = Number of antenatal (neonatal) ARV courses left at the end of the period.

(Objective: No leakage of drug supplies)

### Table 5: Effectiveness indicators of post-partum care

<table>
<thead>
<tr>
<th>Interventions</th>
<th>Infant Feeding Counselling</th>
<th>Integrated Management of the Ill Child</th>
<th>Long term support</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Target Population</strong></td>
<td>HIV+ Mother and infant</td>
<td>% of time with no shortages of cotrimoxazole, penicillin and vaccines at MCH clinic/ health centre level</td>
<td>HIV+ affected families</td>
</tr>
<tr>
<td><strong>Availability</strong></td>
<td>% of time with no shortage of Breast-milk Substitutes or other RF</td>
<td>% of time with no shortages of cotrimoxazole, penicillin and vaccines at MCH clinic/ health centre level</td>
<td>Availability of a network of support (social, health, community volunteers, Pwas, NGOs etc)</td>
</tr>
<tr>
<td></td>
<td>Ratio of lots of BMS to % of HIV+ women who chose RF</td>
<td>% of time with no shortages of cotrimoxazole, penicillin and vaccines at MCH clinic/ health centre level</td>
<td></td>
</tr>
<tr>
<td></td>
<td>difference between stock flows and lots of BMS distributed to HIV+ women</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Accessibility</strong></td>
<td>% of women having delivered over the period considered, living at a specified acceptable distance (in terms of Km, time and cost) from facility in which VCT/ARV/RF is available</td>
<td>% of women having delivered over the period considered, living at a specified acceptable distance (in terms of Km, time and cost) from facility in which paediatric care is available</td>
<td>% of target population living less than 5 Km from a health centre</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>% of AIDS patients living in an area where either local health facility or home based care is provided</td>
</tr>
<tr>
<td><strong>Initial Use</strong></td>
<td>% of HIV+ mothers who were counselled by a qualified nutritional counsellor within two days of delivery</td>
<td>% of infants born to an HIV+ mother having benefited from the services of IMIC at least once</td>
<td>% of target population referred to a network of care and support</td>
</tr>
<tr>
<td></td>
<td>% of HIV+ mothers who were assisted to initiate exclusive BF by a qualified nutritional counsellor</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>% of HIV+ mothers who elect to use RF</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Continuity Coverage</strong></td>
<td>% of infants born to an HIV+ mother who are using RF at 4 months</td>
<td>% of infants born to an HIV+ mother who benefited from IMIC for all episodes of illness</td>
<td>Number of first curative visits for 100 AIDS patients in which full treatment according to standards of care is provided</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>% of children of AIDS affected families who receive proper care from relevant family members</td>
</tr>
<tr>
<td><strong>Quality</strong></td>
<td>% of children born to an HIV+ mother who are replacement fed using a cup at the one month visit</td>
<td>% of children born to an HIV+ mother who were treated by a staff trained in IMCI</td>
<td>Number of first curative visits for 100 AIDS patients in which full treatment according to standards of care is provided</td>
</tr>
<tr>
<td></td>
<td>% of infants born to an HIV-mother who are using RF at 4 months</td>
<td></td>
<td>% of target population who benefit from bimonthly visits from a trained counsellor</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>% of children of AIDS affected families who are accepted in nursery/primary schools</td>
</tr>
<tr>
<td><strong>Impact</strong></td>
<td>% of children born to HIV+ mothers with a weight for age less than 2SD at 4 months, 9 months and 18 months</td>
<td>Illness rates among infants</td>
<td>Average survival rate of AIDS children</td>
</tr>
<tr>
<td></td>
<td>% of children born to HIV- mothers with a weight for age less than 2SD at 4 months, 9 months and 18 months</td>
<td></td>
<td>Quality of life of HIV/AIDS patients</td>
</tr>
</tbody>
</table>

2. Definition: (A-B) + C ? D, where A, B, C, and D are defined as described below:
   - A = Number of BMS lots available at the beginning of the period.
   - B = Number of BMS lots distributed to patients during the period.
   - C = Number of BMS lots delivered to the clinic during the period.
   - D = Number of BMS lots left at the end of the period.
   (Objective: No leakage of BMS supplies)
3. Based on indicator developed and tested by the Evaluation Project, USAID, Indicators for Reproductive Health Program Evaluation, Final Report of the Subcommittee on Quality of Care
4.3. Minimum list of indicators to monitor and evaluate effectiveness:

Although it is possible to define several indicators for each cell of the table and draw a huge list of indicators from such tables, the list of indicators should be kept short enough for routine monitoring to be feasible as part of the routine work of local health staff. The M&E team should thus decide, for each tracer intervention, which are the dimensions of effectiveness the most important to monitor and evaluate.

The criteria for choice are similar to those for the choice of tracers. These criteria are only indicative and may not be all fulfilled by a given indicator:

- The importance of the given dimension for the overall effectiveness of the tracer intervention
- The expected difficulties in the implementation of the tracer intervention (the most problematic dimension).
- Dimension involving new activities we have to learn from
- The possibility to identify indicators easy to measure and providing reliable and interpretable information.

During a meeting of pilot projects teams (Abidjan, May 1999), a minimum list of 22 indicators measuring the key conditions for effectiveness has been agreed upon. The grey cells in the table below represent the minimum set of effectiveness dimensions to monitor and evaluate for key components/tracers of MTCT prevention programs; the numbers represent corresponding indicators as listed and defined in Table 7. It is to note that indicators for delivery of ARV were discussed based on a protocol using a one-month antenatal regimen of ZDV plus the labour doses. Programmes using other ARV regimen such as Nevirapine (NVP) may have to adapt indicators 16, 17 and 18.

Table 6: Key conditions for effectiveness of PMTC

<table>
<thead>
<tr>
<th>Availability of resources</th>
<th>Access</th>
<th>Initial use</th>
<th>Continuity</th>
<th>Quality</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary prevention</td>
<td>1,2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Family planning</td>
<td></td>
<td>3</td>
<td>13, 21</td>
<td></td>
</tr>
<tr>
<td>ANC</td>
<td></td>
<td>4</td>
<td>7, 8</td>
<td>5</td>
</tr>
<tr>
<td>VCT</td>
<td>6</td>
<td>11</td>
<td>19</td>
<td>22</td>
</tr>
<tr>
<td>Infant feeding</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ARV</td>
<td>15</td>
<td>16</td>
<td>17, 18</td>
<td>12</td>
</tr>
<tr>
<td>Safe delivery</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Long-term support</td>
<td>21</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The indicators listed in Table 7 are expressed as proportions of the target population; they are classified according to the target population (see also table 12 for sources of data to measure indicators).

For indicators 4 to 22 the denominator “women having delivered over the period considered” should be understood: women having had at least one contact with MCH services during pregnancy, delivery or 2 weeks post-partum whose delivery should have occurred in the period considered for M&E. For example, if the period under analysis is the first 6 months of the year, all women seen for ANC, delivery or early post-partum whose delivery (delivery date respectively expected, assisted or retrospectively recorded) occurred between the 1st January and the 30th June. Such a definition implies that M&E clinical records should be classified by (expected) delivery date.

Note: If almost all women are seen antenatally, antenatal records only will offer a good approximation of the denominator.
<table>
<thead>
<tr>
<th>Indicator</th>
<th>Definition</th>
<th>Tracer</th>
<th>Dimension of effectiveness</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Availability of condoms</td>
<td>% of time condoms are available in the community</td>
<td>Primary prevention</td>
<td>Availability of resources</td>
</tr>
<tr>
<td>2. Availability of STD drugs</td>
<td>% of time STD drugs are available in the pilot site</td>
<td>Primary prevention</td>
<td>Availability of resources</td>
</tr>
<tr>
<td>3. Use of Family Planning</td>
<td>% of women 15-49 using a modern FP method</td>
<td>FP</td>
<td>Initial use</td>
</tr>
<tr>
<td>4. Use of ANC:</td>
<td>% of women “having delivered over the period considered” who had at least one antenatal care visit</td>
<td>ANC</td>
<td>Initial use</td>
</tr>
<tr>
<td>5. Use of Iron/folic acid supplements during pregnancy</td>
<td>% of women “having delivered over the period considered” who received iron/folate supplements</td>
<td>ANC</td>
<td>Quality</td>
</tr>
<tr>
<td>6. Availability of HIV test</td>
<td>% of time in the period considered with no shortages of HIV test kits (at least 2 types of tests).</td>
<td>VCT</td>
<td>Availability of resources</td>
</tr>
<tr>
<td>7. Use of pre-test counselling</td>
<td>% of pregnant women “having delivered over the period considered” who received pre-test counselling</td>
<td>VCT</td>
<td>Initial use</td>
</tr>
<tr>
<td>8. Use of HIV testing</td>
<td>% of women “having delivered over the period considered” who received HIV testing during pregnancy</td>
<td>VCT</td>
<td>Initial use</td>
</tr>
<tr>
<td>9. Partners tested for HIV</td>
<td>% of women “having delivered over the period considered” whose partner was tested during pregnancy</td>
<td>VCT</td>
<td>Quality</td>
</tr>
<tr>
<td>10. Use of HIV post test counselling services</td>
<td>% of women “having delivered over the period considered” who received post-test counselling.</td>
<td>VCT</td>
<td>Continuity</td>
</tr>
<tr>
<td>11. Infant feeding counselling</td>
<td>% of women “having delivered over the period considered” who received infant feeding counselling</td>
<td>Infant feeding</td>
<td>Initial use</td>
</tr>
<tr>
<td>12. Episiotomy rate</td>
<td>% of HIV-infected women “having delivered over the period considered”, who had an episiotomy</td>
<td>Safe delivery</td>
<td>Quality</td>
</tr>
<tr>
<td>13. Family Planning counselling</td>
<td>% of women “having delivered over the period considered” who received family planning counselling</td>
<td>Family planning</td>
<td>Continuity</td>
</tr>
<tr>
<td>14. Prevalence of the HIV infection among pregnant women</td>
<td>% of women “having delivered over the period considered” who tested HIV+.</td>
<td>This indicator does not measure effectiveness but will be used as denominator for indicators 1-4 to 22.</td>
<td></td>
</tr>
<tr>
<td>15. Availability of ARV drugs in the MCH clinic</td>
<td>% of time in the period considered with no shortages of ARV drugs in the MCH clinic.</td>
<td>ARV</td>
<td>Availability of resources</td>
</tr>
<tr>
<td>16. Initial Use of ARV</td>
<td>% of HIV-infected women “having delivered during the period considered” who received any ARV</td>
<td>ARV</td>
<td>Initial use</td>
</tr>
<tr>
<td>17. Continuity of ARV treatment (if regimen includes a pre-partum component)</td>
<td>% of HIV-infected pregnant women “having delivered over the period considered”, who have taken ARV during at least 2 weeks before delivery</td>
<td>ARV</td>
<td>Continuity</td>
</tr>
<tr>
<td>18. Receipt of ARV during labour</td>
<td>% of HIV-infected women “having delivered over the period considered”, who received the full labour ARV dose</td>
<td>ARV</td>
<td>Continuity</td>
</tr>
<tr>
<td>19. Exclusive Breastfeeding at 4 months among HIV+ mothers</td>
<td>% of HIV+ mothers “having delivered over the period considered” who BF exclusively at 4 months</td>
<td>Infant feeding</td>
<td>Continuity</td>
</tr>
<tr>
<td>20. Family Planning utilisation rate among HIV+ mothers</td>
<td>% of HIV+ mothers “having delivered over the period considered”, who are using a modern method of family planning 6 months after the delivery.</td>
<td>Family planning</td>
<td>Continuity</td>
</tr>
<tr>
<td>21. Referral to a support network</td>
<td>% of HIV+ women “having delivered over the period considered”, who were referred to a support network</td>
<td>long-term support</td>
<td>availability of resources</td>
</tr>
<tr>
<td>22. Exclusive Breastfeeding at 4 months among HIV- mothers</td>
<td>% of HIV- mothers “having delivered over the period considered”, who BF exclusively at 4 months</td>
<td>Infant feeding</td>
<td>quality</td>
</tr>
</tbody>
</table>
4.4. Assessing the quality of counselling

Only quantitative indicators have been suggested so far in the preceding sections. However, one important dimension of effectiveness, namely the quality of counselling, is difficult to quantify and its evaluation will require specific activities such as exit interviews with clients and third-party observation of client/provider interactions (both are recommended).

A complete evaluation of counselling would include:

- Evaluation of political commitment to VCT, national laws and policies related to VCT
- Evaluation of counsellors selection, training, support and “burnout”
- Operational evaluation / capacity to deliver the service (logistic considerations and linkages with support services)
- Evaluation of counselling skills
- Evaluation of counselling content
- Evaluation of client satisfaction
- Evaluation of attitudes to VCT in the general population
- Cost-effectiveness

All these evaluation components are fully detailed in the UNAIDS “Guidelines for evaluating HIV voluntary counselling and testing” (1999). The guidelines also provide tools for evaluation. In the context of pilot projects for prevention of MTCT, evaluation of counselling should at least include evaluation of counselling skills, counselling content and client satisfaction (see of tools in annex).

Evaluation of counselling skills and content will be done through observation of client/provider interaction. This should be completed by a counselling supervisor or counsellors who have research training. It is aimed at assessing the standards of the counselling. The standards assessed are based on the performance skills of the counsellors and these are best assessed through the observation of real counselling situations. Not more than 3-5 sessions need to be observed at each counselling site. Where there are many counsellors, a random sample (3-5), should be selected from among them. For each selected counsellor an observation could be made on the first counselling session conducted on the day of monitoring. When only 1-2 counsellors exist, 3-5 counselling sessions could be selected at random. Before the observer sits in, the client is informed about the observation and its purpose. Consent is sought. The observer must ensure that he/she is as unobtrusive as possible and does not disrupt the counselling session. Assurance of confidentiality must also be given. Immediate feedback to the counsellor by the trained supervisor is advised with an opportunity for the counsellor to express his/her opinions and concerns. Occasionally counsellors feel unhappy about a supervisor observing their session. Where irreconcilable concerns about observations by supervisors occurs alternative methods include using peer counsellors as observers, role play or audio taped consultations.

Finally, client exit interviews are to be conducted through semi-structured interviews, which should be carried out individually by a trained and experienced researcher. The interviewer should be trained to be non-judgmental and allow the interviewee to express his/her anxieties. As it will require some time to perform a small sample of people should be interviewed. To avoid a selection bias, a sampling method can be used: All people receiving (pre- or post test) counselling within a specific period (e.g. 1 week) will be asked by their counsellor to attend a confidential and anonymous exit interview. If the number of people attending the service over this period is too great, random sampling can be adopted to space people through each day and through the week. The client interviews will be voluntary and they should be assured that they are anonymous and confidential.
5. Monitoring and Evaluating Costs and Financing

Health services will require additional inputs to meet the key implementing conditions to prevent effectively the transmission of HIV from Mother to Child. In developing countries, concerns about resources to conduct the project and make it sustainable are paramount. Key resources include trained personnel, support personnel, infrastructure, facilities, materials and supplies.

External donor funding may cover the bulk of the costs of an intervention, but critical resources for ensuring the key implementation conditions are in place may be lacking. For example, the VCT component of the intervention may be jeopardised if health staff feel insecure about their own safety because inadequate funding is secured for gloves and chlorine, even when HIV test and needles are fully funded by donors (Côte d’Ivoire example of Abidjan routine MCH clinic). As another example, the whole programme may be unsuccessful if the quality of basic ANC is not ensured.

The analysis of effectiveness indicators as described in the next section should be able to identify most of the capacity problems. For example, looking for reasons for insufficient quality of counselling may evidence a lack of training of counsellors or a lack of trained counsellors leading untrained personnel to do counselling work (see table 9 in next section for other examples). Such an identification of capacity problems should allow structured identification of unmet needs.

To analyse more systematically the capacity of the program in terms of resources, evaluators can look at the following set of questions regarding the adequacy of resources to run each tracer intervention:

. adequacy of equivalent of full time personnel when related to the amount of work
. adequacy of personnel skills to perform the work
. adequacy of the facilities (space, potential to ensure confidentiality, equipment)
. adequacy of supply stocks

Often, capacity problems will be related to inadequate budget planning or insufficient funding which make the cost analysis area a crucial part of monitoring and evaluation⁴.

---

5.1. Costs, Cost Effectiveness and Financial sustainability

The cost analysis area fulfills three major roles:

For local problem solving and decision making, managers must be able to assess the cost implications of implementing this new intervention. Local MCH service managers need to be able to follow-up the additional (or incremental costs) incurred on top of what is already spent by the existing services to implement the new activities\(^5\). Local operational costs are usually collected routinely for administrative management and budgeting. Simple efficiency measures can also be conducted relating the additional cost of the intervention to the number of women treated.

Cost effectiveness studies allow for estimating the overall cost of an intervention and relate it to health outcomes. These are crucial elements for deciding where to allocate scarce resources. Cost effectiveness analysis is often complex and cumbersome. Allocation of joint cost for calculating unit cost requires specific research techniques. (DIH, 1976). Overall cost effectiveness analyses are usually better conducted through one time study\(^6\). At minimum, the core evaluation of a PMTCT program should relate the additional costs of the intervention incurred by the service providers to the outcomes in terms of children deaths averted.

Specific cost/cost-effectiveness studies can also be conducted, in the context of extended evaluation (see chapter “Extended evaluation”, section 9.3.). In depth cost-effectiveness and cost benefit analysis can be conducted with help of these specific studies, including opportunity costs, indirect costs to households and savings such as those made by reducing the cost of treatment of children.

Monitoring and evaluating the adequacy of funding as compared to costs is critical in low-income countries. Managers therefore have to know whether all critical additional costs linked to the intervention are funded, on which sources the intervention rely, and whether and on which conditions the intervention is financially viable (i.e. additional funding exceeds additional costs). This information is usually available in the peripheral management information system necessary for administrative management and budgeting\(^7\).

In addition, decision-makers need to have insights on the affordability of the intervention as compared to other health interventions. The analysis of affordability requires relating the costs of the intervention to other expenditures incurred by governments, donors and households. The cost of the intervention per capita can be related to other expenditures per capita\(^8,9\).

5.2. Cost and Financing indicators

5.2.1. Cost indicators

It is important that a mechanism is developed for tracking additional costs for MCH services linked to PMTCT. Table 8 lists costs to be monitored and regularly evaluated through the existing administrative management system. Four major indicators shall be monitored and regularly evaluated:

---


• **Annual additional costs to the health services for PMTCT**

Definition: Additional costs to the health services linked to the implementation of the intervention over the period considered.

Data requirements: Aggregated additional costs collected by each MCH clinic, support costs and period in which these costs were incurred.

• **Cost of PMTCT per capita**

Definition: Additional costs to the health services linked to the implementation of the intervention, per capita (per year)

Data requirements: Aggregated additional costs collected by each MCH clinic, support costs in relation to the period considered and to the population of the area covered.

• **Marginal Cost to the health services**

Definition: Additional costs to the health services linked to the implementation of the intervention per mother–child couple treated.

Data requirements: Aggregated additional costs collected by each MCH clinic and number of HIV + women who received at least one dose of ARV

• **Marginal Cost-effectiveness of health services.**

Definition: Ratio of additional costs to the health services linked to the implementation of the intervention over two years, to the number of HIV infections avoided in the same period

Data requirements: Aggregated additional costs collected by each MCH clinic and number of HIV infections avoided (according to impact evaluation data)

### Table 8. Cost Indicators for Monitoring the Costs

<table>
<thead>
<tr>
<th>Stages of Production of Effective Coverage</th>
<th>Total Amount</th>
<th>Source of funding</th>
<th>Categories of Additional Costs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cost of Making Resources Available</td>
<td></td>
<td></td>
<td>Cost of facilities upgrading</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Cost of initial training</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Cost of additional personnel hired</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Cost of establishing a drug stock</td>
</tr>
<tr>
<td>Cost of ensuring Physical Access</td>
<td></td>
<td></td>
<td>Cost of transport for outreach</td>
</tr>
<tr>
<td>Cost of Initial Utilisation</td>
<td></td>
<td></td>
<td>Cost of condoms, STD drugs, contraceptives, ZDV, BMS</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Cost of HIV test and other lab tests</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Overtime of personnel</td>
</tr>
<tr>
<td>Cost of Continuity</td>
<td></td>
<td></td>
<td>Cost of active tracking of defaulting women/partners</td>
</tr>
<tr>
<td>Cost of Quality</td>
<td></td>
<td></td>
<td>Cost of technical training for standards</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Cost of regular refreshing courses for counselling and support</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Cost of nutritional education</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Cost of information leaflets</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Cost information to communities and women in villages</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Cost of development of support groups</td>
</tr>
<tr>
<td>Total Additional Cost</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total Additional Cost Per Woman Treated</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total Additional Cost Per Capita</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
5.2.2. Financing indicators

M&E of the financial sustainability of these services will allow examining the sources of funding of the necessary inputs to fulfil the implementation conditions rapidly. Funding proceeds from central, regional or local levels. Funding can also be mobilised at community level and by PWA groups. Two major indicators can be measured, namely:

Financial sustainability of PMTCT
Definition: ratio of sustainable funding to additional costs (or difference between funding and additional costs)
Data requirements: ratio of the additional cost estimate for PMTCT to the costs to be covered by sustainable funding (e.g. from government and household cost sharing).

Cost Sharing of PMTCT
Definition: part of each funding source in the financing (figure 3).
Data requirements: additional cost to health services, donors and household.

Figure 3. Contributors to additional costs of PMTCT
6. **Analysing effectiveness and cost indicators**

During the implementation process, data are collected on an-going way, as women and children are cared for and followed-up. In routine MCH/Primary Health Care settings, the information collected through that process are often little used for decision-making. Yet the informed decision making process is particularly critical for the implementation of Prevention of Mother To Child transmission of HIV as it should permit:

- **Individual follow-up** according to the specific needs of each woman, ensuring proper treatment, monitoring safety and compliance as well as adjusting care and support on an-going way e.g. ongoing analysis of the individual information will allow identifying whether an HIV+ pregnant woman displays adverse effects linked to the AZT treatment, or whether a woman did not come back for a set appointment, so that she can be visited at home.

- **Early warning**, ensuring timely identification of major/most serious problems in implementation, e.g. identifying whether ANC attendance dramatically dropped following initiation of VCT; identifying immediately major stigma problems in a community.

- **Systematic analysis of** the outputs and outcomes of the local implementation, identifying the major gaps in effectiveness, efficiency and financial sustainability, e.g. assessing regularly which proportion of women are tested, initiate the AZT treatment, receive nutritional counselling, comply to AZT etc... in order to identify the major obstacles to final effectiveness of PMTCT and act upon those. For later expansion of the program it will also be important to identify successes and to analyse the reasons for successes.

The information collected can be analysed at different levels. This may include:

- **Analysis at Community level**: the demand factors (reasons for non use of ANC for example) as well as community awareness/ stigma at this level, are to be analysed with the community stake-holders using participative and qualitative assessment.

- **Analysis at MCH/Health Centre level**: analysis of local progress, coverage, analysis of management issues, identification of obstacles and design of local solutions.

- **Analysis at district level**: analysis of cross-cutting issues, analysis of system support requirements (supervision, supply), comparison of outputs and outcomes of different facilities, identification of best practices.

- **Analysis at national level**: status of progress in implementation identification of policy and reform issues, comparison of alternative strategies and policy decision-making.
Measuring the indicators and plotting them in the graph permits visualising the degree of fulfilment of the key conditions for effectiveness, and identifying at which level the operational problems hampering the actual implementation occur. This allows managers to:

- assess the achievements and obstacles in terms of effectiveness (intermediate and final outputs) cost and financial viability;
- follow the evolution of implementation progress and problems overtime, thus ensuring that service effectiveness is continuously monitored and improved;
- identify specific causes of obstacles and problems affecting the intervention process, thus providing strong hints on the potential causes affecting implementation and helping recognise the level at which problems arise; and
- analyse the impact of specific operational strategies and management actions, comparing indicators overtime so as to pinpoint the impact of specific strategies on the evolution of specific coverage stages these strategies aim to improve.

The analysis can include specific questions to be posed, when analysing the value of an indicator i.e.:
- does reaching a certain value of an indicator trigger a specific analysis of other indicators?
- which value of a given indicator calls for action?

**Figure 4: Plotting M&E indicators**
6.1. Monitoring: Using Indicators for Local Problem Solving and Decision-Making

6.1.1. Monitoring effectiveness of a given tracer intervention

The fulfilment of each dimension of effectiveness can be viewed as a prerequisite for the next dimension to be fulfilled. For example, continuity of use cannot be achieved if initial use is not achieved and the level of the indicator of continuity will be equal or lower than the value of the indicator for use. Availability, accessibility, use and continuity should ideally be 100% for the women targeted by the intervention. It is never the case in practice. Plotting the values of the indicators allows to identify the condition(s) that are poorly achieved and which limits the possibility to fulfil the next condition. In the example plotted below, the bottle neck is obviously between access and use, indicating that despite good availability and good accessibility of the intervention, the women do not use it. In such a case, local manager may wish to look at additional indicators or interview the women to try to understand why women do not use the intervention.

Figure 5. Plotting the different dimensions of effectiveness for a given intervention

In the example situation shown in Figure 6, the different indicators assessing VCT effectiveness are compared overtime.

Figure 6. Comparing effectiveness of VCT over time
At t1, the availability of the HIV test is high (90%). Geographical access of the pregnant women to the clinic offering voluntary testing and counselling is also considered high (80%). However, the use of VCT services (e.g. pre-test counselling) remains quite low (25%) therefore hampers the continuity coverage (e.g. acceptance of the test) and the outcome (e.g. number of women knowing their serological status). Managers should explore the reasons for this low use (e.g., low use of ANC, low acceptability of testing). Managers will then have to design appropriate strategies to solve the problem encountered and reduce the bottleneck in implementation.

At t2 that availability has been restored to 100%; use has been stimulated through appropriate strategies and continuity coverage is also up. Still, continuity coverage remains low compared to use. Specific strategies will therefore have to be designed to address the issues of compliance and continuity of this intervention (i.e. benefiting from adequate post-test counselling). The impact of these new strategies must be monitored three months later.

6.1.2. Using monitoring for problem solving

As shown in the example above, identification of bottle necks call for corrective action\(^\text{10}\). When the value of an indicator is low, causes for this poor result should be searched and strategies to overcome the obstacles defined and implemented.

When causes for problem will be searched, it will be useful to look not only at logistical problems (e.g. inadequate procedures) but also to capacity problems such as insufficient funding, insufficient availability of trained personnel or lack of material.

Table 9 gives practical examples of common effectiveness problems identified by local managers. It also provides examples of corrective operational strategies developed to address these problems and ensure genuine implementation of the prevention of MTCT.

<table>
<thead>
<tr>
<th>Problems</th>
<th>Causes</th>
<th>Strategies</th>
<th>Unresolved Issues For implementation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Availability of resources</td>
<td>Shortages of essential resources</td>
<td>Parallel procurement mechanism for ZDV High cost of procurement Insufficient lab capacity Insufficient training of lab technician</td>
<td>Procurement of ZDV through regular drug supply channel ZDV part of local essential drugs list</td>
</tr>
<tr>
<td>Physical Access</td>
<td>Low access, women leave too far from the facility where the services are offered</td>
<td>High distance, high cost of transport Change of ANC focus from health centre to district hospital</td>
<td>Offering screening and treatment in all districts hospitals of the province</td>
</tr>
<tr>
<td>Initial Use</td>
<td>Women do not come to antenatal care visits HIV+ women do not come although others attend HIV pregnant women come but refuse the HIV test</td>
<td>Acceptability of services is low Fear of discriminatory attitudes Fear of insufficient confidentiality Insufficient quality of pre-test</td>
<td>Referral of pregnant women by the health centres to the district hospital for the first visit Reduction of discrimination by ensuring confidentiality, empathy and caring attitude of personnel</td>
</tr>
<tr>
<td>Continuity</td>
<td>HIV+ women do not come back for post-test HIV+ pregnant women do not complete ARV treatment</td>
<td>Insufficient quality of pre-test counselling Poor understanding of the benefits of the treatment</td>
<td>Training of personnel for counselling Repeated ANC visits for HIV+ pregnant women Peer support</td>
</tr>
</tbody>
</table>

Table 9. Monitoring as a problem-solving tool to implement the Prevention of Mother to Child Transmission activities

6.1.3. Learning from successes

Monitoring can be used not only to identify and solve problems, but also to identify and learn from successes. Since the main goal of the pilot project is to learn from small scale implementation for better planning of large scale implementation, it is important to document and analyze reasons for successes that should be replicated when expanding the program or implementing a similar one elsewhere. For example, it will be helpful to understand what strategy allowed for a very good rate of test acceptance? How did the program succeed in keeping low the morbidity associated with replacement feeding? Why is the medical staff so dedicated to the MTCT program?…

As for problem solving, plotting the indicators into a graph will allow to identify the successes. Then, discussions between all stakeholders (in the community, in the clinic and local decision-makers) should allow the identification of program components catalytic for success. For example, the organization of home visits may be felt essential in educating women to adequately feed their babies; or a mass communication campaign may have been followed by a sudden increase in test acceptance; or the organization of weekly meetings between clinic staff and representatives of the communities may have help to significantly decrease discrimination towards HIV+ people etc…

6.2. Evaluation: Assessing the successes and problems for decision making

Whereas monitoring is essentially for local managers, the objective of evaluation is to assist decision makers when deciding whether the pilot programme should be sustained and expanded. The main question to be answered by the evaluation is: Does the programme reach its objectives?

The recommended core evaluation assesses accomplishment of both interim and long-term goals of the pilot projects.

Evaluation of achievements of long-term goals (reduce rates of transmission, reduce overall mortality and morbidity…) will be detailed in the section 7. on “Impact Evaluation”. Evaluation of process is more related to interim goals. Goals should be defined at the beginning of the program. Interim goals could include, for example:

1) To make available good quality pre, per and post-natal care, family planning services and HIV counselling and testing services to 10,000 pregnant women in each pilot project site.
2) To provide antiretroviral therapy (ARV), delivery care, and a 6-month supply of breast milk substitutes (if the mother wishes to avoid breastfeeding) to HIV-infected pregnant women.
3) To provide follow-up care to HIV-infected mothers and their children.

6.2.1. Aggregating monitoring data

Whereas monitoring of progress is to occur on an ongoing basis (e.g., monthly to every three months) in each clinic/hospital, evaluation of progress for the entire pilot project through analysis of data from all clinics/hospitals is recommended at least every 6 months. This part of the evaluation involves aggregating service-based data from all clinics/hospitals participating in the pilot project. As for routine monitoring, the value of the indicators can be graphed for each period. This allows managers and evaluators to rapidly identify the dynamic of the implementation of their intervention.

For effective evaluation, it is essential that clear achievable objectives are set for each pilot project. Objectives can be chosen on the basis of expected increase from baseline coverage with MCH services, baseline acceptability of HIV testing, baseline infant feeding practices … Such baseline
comparison data will have to be collected at the start of the pilot project (preferably for the particular population included in the pilot project, but if not available, other data may be used, with acknowledgement of its limitations for comparison). These data may be collected from sources outside the pilot projects.

The analysis will consist of comparisons of the value of each indicator to the set objective or to baseline data. Since the results of the evaluation will be used to decide if the MTCT prevention program is to be sustained and expanded, set objectives should be carefully chosen and achievable.

Crosscutting problems common to all clinics are identified. The distribution and variations of indicators’ values between clinics will help to identify key obstacles but also successes and good practices.
Below are some sample objectives for basic indicators for pilot projects.

1: **Availability of condoms**: condoms available 100% of the time in pilot sites and related MCH services
2: **Availability of STD drugs**: STD drugs available 100% of the time in pilot sites
3: **Use of Family Planning**: percent of women 15-49 using a modern FP method increased by 30% compared to baseline rates
4: **Use of ANC**: Provide ANC to more than 75% of childbearing women
5: **Use of Iron/folic acid supplements during pregnancy**: Provide iron/folates to more than 80% of pregnant women attending ANC
6: **Availability of HIV test**: test kits (at least 2 types of tests) available 100% of the time
7: **Use of HIV pre-test counselling**: At least 80% of women attending ANC counselled on HIV and proposed HIV testing
8: **Use of HIV testing**: At least 50% of women counselled being tested
9: **Partners tested for HIV**: At least 50% of partners of tested women being themselves tested
10: **Use of HIV post test counselling services**: 100% of tested women and partners receiving post-test counselling.
11: **Infant feeding counselling**: provide infant feeding counselling to at least 75% of pregnant women
12: **Episiotomy rate**: frequency of episiotomy reduced by 30% compared to baseline frequency
13: **Family Planning counselling**: provide family planning counselling to at least 75% of women
14: **Prevalence of the HIV infection among pregnant women**: This indicator does not measure effectiveness of the program, but is a rough estimate of the denominator for indicators 15 to 21. Setting an objective for this indicator will mean evaluating the impact of the primary HIV prevention of the program.
15: **Availability of ARV drugs in the MCH clinic**: ARV available 100% of the time in the pilot sites
16: **Initial Use of ARV**: At least 75% of HIV-infected women receive any ARV in pregnancy
17: **Continuity of ARV treatment (if ARV regimen includes a pre-partum component)**: At least 85% of HIV+ women who start ARV antenatally have taken ARV during at least 2 weeks before delivery
18: **Receipt of ARV during labour**: At least 75% of HIV+ women receive the intra-partum dose of ARV
19: **Exclusive Breastfeeding at 4 months among HIV+ mothers**: percent of HIV+ mothers “having delivered over the period considered” who BF exclusively at 3 months increased by 100%.
20: **Family Planning utilisation rate among HIV+ mothers**: percent of HIV+ women using a modern FP method increased by 30% compared to baseline rates
21: **Referral to a support network**: at least 90% of HIV+ women referred to a support network
22: **Exclusive Breastfeeding at 4 months among HIV- mothers**: the rate of exclusive BF should not be lower than baseline level

To assess the technical efficiency of the pilot projects, it will also be useful to regularly aggregate data to track the supply and use of drugs and diagnostic tests in pilot project clinics/hospitals. The main issues to be evaluated is the absence of leakage of supplies. For example, it will be useful to look at the differences between stock flows and lots of breastfeeding substitutes distributed to HIV+ women. Other examples of technical efficiency indicators are given in Tables 3, 4, 5 (section 4.2.).

---

11 Note: Numbers of HIV seropositive women who did not receive the pilot project interventions because they were not tested for HIV may be estimated from existing sentinel serosurveillance or through anonymous unlinked surveys conducted specifically for the pilot project (see Population Surveys section under Impact Evaluation).
12 Note: Provision of HIV-related follow-up care to women participating in the pilot projects will in many cases require establishment of linkages with other health facilities or NGOs that are not pilot project sites. To evaluate not only whether referrals for follow-up care are made (as the indicator described above is designed to do), but also whether the referrals are successful, these linkages must ensure access to data in these other facilities where follow-up care is provided. It is also necessary to coordinate management information systems so that medical records kept in the pilot project clinics/hospitals can be linked with the same individuals’ medical records in follow-up care clinics.
13 Definition: (A-B) + C ? D, where A, B, C, and D are defined as described below:
   A = Number of BMS lots available at the beginning of the period.
   B = Number of BMS lots distributed to patients during the period.
   C = Number of BMS lots delivered to the clinic during the period.
   D = Number of BMS lots left at the end of the period.
   (Objective: No leakage of BMS supplies)
7. Evaluation of impact

This chapter provides guidance for standardised impact evaluation of the pilot projects. The topics to be addressed in the core evaluation are considered essential components to evaluation in all settings, and therefore represent the minimum set, rather than a comprehensive list of topics to be addressed by each pilot project site. Additional topics for evaluation can be found in section 9. “extended evaluation”.

Impact deals with positive and negative consequences of a programme. Evaluation of impact is the ultimate measure of success of the pilot projects. The ultimate expected benefit of PMTCT is to reduce child mortality in the pilot project area. The impact of PMTC on mortality will result from the balance between positive consequences: reduction of HIV infections and negative consequences such as a potential mortality increase related to inadequate replacement feeding. Another important area for impact evaluation is to assess the risks and benefits of the promotion of prenatal HIV testing.

Evaluation of impact will involve collection of outcome data to assess the effect of pilot project activities on both participants and on non-participants living in the pilot project area. The main outcomes of interest are:

- HIV infection status of children;
- child mortality;
- social consequences of HIV testing (positive and negative);
- social consequences of replacement feeding (risk of stigma, spillover);

7.1. Impact evaluation design

For evaluation of impact, individual-level data are needed for at least a subset of participants and non-participants, to be able to relate receipt of specific services to the occurrence (or non-occurrence) of HIV transmission and mortality outcomes. In other words, for impact evaluation, it is necessary to know which individuals received which services and what the outcomes were for these individuals, to be able to compare outcomes for groups of individuals who did and did not receive specific services.

For impact evaluation, the proposed intervention follow-up is to be used to collect data on both service receipt and outcomes for the same group of individuals to assess the effectiveness and safety of the interventions promoted by the pilot projects.

The client/provider interaction assessments and intervention follow-up will require data collection on special forms and the intervention follow-up will require a data management system that allows stratified analysis and examination of associations between receipt of interventions and outcomes.

The design of the core evaluation of impact involves both:
1) assessing outcomes among the entire pilot project population and
2) validating these findings and further focusing evaluation within a smaller sample of the pilot project population.

This dual approach of estimating the frequency of outcomes for the entire pilot project population, and more rigorously for a sample of the population, is proposed to maximise the quality of outcome frequency estimation.
7.1.1. Selecting a stratified sample

The validation of findings and focused evaluation through active follow-up of a sample of the pilot population will involve additional follow-up visits of mother-child pairs selected to be part of the sample. It also involves home visits by study staff for individuals who do not return for follow-up, and some additional data collection for all mother-child pairs in the sample.

The stratified sample is to include mother-child pairs in which the mother is HIV seropositive, in which the mother is seronegative, and in which the mother has not been tested for HIV. This systematic sample of mother-child pairs will be asked, as all participants will be, to return to the clinic on a regular schedule, which follows the immunisation schedule. However they will also be asked to return at additional timepoints: 24 months, with at least one follow-up visit after weaning. A suggested schedule (to be adapted according to immunisation schedule) for follow-up of the mother-child pairs included in the systematic sample is 1 month, 3 months, 6 months, 12 months, 18 months, 24 months, and a visit after weaning if weaning occurs after 24 months. Sample size calculations may be done separately for HIV seropositive, HIV seronegative and untested women.

The following is provided as a rough guide for choosing sample size, in recognition that decisions about sample size will be strongly influenced by availability of resources for active follow-up.

<table>
<thead>
<tr>
<th>Calculating sample size</th>
</tr>
</thead>
<tbody>
<tr>
<td>The size of a random sample ($N$) required to produce results of given accuracy and precision can be determined from the formula</td>
</tr>
<tr>
<td>$N = (z^2pq)/d^2$</td>
</tr>
<tr>
<td>To solve the formula for $N$, the number of persons required for the sample, values of the other variables must be provided.</td>
</tr>
<tr>
<td>The value of $d$ corresponds to the precision of the result desired. For example, if the width of the desired confidence interval is +/- 0.05 around the sample mean proportion, $d = 0.05$.</td>
</tr>
<tr>
<td>The value of $z$ corresponds to the confidence limits of the survey result. If confidence limits of 95% are determined to be adequate, this means that the range of +/- 5% from the sample result should indicate the true result in 95 of every 100 surveys performed. Standard statistical tables can be consulted to find values for $z$, the standard normal deviate, corresponding to the confidence limits desired. The value of $z$ for confidence limits of 95% is 1.96.</td>
</tr>
<tr>
<td>The values of $p$ and $q$ correspond to the proportion of persons in the population who have or do not have the characteristic being measured, e.g. $p$ might be the proportion of children infected with HIV and $q$ would then be the proportion not infected with HIV. The addition of $p$ and $q$ must equal 1. To calculate sample size, the study planner must make a best guess about the likely value of $p$ and subtract from 1 to calculate $q$.</td>
</tr>
<tr>
<td>The EpiInfo StatCalc feature provides facilities for estimation of sample size using the formula above.</td>
</tr>
</tbody>
</table>
Calculating confidence intervals

When reporting the observed value of an indicator (p_0) based on the data collected during the follow-up of n_0 women, it is important to specify the level of precision of the estimation p_0. This is done by calculating the 95% confidence interval (CI) of p_0 as follows:

$$95\% \text{ CI: } [p_0 - 1.96 \sqrt{(p_0q_0/n_0)} \; ; \; p_0 + 1.96 \sqrt{(p_0q_0/n_0)}] \quad (\text{where } q_0 = 1 - p_0)$$

Calculating the confidence interval will also allow to specify if the estimation obtained is compatible with, significantly lower or significantly greater than the target set (e.g. 15% for the transmission rate), simply by looking if the target is within the limits of the confidence interval, below the lower limit or above the upper limit.

Practical examples of sample size calculation

HIV-infected women

Suppose, for example, a study planner would like to estimate the mother-to-child transmission rate achieved by the pilot project by monitoring infection status at 1 and 3 months and after weaning for a subset of infants. The planner expects the rate of transmission to be reduced to approximately 15%, and therefore specifies that p = 0.15. In the formula below, this value of p is used to calculate how many infants must be included in the follow-up sample to estimate the true transmission rate with a precision level of +/- 5% Solving the formula:

$$N = \frac{(z^2pq)}{d^2} = \frac{(1.96)^2(0.15)(0.85)}{0.05^2} = \frac{3.84(0.1275)}{0.0025} = 196$$

That is, 196 infants born from HIV+ mothers would have to be included in the sample to estimate a mother-to-child transmission rate of 15% with precision of +/- 5%.

HIV negative and untested women

One of the objective of the pilot projects is to offer replacement feeding to HIV+ women which doesn’t lead to spillover of replacement feeding among HIV-negative and untested women. Therefore, planners may set as objective to obtain a rate of exclusive BF at 4 months among HIV-negative and untested women of 50%. In the formula, p will thus be set at 0.5 and q at 0.5:

$$N = \frac{(z^2pq)}{d^2} = \frac{(1.96)^2(0.50)(0.50)}{0.05^2} = \frac{3.84(0.25)}{0.0025} = 348$$

That is, 348 infants born from HIV(-) and untested mothers would have to be included in the sample to estimate an exclusive BF rate of 50% with precision of +/- 5%. If spill-over is to be assessed separately in HIV- and untested women, the sub-sample should include at least 348 HIV- mothers and 348 untested mothers.

Note: the respective proportions of HIV- and untested women observed in the whole pilot project population should be taken into account for sub-sample estimation either in keeping in the sub-sample the whole pilot project proportions of HIV- and untested women, or by “weighting” the estimations observed separately among HIV- and untested women.

For example, if 60% of women accept to be tested among whom 20% are HIV+, it means that for 100 women in the pilot project, 40 will not be tested, 12 will be tested HIV+ and 48 will be tested HIV-.
The simplest option is to respect this proportion in selecting the sub-sample i.e. 40% untested, 12% HIV+ and 48% HIV-: if the sample size calculation shows that you need to follow at least 196 HIV+ women/children (as in the example above), 196 should represent 12% of the sample; therefore the full sample size will be 196/0.12 = 1633 among whom you will expect 1633 x 0.48 = 784 HIV(-) and 1633 x 0.40 = 653 untested women (far enough to estimate spillover).

Another option is enrol the minimum number of women required in each group (e.g. 196 HIV+, 348 HIV(-) and 348 untested as per examples above) and weight the estimations obtained separately among HIV+(p1), HIV- (p2) and untested women (p3) to obtain an estimation for the whole population (p) whatever the HIV status: 

\[ p = (0.40 \times p3) + (0.12 \times p1) + (0.48 \times p2) \]

In such a case, the confidence interval for p will be:

\[ p \pm 1.96 \sqrt{\frac{0.40^2 \times (p3q3)/n3 + 0.12^2 \times (p1q1)/n1 + 0.48^2 \times (p2q2)/n2}} \]

Estimating overall infant mortality whatever the serological status of the mother

If the infant mortality was around 70 per 1,000 births before the HIV/AIDS spread in the population and raised up to 100 in the pilot area because of AIDS, planners may expect to return to a rate of 80 with the PMTCT program. In such case, p will be set at 0.08 and q at 0.92. and N will be:

\[ N = \frac{(z^2pq)/d^2}{(1.96)^2(0.08)(0.92)/0.05^2} = \frac{(3.84)(0.0736)/0.0025} = 113 \]

Again, the respective proportions of HIV- and untested women observed in the whole pilot project population should be respected in the sub-sample.

Conclusion

The conclusion from these calculations is that the sub-sample should consist of at least 200 HIV+ and 350 HIV(-) and untested mothers and their children.

Randomised selection

After sample size has been determined, select a systematic random sample according to the following method:

Use antenatal care registers from the first 3 months of pilot project operation to determine antenatal clinic attendance. Project total attendance for a 2 year period. Calculate the sampling interval by dividing the total number in the sampling frame by the desired sample size. Calculate how many women must be chosen per month to reach desired sample size. Each month, choose a sample from the antenatal care register. Number each woman sequentially. Select a random number (from a random number list or use the EpiInfo EpiTable feature). Construct the sample of women by choosing every nth woman (based on sampling interval), starting with the woman who is [random # selected in preceding step]. If necessary, replace women who cannot participate in follow-up by selecting the next women on the monthly antenatal care register, starting over at the top of the list if necessary.

7.1.2. Comparison groups

To evaluate impact, it is not enough to examine outcomes among individuals who participated in the pilot projects, and received the interventions offered. It is also necessary to compare this frequency with frequency of outcomes in a group of individuals who have not received the interventions. Because the point of the pilot projects is to offer interventions to all women in the participating clinics/hospitals, there may not be a readily accessible and sufficiently large
comparison group of individuals who have not received the interventions.

Baseline population surveys on the general population living in regions where the projects will be operating have been suggested as a source of comparative information, specifically on child mortality, antenatal care use and spillover of replacement feeding into the population of HIV-uninfected women. Census information or other population lists may be used as a sampling frame. Sample size may be calculated as described above.

It is recognised that pilot projects sometimes may not possess sufficient personnel or logistic resources to undertake certain types of survey activities on their own. Data collection for population surveys may be undertaken by the national statistics office or similar specialised agency in collaboration with the agencies (such as the pilot projects) for which the survey results have programmatic implications. If population surveys are beyond the pilot project’s capacity, collaboration of pilot project managers with survey agencies in specifying survey content or measurement objectives, design of the questionnaire and tabulation plan, analyses of the data and report preparation is encouraged, as is “contracting out” relevant responsibilities for population surveys to researchers or institutions external to the program, with close consultation by pilot project managers on design, measurement and analysis.

Comparison groups are suggested for all indicators proposed in the sections below.

7.2. Impact of pilot projects on HIV transmission from mothers to infants

Questions: How much transmission is prevented by use of ARV in the pilot project population? How much transmission is prevented by the use of breast milk substitutes? How much overall transmission is prevented through the interventions offered by the pilot projects?

Because the intervention to prevent mother-to-infant transmission of HIV has two components, use of ARV to prevent perinatal transmission and reduce the risk of post-partum transmission through infant feeding counselling, the ideal evaluation would estimate not only the overall transmission rate, but both the perinatal and postnatal transmission rates. Because not all pilot project sites may have the capability to estimate both, options are given.

Outcome Evaluation Indicator. Infant Infection Status

Definitions: (see text box on determining infection status)
- HIV diagnosis by the standard Ghent definition based on clinical AIDS or a positive serology at 15 months or 3 months after weaning (definition 1)
- HIV diagnosis by early viral nucleic acid testing, i.e. PCR at 1 or 2 months of age (definition 2)

Data Requirements: HIV diagnostic testing of HIV-exposed infants.
Data Sources: Child Health Record, intervention follow-up
Data Collection Timepoints (to be adapted according to immunisation schedule):
- 15 months of age or older, after weaning (definition 1)
- 1 and 3 months, and 3 months after weaning and blood spot at birth (definition 2)
Data Analysis Timepoints: 12 months and 24 months after the start of the intervention

Note: Diagnostic testing of the infant is only to be done if the mother is HIV-positive, and with consent to conduct the procedure.
Laboratory diagnosis of HIV infection in children

The laboratory diagnosis of HIV infection in children can be made by four different techniques: antibody testing, viral antigen testing, viral nucleic acid testing, and viral culture. HIV antibody measurement is the most commonly used technique worldwide but is of limited value in the first year of life due to passive transfer of maternal antibodies. For half of the uninfected HIV-exposed infants the maternal antibodies will have disappeared by nine months of age. A positive antibody test after 15 months can be considered evidence of HIV infection in the child. Initial studies of the P24 antigen test as a diagnostic tool of HIV infection in infants have been disappointing due to low sensitivity, even after immune complex dissociation. Viral nucleic acid detection techniques (e.g., polymerase chain reaction = PCR) are now widely used for the early diagnosis of HIV infection in young infants in developed countries but they remain expensive and generally unavailable in many areas of the world. A positive virologic test (i.e., detection of HIV by culture or DNA or RNA PCR) indicates possible HIV infection and should be confirmed by a repeat virologic test on a second specimen [1]. However, the sensitivity of DNA PCR for a single positive result on a specimen drawn at or after 1 month of age has been reported to be 97% [3].

A standard methodological approach to estimate the risk of mother-to-child transmission has been developed by the Ghent International Working Group on MTCT of HIV [2]. Agreement was reached on definitions of HIV-related signs/symptoms, paediatric AIDS and HIV-related deaths. In the absence of early viral diagnostic assays, children born to HIV-infected mothers are classified as HIV-infected if they fulfil the WHO clinical case definition for paediatric AIDS and/or if they are seropositive at 15 months of age. Infants who died before infection status could be determined by serology are considered HIV-infected if severe infection or persistent diarrhoea was the probable cause of death and at least one HIV-related sign or symptom was present at the last examination. When children are breast-fed, seroconversion does not guarantee that the child will remain HIV-uninfected. A serological test should always be performed on a blood sample collected several months after breast-feeding has ceased.

In settings where infant HIV status can be evaluated by PCR, a blood sample should ideally be stored for early diagnostic testing before the infant is aged 48 hours, at age 1-2 months, and at age 3-6 months. Blood collection on filter paper may be the most practical approach in developing countries [3]. Targeted testing of these early specimens at a later time will allow for resolving HIV status among indeterminate infants who died early or were lost to follow-up. In addition, testing at each of these time points can determine probable timing of HIV transmission (intrauterine, peripartum, postnatal) among HIV-infected infants.

References

Estimating MTCT for the Entire Pilot Project Population

All HIV-exposed children identified by the pilot projects are to have clinical follow-up to determine infection status, and exposure to ARV during gestation, labour and delivery and the neonatal period (if applicable) will be recorded. Depending on resources and laboratory capability, definition 1 or 2 may be chosen for estimation of the mother-to-child HIV transmission rate. It is likely that follow-up may be incomplete (and infection status unknown) for a proportion of the children.

Estimating Mother-to-Child HIV Transmission for the Stratified Sample

Because home visits will be made for the children in the sample who do not return for a follow-up visit, data collection is likely to be more complete for this group. It may be more feasible to collect infant blood more frequently and to use PCR testing for children in the sample, than for the entire pilot project population, depending on resources and laboratory capacity. Ideally, HIV testing by PCR would be done at 1 month of age, 3 months of age, and after weaning. It is also recommended
that a blood spot be collected on filter paper at birth and at the 6 and 12 month visits for each child in the stratified sample. These blood spots would only be tested by PCR to determine HIV infection status for children who died or were lost to follow-up (who could not be found by home visit).

**Comparison Group for Mother-to-Child HIV Transmission**

It is important to answer the questions, “How much transmission is prevented by use of ARV in the pilot project population?” and “How much transmission is prevented by the use of breast milk substitutes?” To do that, it is necessary to compare the transmission rate among mother-child pairs receiving the intervention(s), ARV and breast milk substitutes, with the rate among mother-child pairs not receiving the intervention(s). However, in the pilot projects, all HIV-infected women identified will be offered the interventions. Therefore the women who were identified as HIV-infected but did not receive ARV during gestation/labour and delivery is likely to be small, and perhaps different with regard to risk factors for transmission from women who received ARV. Therefore, comparison of transmission rates between mother-child pairs who received ARV with an internal comparison group of mother-child pairs who did not receive ARV may not be feasible. Two other options exist for measuring the impact of the pilot projects on mother-infant transmission, but each has limitations. The simplest method is to set a reasonable target for transmission reduction, e.g., to a rate of 15%, and to compare the transmission rate achieved in the pilot project against this target. Another option is to use a historical comparison group.

A historical comparison group for mother-to-child HIV transmission rates already exists in many of the pilot sites since observational cohort studies have been conducted in these locations in the past. While such comparison is not free of biases, historical rates of mother-to-child HIV transmission (without any antiretroviral intervention) have been relatively stable; most studies in the developing world have reported transmission rates around 25 to 30%, especially in those countries with a mature HIV epidemic. These rates may be somewhat higher in countries in the midst of an emerging HIV epidemic.

### 7.3. Impact of pilot projects on Infant Mortality

**Questions**: What is the impact of the pilot project intervention package on mortality among infants and children? Is replacement feeding increasing the mortality among HIV-exposed children?

Infant Mortality Rate (IMR) is suggested as the best common indicator. It should however be recognised that this indicator will more completely reflect the possible negative impact of infant feeding (deaths from infectious diseases other than HIV) than it will reflect prevention of deaths attributable to HIV. HIV-related deaths are more likely to occur after 12 months of age. If possible, mortality through age 24 months (or even better through age 5 years) should also be measured, but an extra year of follow-up would be needed to measure under-2 mortality (see section 9. “extended evaluation”).

**Outcome Evaluation Indicator. Infant Mortality (IMR)**

Definition: Death rate among children included in the pilot project before age 1 year.

Data Requirements: Deaths among children born during the pilot project
Data Sources: Child Health Record and intervention follow-up.
Data Collection Timepoints: ongoing
Data Analysis Timepoint: 12 months after the birth of the last child enrolled in the first year of the project
Infant Mortality in the Entire Pilot Project Population

As part of regular clinical follow-up, deaths among children participating in the pilot project will be recorded, therefore an infant death rate for the pilot project population can be estimated. However, it is likely that a large proportion of deaths will be unknown to the health care system through routine follow-up.

Infant Mortality in the Stratified Sample

Among children in the stratified sample, it will be possible to have better ascertainment of mortality, because home visits will be made if a mother and child do not return for follow-up visits. If a child died outside a hospital setting, it may be possible to determine the probable cause of death through a verbal autopsy technique. Efforts have been made to standardise data collection methods and interpretation of verbal autopsies used in the developing world. The verbal autopsy technique assumes that individual disease entities have discrete symptom complexes and that these can be accurately recognised and recalled by relatives, usually the mother. For this purpose, a standard interview form should be designed in the local language and results could be validated for the subset of cases where the child died at a hospital. Verbal autopsies have been shown to have limited utility for distinguishing deaths associated with HIV infection but they may be very useful for distinguishing certain causes of death such as malnutrition and diarrhoea (references 1-3 below). See verbal autopsy questionnaire and algorithms in the Annex.

Comparison Group for Impact on Infant Mortality

The overall impact of the pilot projects on child mortality will depend on how much mother-to-child HIV transmission is prevented and how well the frequency of death of children from other causes can be minimised, particularly among HIV-exposed children who are fed breast milk substitutes. To answer the question “What is the overall impact of the pilot project interventions on mortality among children less than 1 year of age?” it would be necessary to compare mortality among children receiving and not receiving the interventions. However, this comparison is complicated in the pilot project populations because the children born to women identified as HIV-infected will have received the interventions. There will therefore not be an adequate internal comparison group among children born to HIV-infected women. An alternative is to compare the child mortality indicator to a historical control or concurrent survey of the pilot project population (preceding birth technique, reference 4 below) or a neighbouring population (see reference 5 below). However, these comparisons are also subject to bias if the pilot project population and the comparison population are different with respect to other risk factors for death (other than HIV and causes of mortality related to replacement feeding). See reference 6 below for a review of mortality measurement issues.

To answer the question ‘Is replacement feeding increasing the infant mortality among HIV-exposed children?’ use of an internal comparison group will be necessary. However, comparing mortality among children born to HIV-infected mothers and fed breast milk substitutes and children born to uninfected mothers and breastfed is complicated by the fact that none of the children in the comparison group would be at risk of death from HIV infection. Therefore, it is recommended that the mortality rates among breastfed and non-breastfed children be compared only for children born from HIV+ mothers (or even only for children born from HIV+ mothers and not infected at birth). If cause of death information is available, the diarrheal disease and respiratory tract infection-specific mortality rates might be compared. This comparison assumes that the two groups are similar with respect to other risk factors for death (besides feeding method).
References for Infant/Child Mortality Sub-Section


7.4. Social consequences of HIV testing

7.4.1. Measuring positive and negative life events

Question: Is knowledge of HIV status associated with abandonment, ostracism, and/or discrimination? Is knowledge of HIV status associated with positive changes in sexual behaviours, better access to medical and social support or increased support from the community?

Outcome Evaluation Indicator. Negative life events following HIV testing

Definition: Proportion of women who were tested for HIV who experienced any of the following events* after being tested for HIV:

- Break up of marriage or primary partnership
- Physical abuse by spouse/sexual partner
- Neglected by family
- Disowned by family
- Discrimination by health professionals
- Discrimination by employers
- Estranged by peers

* the list being not exhaustive, it is recommended to record spontaneous mentioning of other severe negative events.

**Indicator adapted from AIDSCAP/WHO/CAPS Counselling and Testing Efficacy Study: C& T 6-month instrument.
Outcome Evaluation Indicator. Positive life events following HIV testing

Definition: Proportion of women who were tested for HIV who experienced any of the following events* after being tested for HIV:

Discovery of an unexpected HIV(-) status
Access to the full package of interventions to reduce MTCT
Financial support from family/community
Access to medical care for herself or a sick member of her family
Access to an income generating activity
Use of condoms with partners of different or unknown HIV status
Join an association of PLWAs

* the list being not exhaustive, it is recommended to record spontaneous mentioning of other positive events.

Data Requirements: Number of women who were tested for HIV, and among these, number who experienced the negative and positive life events above following receipt of test results.

Data Source: Intervention follow-up interviews
Data Collection Timepoints: Visit following receipt of HIV test results.
Data Analysis Timepoint: 12 and 24 months after the start of the intervention.

Social consequences of HIV Testing in the Entire Pilot Project Population

Because assessment of the social consequences of HIV testing involves interviewing women, which is labour intensive, it is recommended that the evaluation be done only for the stratified sample.

Social consequences of HIV Testing in the Stratified Sample

To estimate the social consequences of HIV testing for the stratified sample, it will be necessary to interview women during the visit following receipt of HIV test results.

Impact of the HIV Testing on Positive and Negative Life Events

The occurrence of any of the positive and negative life events at the visit following receipt of HIV test results should be compared for HIV seropositive and HIV seronegative women. It will be important to collect additional socio-demographic information, to control for differences among these groups (other than HIV serostatus) that may affect the frequency of positive and negative life events.

References for social consequences of HIV Testing


7.4.2. Evaluation of attitudes to VCT in the general population

One of the hopes of improving the access to and acceptability of VCT is to decrease stigma and promote “normalisation” of HIV in communities. The evaluation of the prenatal VCT services should therefore not be restricted to the attending population but could involve assessing impact and acceptability in the community.

Areas which could be examined include:
- awareness of VCT testing services
- awareness of HIV support services
- prevalence of testing in the community
- acceptability of VCT
- attitudes towards PLHA
- views on confidentiality and disclosure

Community surveys and key informant interviews with a comparison “Before and After” the pilot project would examine community attitudes to VCT and HIV and attitudes of key informants (such as church or spiritual leaders, youth workers, community leaders, teachers, traditional medical practitioners) view the value of VCT.

Two possible tools are:
(i) A semi-structured key informant interview, which should be carried out individually by a trained and experienced researcher. As it will require some time to perform a small sample of people should be interviewed.
(ii) Focus group discussions or semi-structured interviews with community members. To avoid a biased sample it will be important to have a random sample from, for example a household survey. If focus groups are used it may be appropriate to carry out several focus group discussions with different groups such as women, men, younger women and younger men as people may feel more comfortable and able to talk more freely with their peers.

7.5. Consequences of infant feeding counselling in the context of HIV

7.5.1. Social Risk of Replacement Feeding

**Question:** Is replacement feeding associated with stigma, abandonment, ostracism, and/or discrimination?

**Outcome Evaluation Indicator.** *Negative life events following use of breast milk substitutes*

Definition: Proportion of women who used breast milk substitutes who experienced any of the following events* after being tested for HIV:
- Break up of marriage or primary partnership
- Break up of sexual relationships
- Physical abuse by spouse/sexual partner
- Neglected by family
- Disowned by family
- Discrimination by health professionals
- Discrimination by employers
- Estranged by peers

* the list being not exhaustive, it is recommended to record spontaneous mentioning of other severe negative events.
Data Requirements: Number of women who use breast milk substitutes exclusively, breast milk exclusively or mixed feeding during the first six months of life, and among these, number who experienced any of the negative life events above.

Data Source: Intervention follow-up interview  
Data Collection Timepoints: One-month follow-up visit and each follow-up visit thereafter.  
Data Analysis Timepoints: 24 months after the start of the intervention.

**Social Risk of Replacement Feeding on Entire Project Population**

As for assessment of the social risk of HIV testing, assessment of the risk of replacement feeding involves interviewing women, which is a labour-intensive process. Therefore, it is recommended that the evaluation be done only for the stratified sample.

**Social Risk of Replacement Feeding for the Stratified Sample**

To estimate the social risk of replacement feeding for the stratified sample, HIV-infected women in the sample are to be interviewed at each postpartum follow-up visit beginning with the 1-month visit.

**Replacement Feeding on Risk of Negative Life Events**

To assess the impact of replacement feeding on risk of negative life events, it will be necessary to compare the frequency of negative life events among HIV-infected women who elect to employ the following different feeding methods during the first six months postpartum: use of breast milk substitutes exclusively, mixed feeding strategy (breast milk substitutes and breastfeeding) and exclusive breastfeeding. The analysis could potentially become complicated because negative life events attributable to the stigma of replacement feeding may occur at any time following use of breast milk substitutes. The analysis may be simplified by treating the occurrence of any negative life event at any time following use of breast milk substitutes as the outcome of interest.

**7.5.2. Replacement Feeding “Spillover” to HIV-Uninfected Women**

**Question:** “Does offering replacement feeding to HIV-infected women identified through the pilot projects increase the frequency of replacement feeding by uninfected and untested women?

**Outcome Evaluation Indicator.** Use of breast milk substitutes among HIV-uninfected and untested women

Definition: Proportion of HIV-uninfected and untested women using any breast milk substitutes at 1, 3 and 6 months postpartum.

Data Requirements: Number of uninfected (untested) women, and of these, number who used any breast milk substitutes at all during the 3 early postpartum timepoints.

Data Source: MCH Cards, intervention follow-up interview  
Data Collection Timepoints: 1, 3 and 6 months postpartum (to be adapted according to immunisation schedule).  
Data Analysis Timepoints: every 6 months for the previous 6 months (include in the interim evaluation report)
Replacement Feeding Spillover for the Entire Pilot Project Population

Feeding method will be recorded on the Child Health Card for all children of uninfected mothers participating in the pilot projects. Therefore, it is possible to evaluate replacement feeding spillover for the entire pilot project population. However, because careful documentation of feeding method is necessary for this indicator, it is recommended that evaluation be focused on uninfected and untested women included in the stratified sample.

Replacement Feeding Spillover for the Stratified Sample

To estimate occurrence of replacement feeding spillover for the stratified sample, it will be necessary to interview women during follow-up visits regarding their infant feeding practices. The staff should record whether the child is being exclusively breastfed, predominantly breastfed, exclusively receiving breast milk substitutes, or predominantly receiving breast milk substitutes.

The following definitions should be used for these concepts:

- **Exclusively breastfed**: children who receive only breast milk with no other liquids or solids, with the exception of drops or syrups consisting of vitamins, mineral supplements, or medicines
- **Predominantly breastfed**: children who receive breast milk along with water, water-based drinks (sweetened and flavored water, teas, infusions, etc.), fruit juice, or Oral Rehydration Salts (ORS) solution, but does not receive any other food-based fluids or solids.
- **Exclusively fed breast milk substitutes**: children who receive only breast milk substitutes, with no other liquids or solids, with the exception of drops or syrups consisting of vitamins, mineral supplements, or medicines
- **Predominantly fed breast milk substitutes**: children who receive breast milk substitutes along with water, water-based drinks (sweetened and flavored water, teas, infusions, etc.), fruit juice, Oral Rehydration Salts (ORS) solution, but does not receive any other food-based fluids or solids.
- **Mixed feeding**: Children who received both breast milk and breast milk substitutes in the 24 hours before the visit

Impact of Replacement Feeding Among HIV-Uninfected Women

To answer the question, “Does offering replacement feeding to HIV-infected women identified through the pilot projects increase the frequency of replacement feeding by uninfected and untested women?” it is necessary to compare frequency of replacement feeding among HIV-infected, uninfected women, and untested women before and after the pilot project interventions began. An internal comparison of women included in the stratified sample will partly address whether replacement feeding is being practised by HIV-uninfected women. But to address whether replacement feeding as increased after implementation of the pilot projects, a baseline survey of women attending pilot project clinics for care and/or a baseline survey of the general population of women of childbearing age living in the region of the pilot projects will be needed. Historical data on the use of replacement feeding in this population may be of sufficient quality to use instead of a baseline survey. Any of these would serve as comparison for the uninfected/untested women participating in the pilot projects.

It may be useful also to collect additional information about determinants of infected and uninfected women’s choice of replacement feeding.

References

8. Management Information Systems for M&E

Use of M&E indicators requires appropriate, functional and effective information systems. The management systems that are required for M&E would include:

- service-based record keeping for administrative management;
- service-based record keeping for clinical management (registers, files and forms);
- supply inventories and accounting, administrative record keeping; and
- population based information: census, demographic data (fertility rates), epidemiological data (HIV rate among pregnant women).

The service-based record keeping should use the existing tools of the management information system as much as possible. If these tools are to be modified, special attention should be given to reviewing the Reproductive Health and MCH information system as a whole to integrate all components of the PMTCT intervention appropriately.

8.1.1. Service Provision Data

The experience of many countries in establishing a sound management information system suggests that a two-pronged approach is usually appropriate for following up MCH services. These are:

- maintaining records in the MCH clinic in registers or cards (e.g., MCH Form, Pregnancy Form, Well Baby Form, Under 3 Form); and
- providing an information tool to be kept by each woman-child pair who attends MCH services (Pregnancy Card, MCH Booklet, Mother and Child Card, MCH Card, Child Card). This tool contains an abbreviated record of intervention components received.

There are a number of data elements that need to be included in a Management Information System for the MCH service to ensure that it can assist M&E of PMTCT. These data are listed in the 2 tables below and can be easily extracted from individual forms such as pregnancy, delivery or child health cards (see examples of cards below).

### Table 10: Pregnancy and delivery data form retained at health facility or by the mother

<table>
<thead>
<tr>
<th>ANC visits</th>
<th>Receipt of Iron/Folic Acid</th>
<th>Village or Neighbourhood of origin</th>
<th>Result of compliance to iron/folic acid</th>
</tr>
</thead>
<tbody>
<tr>
<td>VCT pre-test</td>
<td>Date of VCT pre-test</td>
<td>Result of HIV test</td>
<td>Date of VCT post-test</td>
</tr>
<tr>
<td>VCT test</td>
<td>Date of VCT test</td>
<td>Result of HIV test</td>
<td>Date of VCT post-test</td>
</tr>
<tr>
<td>ARV</td>
<td>Result of Hb test</td>
<td>Result of FBC</td>
<td>Date of initiation of ARV treatment</td>
</tr>
<tr>
<td>Safe Delivery</td>
<td>Date of delivery</td>
<td>Dose or Quantity of ARV given during delivery</td>
<td>Episiotomy Yes/No</td>
</tr>
</tbody>
</table>

### Table 11: Child follow-up data* form retained at health facility or by the mother

<table>
<thead>
<tr>
<th>Infant Feeding Counselling</th>
<th>Date of birth</th>
<th>Date of Initiation of RF</th>
<th>Growth Monitoring</th>
<th>Type of feeding at each visit</th>
<th>Nutrition Action Taken</th>
</tr>
</thead>
<tbody>
<tr>
<td>Immunisation dates</td>
<td>Dates of visits</td>
<td>Date and type of illness episodes</td>
<td>Treatment of illness episodes</td>
<td>HIV status at 15 months</td>
<td></td>
</tr>
</tbody>
</table>

* Receipt of ARV by the child should also be noted if the ARV regimen used has a post-partum component to the child
Pregnancy Card

No. Date………… Name……………………………Age ……

Occupation …………… Neighborhood of Origin/address ……………………………

Height …… cms Date of Vaccination TT1 …….. TT2 ……..

Past Illness and Pregnancy History

Parity …….. Last Abortion ……..

<table>
<thead>
<tr>
<th>Normal</th>
<th>Abnormal</th>
<th>Stillbirth</th>
<th>Delivery Place</th>
</tr>
</thead>
</table>

Previous pregnancy history ______ ______ ______ ______

Significant History (Past Preg.) ______ ______ ______ ______

Other disease history/Personal dis. ________________________________

Comments ________________________________

Laboratory test / Immunization / Significant investigation

<table>
<thead>
<tr>
<th>Lab exams</th>
<th>VCT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date</td>
<td>Result</td>
</tr>
<tr>
<td>Hct</td>
<td></td>
</tr>
<tr>
<td>Hb.</td>
<td></td>
</tr>
<tr>
<td>…</td>
<td></td>
</tr>
<tr>
<td>Bl.gr</td>
<td></td>
</tr>
<tr>
<td>HbsAG</td>
<td></td>
</tr>
</tbody>
</table>

Treatment Plan

Ex. ZDV 2 tab per day, Iron Folic Acid 1 tab per day

Start-up date:……….. Number of missed doses: ……………………………..

Adverse Effects: ______________ Other problems (Stigma ?): ____________

Delivery and Postpartum Card

Delivery History

Date _____ Place _____ Type of delivery _____ Complication ________

Child Weight _____ Sex _____ HIV Status ______

Episiotomy RPM

Postpartum (delivery – 6 wks)

MOTHER

Date BT BP Lochia Abdominal perineal wound Feeding Others Signs Decision Follow-up

<table>
<thead>
<tr>
<th>BT</th>
<th>BP</th>
<th>Lochia</th>
<th>Abdominal</th>
<th>perineal wound</th>
<th>Feeding</th>
<th>Others Signs</th>
<th>Decision</th>
<th>Follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Breast</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Mixed</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

INFANT

Date BW. Umbilicus BMS Cup Bottle Date initiation BMS Others liquids/foods Pathologies

<table>
<thead>
<tr>
<th>Date</th>
<th>BW.</th>
<th>Umbilicus</th>
<th>BMS</th>
<th>Cup</th>
<th>Bottle</th>
<th>Date initiation</th>
<th>BMS</th>
<th>Others liquids/foods</th>
<th>Pathologies</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
**Child Health card**

Name:……………….    Sex:…………    Date of Birth:…./…./…..

Birth weight:_________    HIV status of mother:_________

<table>
<thead>
<tr>
<th>Time</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>B1</th>
<th>B2</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Appoint</td>
<td>Done</td>
<td>Appoint</td>
<td>Done</td>
<td>Appoint</td>
</tr>
<tr>
<td>BCG</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HBV</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DPT</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>OPV</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Measle</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

HIV status at … months:

Remarks:

**Medical Follow-up**

<table>
<thead>
<tr>
<th>Appointment Date</th>
<th>Visit Date</th>
<th>Cause of no show or late follow up</th>
<th>Problem Findings</th>
<th>Diagnosis</th>
<th>Plan of treatment</th>
</tr>
</thead>
</table>

**Infant feeding** (Please record / for activity has been doing and X for no activity)

<table>
<thead>
<tr>
<th>Date</th>
<th>Age</th>
<th>Breast Milk</th>
<th>BMS or other RF</th>
<th>Bottle</th>
<th>Cup</th>
<th>Supplementary food</th>
</tr>
</thead>
</table>

**Growth Development** (Please record illness episodes on the curve)

```
<table>
<thead>
<tr>
<th>Months</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
<th>11</th>
<th>12</th>
<th>13</th>
<th>14</th>
<th>15</th>
<th>16</th>
<th>17</th>
<th>18</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weight</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
8.1.2. Resources Management Data

Most MCH services already have accounting systems to track the use of resources. To inventory supplies of HIV test kits, lab tests, anti-retroviral drugs and RF, existing information systems will have to be adapted and reinforced.

It is therefore suggested that the information system keep track of:

- availability (out of stocks/shortages);
- consumption (quantity used per period);
- adequacy between the quantity of resources used, and the number of women and children served;
- costs;
- funding source.

Below are examples of forms for monitoring stocks and use of resources.

**Stock Form for each new drug or test**

<table>
<thead>
<tr>
<th>ZDV</th>
<th>Quantity in stock (A)</th>
<th>Quantity received (B)</th>
<th>Quantity taken out (C)</th>
<th>Total in stock (A+B-C)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Entry</td>
<td>Exit</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Data form to monitor the use of resources**

<table>
<thead>
<tr>
<th>Quantity of Drugs used in the Month of</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>...</th>
<th>30</th>
<th>31</th>
<th>Total quantity used in a month</th>
<th>Unit Cost</th>
<th>Total Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cotrimoxazole</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oxytocin</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Iron</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Folic acid</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HB test</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HIV tests</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>FBC tests</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ZDV</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>BMS</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
8.1.3. Measuring indicators

Most indicators can be measured using either cumulative data collected through logbooks and registers or individual information collected through clinical management records. Effectiveness indicator number 8 for example: “percent of pregnant women who received HIV testing during the period considered” can be measured as the number of tests performed (from stock forms) divided by the number of women (from a register), or analysed from a database containing individual information.

The first option has the advantage of simplicity since cumulative “output” data are readily available (number of antenatal visits, number of HIV tests conducted, or number of ARV treatments given etc.). The approach however has several disadvantages: It is sensitive to short term fluctuations in output, which does not relate necessarily to effective coverage. In addition to this, output variables are collected independently and there is no information on the different outputs in relation to the same woman. Furthermore, it can be considered simple only if there is no other information system in place. Last, cumulative data will not allow impact evaluation for which it is necessary to know which individuals received which services and what the outcomes were for these individuals, to be able to compare outcomes for groups of individuals who did and did not receive specific services.

In contrast, an information system based on service data on women having delivered in the period considered and compiled from the MCH cards and forms, allow to examine to what extent a woman has been covered fully. This approach does not require extra work for data collection as it combines clinical management and monitoring data collection. Its disadvantage is that the reorganisation of MIS has to be done at the same time as reorganisation of services since the clinical management information system has to be organised in a way that makes collection and compilation of data easy.

The table below provides information on where to find the data and how to measure the 22 indicators described in section 4.3. to monitor effectiveness.
<table>
<thead>
<tr>
<th>Indicator</th>
<th>Numerator definition</th>
<th>Denominator definition</th>
<th>Data source</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Availability of condoms</td>
<td># condoms available in pilot site and related services for the period considered</td>
<td># clients attending pilot site and related services for the period considered</td>
<td>Site’s registers</td>
</tr>
<tr>
<td>2. Availability of STD drugs</td>
<td># of days with no shortage of STD drugs</td>
<td># days in the period considered</td>
<td>Calendar</td>
</tr>
<tr>
<td>3. Use of Family Planning</td>
<td># of women 15-49 using a modern FP method in the area covered by pilot project</td>
<td># of women 15-49 living in the area covered by pilot project</td>
<td>Census</td>
</tr>
<tr>
<td>4. Use of ANC</td>
<td># pregnant women with at least one ANC visit</td>
<td># of pregnant women in the area covered by pilot project</td>
<td>Census Fertility rate</td>
</tr>
<tr>
<td>5. Use of Iron/folic acid</td>
<td># women who delivered during the period considered* who received iron and folates</td>
<td># of women with at least one contact with MCH (either pre, per or post partum) whose date of delivery corresponds to the considered period</td>
<td>MCH cards Registers</td>
</tr>
<tr>
<td>6. Availability of HIV test</td>
<td># days with no shortage of tests kits (at least 2 types of kits)</td>
<td># in the period considered</td>
<td>Calendar</td>
</tr>
<tr>
<td>7. Use of HIV pre-test counselling</td>
<td># women who delivered during the period considered* who received pre-test counselling</td>
<td>MCH cards Registers</td>
<td></td>
</tr>
<tr>
<td>8. Use of HIV testing</td>
<td># women who delivered during the period considered* who were tested for HIV</td>
<td>MCH cards Registers</td>
<td></td>
</tr>
<tr>
<td>9. Partners tested for HIV</td>
<td># women who delivered during the period considered* whose partners were tested</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10. Use of HIV post-test counselling</td>
<td># women who delivered during the period considered* who received post-test counselling</td>
<td></td>
<td></td>
</tr>
<tr>
<td>11. Infant feeding counselling</td>
<td># women who delivered during the period considered* who received infant feeding counselling prenatally</td>
<td></td>
<td></td>
</tr>
<tr>
<td>12. Episiotomy rate</td>
<td># HIV+ women who delivered during the period considered* who delivered without episiotomy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>13. Family Planning counselling</td>
<td># women who delivered during the period considered* who received FP counselling before delivery</td>
<td></td>
<td></td>
</tr>
<tr>
<td>14. HIV Prevalence</td>
<td># HIV+ women who delivered during the period considered*</td>
<td># women tested for HIV who delivered during the period considered*</td>
<td></td>
</tr>
<tr>
<td>15. Availability of ARV drugs</td>
<td># of days without shortage of ARV</td>
<td># of days in the period considered</td>
<td>Calendar</td>
</tr>
<tr>
<td>16. Initial Use of ARV</td>
<td># HIV+ women who delivered during the period considered* who initiated ARV treatment</td>
<td>MCH forms Registers</td>
<td></td>
</tr>
<tr>
<td>17. Continuity of ARV</td>
<td># HIV+ women who delivered during the period considered* who received ARV during at least the 2 weeks before delivery</td>
<td>MCH forms Registers</td>
<td></td>
</tr>
<tr>
<td>18. ARV during labour</td>
<td># HIV+ women who delivered during the period considered* who received the intra-partum dose of ARV</td>
<td></td>
<td></td>
</tr>
<tr>
<td>19. Exclusive BF at 3 months among HIV+</td>
<td># HIV+ women who delivered during the period considered* who exclusively BF up to 3 months</td>
<td></td>
<td></td>
</tr>
<tr>
<td>20. Use of Family Planning by HIV+</td>
<td># HIV+ women who delivered during the period considered* who use a modern FP method after delivery</td>
<td></td>
<td></td>
</tr>
<tr>
<td>21. Referral to a support network</td>
<td># women who delivered during the period considered* referred for long term care</td>
<td></td>
<td></td>
</tr>
<tr>
<td>22. Exclusive BF at 3 months among HIV-</td>
<td># HIV- and untested women who delivered during the period considered* who exclusively BF up to 3 months</td>
<td>MCH cards Registers</td>
<td></td>
</tr>
</tbody>
</table>

* women with at least one contact with MCH services (either pre, per or post partum) whose date of delivery falls into the period considered for monitoring analysis.
9. Extended Evaluation Topics

This last chapter provides guidance on several extended (or optional) evaluation topics. These topics may be seen as essential in some participating programs while in other settings they may be viewed as less important or overly labour-intensive. Based on local/national needs and available resources, program planners in each country must prioritise which one(s), if any, of these extended evaluation topics they will address as integral components of their program.

The focus of this chapter is on the conduct of applied research and surveillance to address specific unresolved issues, to optimise the impact and cost-effectiveness, and to minimise the risks of an intervention program designed to reduce mother-to-child transmission (MCT) of HIV in resource-poor settings. Each extended evaluation topic is introduced and described concisely in this document. Readers in need of a more comprehensive discussion on methodological issues are referred to the selection of “Recommended further readings”.

9.1. Impact on Child Mortality

During the pilot project (usually 2 years), only infant mortality can be measured. However, gains in terms of HIV related mortality will be better measured if follow-up of children is longer, up to 2 years or even better 5 years of age. Since the principal objective of the pilot projects is to reduce overall child mortality by reducing HIV related mortality without increasing mortality related to other causes (especially replacement feeding), the best measure of impact would be child mortality.

Indicator definition: Death rate among children included in the pilot project before age 2 (or 5) years

Data Requirements: Deaths among children born during the pilot project and in the following year (at least 3 years of follow-up)
Data Sources: Child Health Record and intervention follow-up.
Data Collection Timepoints: ongoing
Data Analysis Timepoint: 24 (or 60) months after the birth of the last child enrolled in the first year of the project

References and Discussion regarding measurement of the indicator and comparison groups is detailed in the section 7. “Impact Evaluation”, sub-section “Infant mortality”.

9.2. Impact of infant feeding counselling

Two major indicators should be measured during core evaluation: Social risk for women who will chose replacement feeding and the risk of spillover (see section 7. “Impact evaluation”). Three other indicators could be useful in assessing the impact of infant feeding counselling: rates of exclusive breastfeeding, child growth and birth spacing.

9.2.1. Strengthening of breastfeeding practices

Offering systematic infant feeding counselling in pilot project may support the promotion of breastfeeding among HIV(-) and untested women. Such a positive effect could be easily measured at the same time as spillover risk.
**Question:** What is the impact of infant feeding counselling on rates of exclusive breastfeeding at 3 months?

**Outcome Evaluation Indicator.** *Rate of exclusive breastfeeding at 4 months*

Definitions: Proportion of children born from HIV-uninfected and untested women who are exclusively breastfed at 4 months (see p. 48 for definitions of infant feeding patterns.

Data Requirements: Number of uninfected (untested) women, and of these, number who exclusively breastfed their children up to at least 4 months

Data Source: MCH Cards, intervention follow-up interview

Data Collection Timepoints: 4 months postpartum.

Data Analysis Timepoints: every 6 months for the previous 6 months (include in the interim evaluation report)

**Measurement of the indicator and comparison groups:** See section on spill-over in “Impact evaluation”.

**9.2.2. Child Growth**

**Question:** What is the impact of replacement feeding on child growth?

**Outcome Evaluation Indicator.** *Child Growth*

Definitions:
--general malnutrition measure, (definition 1):.
weight for age below minus 2 standard deviations from the median of the NCHS/CDC/WHO international reference population at 6 months, 12 months, and 24 months of age

--(definition 2, expanded):
weight for age and each of the following: height for age (for chronic malnutrition), weight for height (for acute malnutrition), and mid upper arm circumference (general malnutrition) below minus 2 standard deviations from the median of the NCHS/CDC/WHO international reference population at 6 months, 12 months, and 24 months of age.

Data Requirements: weight measurements at at least 3 timepoints (definition 1)
weight, height, and mid upper arm circumference measurements at at least 3 timepoints (definition 2)

Data Sources: Child Health Record, intervention follow-up

Data Collection Timepoints: 6, 12, and 24 months of age

Data Analysis Timepoints: 12 months and 24 months after the start of the intervention

**Impact on Child Growth for the Entire Pilot Project Population**

As part of regular clinical follow-up, weight will be recorded at all clinic visits for the entire pilot project population (see Child Health Record). Therefore, the growth indicator (definition 1, weight for age) will be available for all children in the pilot project population. Method of feeding (breast milk or breast milk substitutes or both) will also be recorded for every child, so it will be possible to investigate the association between infant feeding method and growth. However, weight for age is not a very specific malnutrition indicator, and more detailed study of both feeding practices and growth on a smaller group (sample of the entire population) would add valuable information.
Impact on Child Growth for the Stratified Sample

To validate weight for age, etc., as malnutrition indicators, it is recommended that the additional indicators (height for age, weight for height, and mid upper arm circumference) be measured for each child in the stratified sample. It is also recommended that a more detailed collection of feeding practices be completed at least for children in the stratified sample, that is, at each visit, the staff should record whether the child is being exclusively breastfed, predominantly breastfed, exclusively receiving breast milk substitutes, or predominantly receiving breast milk substitutes.

Comparison Group for Impact on Child Growth

To answer the question “What is the impact of replacement feeding on child growth?” it is necessary to compare the growth indicators for children receiving and not receiving replacement feeding. However, this comparison is complicated in the pilot project populations because most of the children who receive replacement feeding are likely to be children born to HIV seropositive mothers and most of the children receiving breast milk are likely to have been born to HIV seronegative mothers, and these two groups may inherently differ in their growth patterns, even when HIV infection status of the child is taken into account. For example, uninfected children of HIV seropositive mothers may grow less well if their mothers are ill and less able to care for them, regardless of feeding method. Nevertheless, if HIV infection status of the child is taken into account, one option for estimating impact on child growth is to use an internal comparison, that is, compare growth indicators among children in the stratified sample according to whether they received breast milk or breast milk substitutes exclusively, predominantly or in combination, and whether their mother is HIV-seropositive or HIV-seronegative. If this is done, the indicator should be assessed for all children in the stratified sample, those born to HIV seropositive mothers, to seronegative mothers, and to mothers who have not been tested for HIV.

Another alternative is to compare the weight for age indicator for the entire pilot project population with a historical control (e.g. data from the country-specific Demographic and Health Survey) or concurrent survey of a neighbouring population. However, these comparisons are also subject to bias if the pilot project population and the comparison population are different with respect to risk factors for poor growth (other than feeding method).

9.2.3. Birth Intervals

Question: What is the impact of replacement feeding on birth intervals?

Outcome Evaluation Indicator. **Birth Interval**

Definition: Proportion of HIV-infected women delivering a second child < 24 months from the birth of the index child.

Data Requirements: Among women who deliver a baby in the first year of the pilot project, number of births less than 24 months after birth of the index child. Note that in addition to the 2 years of the pilot project, an extra year of follow-up would be needed to measure birth interval. Such an extended follow-up may be planned if impact of the pilot project on child mortality is to be assessed (see section on infant and child mortality).

Data Source: MCH Cards and intervention follow-up

Data Collection Timepoints: Ongoing

Data Analysis Timepoint: 24 months after the birth of the last child in the first year of the pilot project.
Birth Interval in the Entire Pilot Project Population

As pregnancies will be recorded on the MCH card, the birth interval indicator can be estimated for the entire pilot project population. The accuracy of the indicator will be greater where there is relatively little population migration, and where women return to the same antenatal clinic that provided antenatal care during their first pregnancy.

Birth Interval for the Stratified Sample

Better ascertainment of birth interval information is possible for women included in the stratified sample. However, because women selected to be part of the sample are accrued over time, not all women in the sample will have enough follow-up time to estimate the birth interval indicator. It is therefore recommended that this indicator be estimated among all women who deliver a baby in the first year of the pilot project.

Comparison Group for Impact on Birth Intervals

To answer the question “What is the impact of replacement feeding on birth intervals?” the ideal comparison group for HIV-infected women using breast milk substitutes is HIV-infected women who breastfeed. Factors other than feeding method which may influence birth interval (for example, advanced disease state and use of contraceptives) may affect this comparison and should be considered. Because there may be few HIV-infected women who breastfeed (if acceptance of replacement feeding is high), it is advisable also to collect information on birth intervals among HIV-uninfected women who breastfeed for comparison. Just as for the comparison of birth intervals among HIV-infected women who do and do not breastfeed, it is important to consider other factors (besides feeding method) that may influence birth intervals. Feeding method is recorded in the MCH card and therefore can be linked with birth interval information to examine the association between these two factors.

9.2.4. Other evaluation issues related to infant feeding

The pilot projects may want to add an assessment of excess morbidity (illness episodes and number/severity of hospitalisations) among infants born to HIV-positive mothers to the Core Evaluation data collection among a sample of mother-infant pairs. Research on early weaning practices and the impact of different options for RF on infants born to HIV infected women are also needed to assist women in different settings in decision making about this important issue.

Qualitative research on the determinants of RF choices mothers make and the retention/quality of counselling HIV-positive mothers receive at the clinic about HIV infection through breast-feeding would be worthwhile. If the mother has decided to use BMS, can she use the breast milk substitute safely (e.g., availability of a safe and clean water supply in her compound; use of a cup versus a bottle)? the distribution and correct use of breast milk substitutes could be carefully monitored.

Research may also indicate which measures could be effective in ensuring that HIV-infected mothers who choose not to breastfeed are not discriminated against. Ways to deal effectively with difficult questions or situations, especially in settings where breast-feeding is the norm, could result from qualitative research on these issues in the specific community setting.
9.2.5. Additional references on Infant Feeding

Kuhn L, Stein Z. Infant survival, HIV infection, and feeding alternatives in less-developed countries. *Am J Public Health* 1997; 87:926-931.


WHO. *HIV and Infant Feeding: A training module (1999)*


9.3. Cost-Effectiveness and Cost-Benefit of the Intervention Program

**Question:** What is the cost per each year of life saved by the intervention?

**Evaluation Indicator:** Cost per DALY (disability-adjusted life-year)

**Definitions:**
Costs are defined as the monetary value of resources utilised as a result of the intervention. The outcome (effectiveness) of the intervention may be measured in several ways, including clinical outcome (paediatric HIV infections, mortality in children under two years of age), monetary benefits, and quality of life, often combined with survival to produce expected productivity or disability-adjusted life-years (DALY). Costs and outcomes occurring over time must be the subject of discounting, which under perfect markets equals the opportunity cost of capital employed (see references). By convention, evaluations comparing monetary outcomes are termed ‘cost-benefit’, whereas evaluations comparing monetary costs with non-monetary outcomes are termed ‘cost-effectiveness’.

**Data requirements:**
The economic evaluation of MCT interventions requires a team member or outside evaluator with specialised expertise in health economics. Methodological recommendations on how to best perform and report cost-effectiveness analyses have recently been published by a consensus panel of experts (see Weinstein et al. and Siegel et al.). These recommendations address:

i. components belonging in the numerator and denominator of a cost-effectiveness (C/E) ratio;

ii. measuring the costs resulting from the intervention in a standardised fashion (for the numerator of the C/E ratio);
iii. valuing health consequences in the denominator of a C/E ratio;
iv. estimating effectiveness of the intervention;
v. incorporating time preference and discounting; and
vi. handling uncertainty with regard to estimates of effectiveness and costs.

The validity of a cost-effectiveness analysis depends crucially on the quality of the underlying data that describe the effectiveness of the intervention. Acceptable data for estimation of effectiveness may come from randomised controlled trials and from ‘real world’ observational studies such as the planned pilot projects to reduce MCT.

Calculation of the estimated number of paediatric HIV infections averted (or estimated number of childhood deaths averted) and their cost would be the main parameters for a cost-effectiveness analysis of the pilot projects. Cost-effectiveness can be defined in several ways, for example as cost per infection averted or as cost per potential life-year gained. Capacity requirements in terms of staff and infrastructure required to effectively implement the intervention also need to be taken into account (Wilkinson et al.).

Modelling exercises have shown that the expected cost-benefit of a MCT risk reduction program depends critically on the cost of the antiretroviral drug regimen utilised (see references). Other parameters associated with a higher cost-benefit ratio are high costs for screening, counselling, and antenatal care, low efficacy of the intervention, low costs for paediatric treatment of HIV-related disease and estimated productivity losses, low prevalence of HIV infection among women of childbearing age, and low treatment compliance rates. Movement of one or more of these parameter values in the opposite direction would make the intervention more cost-beneficial. To understand the implications of parameter variation and differing assumptions, economic evaluations should include a sensitivity analysis of the most important variables thought to influence effectiveness and costs. It is through sensitivity analyses that the importance of many variables can be determined.

Several issues, explicitly absent from most economic models considered thus far, include replacement feeding and its implications on a population level as well as increased costs of care for orphans, which to some degree could offset the treatment cost saved by less HIV infection among infants.

**Comparisons:**
Economic evaluation of an intervention program to reduce MTCT will typically involve a relative assessment (i.e., a comparison of the impact of two or more approaches, one of which will usually be the status quo or no intervention).

Under realistic conditions of health care delivery and consumer behaviour, effectiveness may not mirror that achieved in clinical trials. Reducing the risk of MCT of HIV is only one of many demands on health care systems, particularly in the poorest environments. Cost-effectiveness measures are especially useful when one must choose between alternative disease prevention strategies, given limited resources. They enable health policymakers to be explicit about beliefs and assumptions that underlie the allocation of scarce resources and the determination of optimal preventive strategies. Therefore, well-defined economic analyses on cost-effectiveness and cost-benefit of antiretroviral therapy in the prevention of MCT in resource-poor countries will remain vital.
Recommended Further Readings on Cost Effectiveness


9.4. Evaluation of Voluntary Counselling and testing

9.4.1. Rapid Testing for HIV Antibody

There has been a rapid evolution in diagnostic technology since the first HIV antibody tests became commercially available in 1985. Enzyme-linked immunosorbent assays (ELISAs) are still the most widely used, but many simple and rapid HIV tests have been developed which offer a number of advantages in certain circumstances. The prevention of MCT of HIV, in particular, necessitates timely voluntary counselling and testing (VCT) during pregnancy. In the case of communities where many women receive inadequate or no prenatal care, rapid diagnostic tests and appropriate implementation of antiretroviral therapy during labour – or to the neonate in the immediate postpartum period – offer an opportunity to further reduce perinatal HIV transmission. These developments are creating new demands for HIV testing and different requirements for assays in terms of their operational characteristics (see readings).

The availability of rapid HIV testing in pilot sites can greatly facilitate the expansion and effectiveness of VCT in prenatal care services. Pregnant women attending pre-test counselling must have the opportunity to reflect about their decision to be tested. However, when they are ready, simple rapid tests allowing same-day results may remove major practical obstacles, thereby contributing to the overall success of the intervention program. In many developing country settings, a significant number of pregnant women do not return to collect their HIV test results for a variety of reasons: fear of being rejected due to concerns about confidentiality, lack of hope or simple logistics. Those who are in fact seropositive have been shown to be less likely to return than those who are seronegative, showing that failure to collect test results is not a random event. Rapid testing, on the other hand, could make it more difficult for a woman to refuse HIV testing and this issue deserves further study.
In settings where women often attend prenatal care late in the course of pregnancy, the use of simple rapid HIV testing can reduce the delay between testing and starting the antiretroviral intervention. Operational research is needed to demonstrate that same-day results can be provided in VCT of pregnant women participating in the MCT intervention projects without compromising the quality of counselling or the accuracy of HIV testing.

9.4.2. **Comparative evaluation of different methods of counselling**

Providing counselling and voluntary testing for HIV in pregnancy-related services is easier said than done and will represent an important part of the costs of the MTCT interventions. It would be very useful to test operational options which are as simple and as cheap as possible.

For example, training existing staff to provide additional advice on HIV care and prevention in the context of pregnancy may be easier than training professional counsellors to deal with all the medical questions that may arise around the subject of reproductive health and childbearing; to reduce the time needed for individual pre-test counselling, much of the routine provision of basic information about HIV transmission, prevention and testing, can be done in groups and carried out by staff with little special training in counselling; some post-test information, such as reinforced prevention information relevant to all clients regardless of HIV status, can also be given in groups.

Since each pilot project will be conducted in several clinics, it will be possible to apply a different way of counselling in one of the clinic and compare the quality of counselling, the satisfaction of counsellors and clients between clinics.

9.4.3. **Recommended further reading:**

Counselling and voluntary HIV testing for pregnant women in high prevalence countries: Guidance for services providers. UNAIDS (1999)


Organising the integration of voluntary counselling and testing for HIV infection in antenatal care: A practical guide. WHO 1999

Guidelines for evaluating HIV voluntary counselling and testing. UNAIDS 1999.


Minkoff H, O’Sullivan MJ. The case for rapid HIV testing during labour. *JAMA* 1998; 279:1743-44.

9.5. Adherence to Antiretroviral Therapy

Medication adherence in perinatal HIV prophylaxis is complicated, beyond the practical difficulty of administering medication on a regular basis. Patterns of acceptance and adherence have not been investigated in depth, and little is known about specific adherence behaviours for the ZDV prophylactic regimen. The beliefs and psychosocial factors that influence the mother’s adherence behaviour (e.g., belief in drug efficacy, social support, home visits) need further elucidation. Since self-report usually overestimates medication adherence, physiological indices such as urine assay and mean corpuscular volume (MCV) of erythrocytes, can be employed to assess adherence. MCV has been frequently utilised as an indirect and objective index of long-term adherence to ZDV in prior studies because macrocytosis is a common side effect of consistent use (Samet et al.).

Perceptions of the efficacy of antiretroviral therapy can also be investigated because prior studies of adherence with antiretroviral therapy in industrialised countries have found that perceived efficacy was associated with greater adherence. The relationship of social network factors and demographic characteristics to adherence have not been systematically explored among pregnant women. Future research in this area could lead to the development of behavioural interventions tailored to the specific needs of HIV-infected pregnant women.

References on Adherence to Antiretroviral Therapy


9.6. Referral to support services

Implementation of a VCT capacity in a context where it was not available previously will lead to early identification of non-symptomatic HIV+ women and HIV affected families. Caring of HIV affected family members include long term components of health care, counselling and social support. Optimal follow-up of the mother’s health should be ensured according to national standards. In high prevalence areas a wide range of care and support activities may already be in place in the community. It will be important for counsellors to be aware of these resources and be able to make appropriate referrals. Counsellors must also be aware of the special medical needs of PLHA. The package of TB care (including TB screening and TB preventive therapy) may be available; in some countries ARV therapy is available, though often only for a minority. The spiritual needs of PLHA have been shown to be important in many countries and counsellors should be aware of these for referral.

Referrals to support services (medical, social and emotional, family planning services, STI services, antenatal services, home based care services and palliative care services), spiritual services and traditional healers, PLHA support groups, community groups and NGOs could be evaluated. An option for such an evaluation would be to add an indicator to the list of “core indicators”:

**Question:** “Are HIV-seropositive women being successfully referred for follow-up care and support?”
**Outcome Evaluation Indicator.** _Successful referral for follow-up care and support_

Definition: Proportion of HIV-infected women who have been to a support service for HIV-related follow-up care at least once in the first six months postpartum.

Data Requirements: Number of HIV-infected women, and of these, number who have been to a support service for follow-up care related to their HIV infection at each of 3 early postpartum timepoints.

Data Source: MCH Cards, intervention follow-up interview

Data Collection Timepoints: 1, 3 and 6 months postpartum.

Data Analysis Timepoints: every 6 months for the previous 6 months

Note: No comparison group is necessary for this indicator.

**Reference for Follow-up Sub-Section**

Greenberg JB, and Neumann MS. What we have learned from the AIDS evaluation of street outreach projects. US Department of Health and Human Services, Centers for Disease Control and Prevention.

TASO/WHO: TASO Uganda the inside story. WHO/GPA/HCS/95.1

9.7. **Incidence of HIV Infection among Women during Lactation**

Several studies conducted in countries participating in the pilot projects have shown a high incidence of HIV infection among women of childbearing age, especially among young women who were recently pregnant (Bulterys et al, Wawer et al.). As the primary stage of HIV infection appears more highly infectious, a sizeable portion of postnatal HIV transmission through breastfeeding may be due to incident HIV infections among initially HIV seronegative mothers (Jacquez, Van de Perre et al.). Sexual abstinence after childbirth, a traditional custom in many areas of West and Central Africa, may inadvertently contribute to a higher risk of incident HIV infection during lactation because postpartum abstinence may increase the probability that husbands will seek non-regular sexual partners (Cleland et al.).

9.7.1. **Question: What is the rate of HIV infection acquired during lactation?**

**Evaluation indicator:** _Incidence of HIV infection in lactating women_

Definition:
proportion of initially HIV(-) women who get HIV infection during lactation

Data requirements:
Prospective cohort study of initially HIV seronegative women to determine the incidence of HIV infection during lactation.

Methods for the determination of HIV incidence have been proposed in the context of preparation for HIV vaccine efficacy trials in the developing world (Heyward et al.). These methods are also relevant to determine the extent of maternal incident HIV infection during lactation. Since bias will occur if individuals lost to follow-up have differing risks from those retained, every effort should be made to retain as many individuals as possible in the cohort of initially seronegative women. A schedule of 6-month visits with appropriate incentives may be adequate for this purpose.

In-depth studies of sexual risk behaviour during the postnatal period and feasibility studies of
interventions designed to reduce such risk-taking behaviour among women and their sex partners could be devised to supplement other HIV prevention activities to be implemented by the pilot projects. Active promotion of condom use, decreasing the number of sex partners, and treatment of other sexually transmitted disease will be likely components of any intervention program aiming to reduce incident HIV infection among lactating mothers. Identifying culturally appropriate ways to involve the male partner in such HIV prevention activities will be crucial to their success.

References for Incidence of HIV Among Lactating Women


## Annex 1: Tools for Evaluation of counselling

The following check list can be used where VCT is offered as part of interventions to reduce MTCT of HIV. The following check lists suggests minimum contents and quality of pre and post-test counselling.

1. Observational study of pre-test content

<table>
<thead>
<tr>
<th>GROUP EDUCATION TOPICS</th>
<th>INDIVIDUAL COUNSELLING TOPICS</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1. HIV-Related Issues</strong></td>
<td><strong>1. HIV-Related Issues</strong></td>
</tr>
<tr>
<td>• Knowledge about HIV and transmission</td>
<td>• Assessment of personal risk of HIV exposure and how to avoid it (e.g., safer sex)</td>
</tr>
<tr>
<td>• Misconceptions about HIV transmission</td>
<td>• Capacity to cope with a positive result</td>
</tr>
<tr>
<td>• Misconceptions about HIV and transmission</td>
<td>• Potential needs and possible support</td>
</tr>
<tr>
<td>▪ Means for prevention</td>
<td>• Clarification of understanding about information given</td>
</tr>
<tr>
<td>• The HIV testing process</td>
<td>• Time to think through issues and for answering questions</td>
</tr>
<tr>
<td>• The ‘window period’</td>
<td>• Informed consent/dissent given freely</td>
</tr>
<tr>
<td>• The meaning and possible implications of +ve and –ve results</td>
<td>• Follow-up arrangements after counselling session</td>
</tr>
<tr>
<td>• The value of getting partner/father involved</td>
<td></td>
</tr>
<tr>
<td>• Potential needs and available support</td>
<td></td>
</tr>
<tr>
<td><strong>2. MTCT-Related Issues</strong></td>
<td><strong>2. MTCT-Related Issues</strong></td>
</tr>
<tr>
<td>• Full information about HIV in pregnancy and risk of transmission to the infant</td>
<td>• Implications of a positive result for the baby and for future children</td>
</tr>
<tr>
<td>• Possible benefits of knowing HIV status and interventions available if positive</td>
<td>• Implications of a positive result for decisions about infant feeding</td>
</tr>
<tr>
<td>• Testing is not mandatory and antenatal care and other services will not be denied if she decides not to be tested</td>
<td>• Implications of a positive result for the relationship with the baby’s father</td>
</tr>
<tr>
<td>• ARV therapy for MTCT is not a cure/treatment for mother</td>
<td>• Desirability of getting partner/father involved</td>
</tr>
<tr>
<td>• The need to attend maternity services regularly</td>
<td>• Options for TOP (if available legally and safely)</td>
</tr>
<tr>
<td>▪ Known adverse effects and drug interactions</td>
<td>• Previous ARV use</td>
</tr>
<tr>
<td>▪ Promotion of breastfeeding for mothers not known as HIV+</td>
<td>• Check for understanding</td>
</tr>
<tr>
<td>▪ Issues related to family planning</td>
<td></td>
</tr>
</tbody>
</table>
2. Observational study of post-test content
As with post-test counselling in other circumstances, results should always be given individually or to couples who were tested together. The following check list suggests minimum contents of post-test counselling

INDIVIDUAL COUNSELLING TOPICS

1. Breaking the News
   - Results given simply and clearly
   - Time allowed for result to sink in
   - Checking for understanding
   - Discussion of the meaning of the result for the client
   - Discussion of personal, family and social implications
   - Who to tell, and how to tell them
   - Managing immediate emotional reactions
   - Checking for immediate follow-up support outside the clinic
   - Review options and resources
   - Immediate plans, intentions and actions reviewed

2. MTCT-Related Issues
   - Explanation of the delivery processes (e.g., maintaining confidentiality through ARV administration in labour)
   - Implications of the positive result for the baby and for future children
   - Implications of the positive result for decisions about infant feeding (e.g., benefits and risks of breastfeeding) and information on feeding options
   - Information on family planning
   - Previous ARV use
   - Explanation of the ARV regimen and the role of ARVs
   - The need for medicines to be taken regularly and according to the regime

3. HIV-Related Issues
   - Implications of sharing the positive result for the relationship with the baby’s father, and the family
   - Desirability of getting the father involved in counselling and follow-up
   - Information about safer sex and using condoms to prevent transmission of HIV and STIs
   - Options for TOP (if available legally and safely)
   - Information about care of the child (including nutritional advice, seeking early treatment for illnesses)
   - Information on support services in the community

   - Check for understanding
   - Next appointment made (possibly with partner)
3. **Counsellor skills**
The following check lists suggests a minimum quality for pre and post-test counselling skills.

<table>
<thead>
<tr>
<th>FUNCTION</th>
<th>SKILLS</th>
</tr>
</thead>
</table>
| 1. **Interpersonal Relationship** | Introduces self  
                             | Listens actively and supportively  
                             | Non-judgmental |
| 2. **Information-gathering**       | Uses open questions  
                             | Seeks clarification  
                             | Summarizes appropriately |
| 3. **Information-giving**         | Clear and simple  
                             | Gives time to respond  
                             | Checks for (mis)understanding  
                             | Summarizes appropriately |
| 4. **Special Circumstances**     | Appropriate and sensitive discussion  
                             | Prioritises issues with the client  
                             | Manages client distress sensitively and appropriately  
                             | Flexible in involving partner |

4. **Assessing acceptance of counselling in MCH settings with exit interviews**

This is a semi-structured interview. It aims to help assess client satisfaction in counselling, and should be administered by a trained researcher. It should be used on a convenience sample of, e.g., all people receiving counselling within a specific period (e.g., 1 week), who have agreed to be interviewed in this way when asked previously by their counsellor. If the numbers are too large, random sampling may be used at specific periods each day through the week.

**The exit interview should be voluntary, undertaken in privacy and confidentiality assured.**

Have you talked to your counsellor today about (you may answer more than one):

I. Having an HIV test Yes No
II. Receiving test results Yes No
III. Issues associated with having been tested some time ago Yes No
IV. The health of your baby Yes No

Did you come specifically to discuss testing for HIV? Yes No
Did you come specifically to discuss receiving treatment to protect your baby from HIV? Yes No

How long did you wait for your first appointment to visit the Clinic? ___________ days
How long did you wait before someone talked with you in the Clinic? ___________ mins
How much time did you spend with your counsellor today? ___________ mins
How many visits have you made to your counsellor at this Clinic? ___________ visits
Did you feel comfortable with your counsellor? Yes No
Was there enough privacy during your counselling? Yes No
What were the good things about your counselling?
________________________________________________________________________________
________________________________________________________________________________
What were the bad things about your counselling?
________________________________________________________________________________
________________________________________________________________________________
What information did you receive from the counsellor?
________________________________________________________________________________
Did you see the same counsellor before and after the test? Yes No
Did you want to see a particular counsellor this time (a specific person)? Yes No
Would you recommend using this service to a friend or family member? Yes No
Why? ________________________________________________________________________
_______________________________________________________________________________
_______________________________________________________________________________
Annex 2 : Verbal autopsy questionnaire

1. Background information from death reporter:

Death reporter’s code number :
Address of household :
Name of the child :
Sex of the Child
Date of report:

2. Injury

Child’s age at the time of death:
Did … die from an injury, bite, poisoning or drowning?
If yes: What kind of injury?
(Motor vehicle accident, fall, drowning, poisoning, Bite or sting by venomous animals, burn, violence, birth injury, other)
   Did … die within 24 hours of this injury?

*If the child died within 24 hours, stop interview*

3. Neonatal deaths (before 28 days of life)

3.1 Child’s age in days at the time of death:
3.2 Did the pregnancy end early, on time, or late?
3.3 Did the waters break before labor? (if yes, how much time before: less or more than 1 day?)
3.4 How much time did the labor/delivery take (less or more than 12 hours?)
3.5 Did … have any malformations at birth? If yes where (head, body, arms, legs)?
3.6 At the time of birth was … very small? Smaller than usual? About average? Larger than usual?
3.7 Was … able to breath after the birth?
3.8 Was … able to suckle after birth? If yes, did … stop suckling? How many days after birth?
3.9 Was … able to cry after birth? If yes, did … stop crying? How many days after birth?

During the illness that led to death,
3.10 Did … have spasms or convulsions?
3.11 Did … become unresponsive/unconscious?
3.12 Did … have a bulging fontanelle?
3.13 Did … have redness or drainage from the umbilical cord stump?
3.14 Did … have a skin rash with bumps containing pus?
3.15 Did … have a fever? If yes, how many days did the fever last?
3.16 Did … have frequent liquid, watery or loose stools?
3.17 Did … have diarrhea? If yes for how many days? Was there visible blood?
3.18 Did … have a cough? If yes, for how many days?
3.19 Did … have difficult breathing?
3.20 Did … have fast breathing?
3.21 Did … have indrawing of the chest?
4. Post-neonatal deaths (death at 28 or more days of age)

4.1 Child’s age in completed months

During the illness that led to death,
4.2 Did … have a fever? If yes, how many days did the fever last?
4.3 Did … have frequent liquid, watery or loose stools?
4.4 Did … have diarrhea? If yes for how many days? Was there visible blood?
4.5 Did … have a cough? If yes, for how many days?
4.6 Did … have difficult breathing?
4.7 Did … have fast breathing?
4.8 Did … have indrawing of the chest?
4.9 Did … experience any generalized convulsions?
4.10 Was … unconscious?
4.11 Did … stop being able to grasp? How long before death?
4.12 Did … stop being able to respond to a voice? How long before death?
4.13 Did … stop being able to follow movements with his/her eyes? How long before death?
4.14 Did … have a stiff neck?
4.15 Did … have a bulging fontanelle?
4.16 Did … have a skin rash? Where (face, body, legs, arms)? For how many days?
4.17 Did … bleed into his/her skin or from any opening?
4.18 Was … very thin during the month before (s)he died?
4.19 Did … have swollen legs or feet?
4.20 Did … have “kwashiorkor”
4.21 Did … have pale palms?
4.22 Did … have white nails?
CRITERIA FOR DIAGNOSES BY VERBAL AUTOPSY

**Pneumonia**
- either cough or difficult breathing, and either fast breathing or chest indrawing

**Acute diarrhea**
- frequent liquid, watery, loose stools or diarrhea for less than 14 days, and no blood in the stools

**Acute dysentery**
- frequent liquid, watery, loose stools or diarrhea for less than 14 days, and blood in the stools

**Persistent diarrhea**
- frequent liquid, watery, loose stools or diarrhea for more than 14 days, and no blood in the stools

**Persistent dysentery**
- frequent liquid, watery, loose stools or diarrhea for more than 14 days, and blood in the stools

**Measles**
- at least 4 months old, and fever and rash for 3 or more days, and rash on the face

**Severe malnutrition**
- 28 or more days old who was very thin or had swollen legs/feet or had kwashiorkor

**Meningitis**
- neonate with fever and bulging fontanelle, and either convulsions or unresponsive/unconscious
  - Postneonate with fever, and either stiff neck or bulging fontanelle, and either convulsions, unconscious, stopped being able to grasp, stopped being able to follow movements with eyes, or stopped being able to respond to a voice (all for more than 12 hours)

**Bacteremia/septicemia**
- neonate in whom the waters broke more than one day before labor or had redness or drainage of the umbilical cord stump or had a skin rash with bumps containing pus, and fever, and no pneumonia/meningitis
  - Postneonate with fever, and one or more of the following signs: unconscious, stopped being able to grasp, stopped being able to follow movements with eyes, or stopped being able to respond to a voice, and no pneumonia/meningitis

**Dengue fever**
- postneonate with fever and hemorrhage from an orifice or into the skin

**Malaria**
- postneonate with fever, and no stiff neck, and no bulging fontanelle, and no measles, and either convulsions, unconscious, stopped being able to grasp, stopped being able to follow movements with eyes, or stopped being able to respond to a voice (all of the last 3 for more than 12 hours) or difficult breathing.

**Injury**
- death due to an injury sustained after birth and not a birth injury

**Birth trauma**
- neonate who died of a birth injury
Birth asphyxia  neonate who was not able to breathe after birth, and had no fever and had one or more of the following signs: convulsions/spasms or not able to suckle in a normal way after birth or not able to cry after birth

Low birth weight/prematurity  neonate whose pregnancy ended early or was very small at birth

Congenital malformation  neonate who was malformed at birth

Neonatal tetanus  neonate who was able to suckle and cry normally at birth, and stopped suckling or crying at more than 2 days of age, and had either spasms or convulsions. The diagnosis of neonatal tetanus should not be made in the presence of birth asphyxia or birth trauma