

# Technical Guidance Note for Global Fund HIV Proposals



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## Prevention of Mother-To-Child Transmission of HIV

September 2011

**This technical guidance note provides practical advice to consultants and country teams working on the development of Global Fund proposals on how to integrate prevention of mother-to-child transmission of HIV (PMTCT) efforts into the AIDS component of the applications.**

**This document gives an overview of the core information on PMTCT programming along with recent updates and developments on the *Global Plan to Eliminate New HIV Infections among Children by 2015 and Keeping Their Mothers Alive*<sup>1</sup>. In addition, the guidance reinforces key messages and provides concrete examples for various technical elements that the country teams may find helpful in elaborating details of the Service Delivery Area**

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1. [http://www.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2011/201110609\\_JC2137\\_Global-Plan-Elimination-HIV-Children\\_en.pdf](http://www.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2011/201110609_JC2137_Global-Plan-Elimination-HIV-Children_en.pdf)

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## A. Introduction

Most countries have programmes to prevent mother-to-child transmission of HIV and are scaling-up their programmes to provide comprehensive prevention, care and support to women, and their children and families. WHO recently revised its guidelines on the use of antiretroviral drugs to prevent MTCT and on HIV and infant feeding. The revised recommendations propose earlier initiation of antiretroviral treatment for larger group of pregnant women living with HIV to benefit both the health of the mother and maximally reduce HIV transmission to her child. In addition, they recommend provision of one of two highly effective ARV prophylaxis options earlier in pregnancy for expectant women living with HIV who do not need antiretroviral treatment for their own health. Particular emphasis is given to provision of ARV prophylaxis to the mother or the child to reduce the risk of HIV transmission during the breastfeeding period.

The recent launch of the *Global Plan for Elimination of New HIV Infections Among Children by 2015 and Keeping Their Mothers Alive*<sup>2</sup> and the commitment from UN member states, donors and implementing partners to achieve these ambitious goals lends even greater importance to PMTCT activities within Round 11 of the Global Fund to Fight AIDS, TB and Malaria. In the context of the development of the proposal, countries need to define the status of implementation of the PMTCT programme, and identify financial and implementation gaps. This will ensure additionality and complementarity of the potential resources from Global Fund to the various in-country initiatives and funding opportunities from the national government and partners.

The national PMTCT technical working group should bring together partners in sexual and reproductive health (SRH), maternal, newborn and child health (MNCH), national HIV and nutrition programme managers as well as the civil society, NGOs, peoples living with HIV and key donors and implementing partners. A sub-set of this group should be tasked full-time with developing the health systems strengthening component to be included in the general proposal. The PMTCT technical working group should work as a subgroup of the larger team in charge of developing the HIV proposal.

The technical working group should work in a consultative and inclusive manner and may be especially useful in conducting the situation and response analysis. Before starting the development of the proposal, it is essential to review the comments of the technical review panel on the previous proposals. This will help to identify and analyse the weaknesses of the previous proposal and to properly address the issues raised in the current proposal.

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<sup>2</sup> UNAIDS 2011. Global plan towards the elimination of new HIV infections among children by 2015 and keeping their mothers alive. See link [http://www.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2011/20110609\\_JC2137\\_Global-Plan-Elimination-HIV-Children\\_en.pdf](http://www.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2011/20110609_JC2137_Global-Plan-Elimination-HIV-Children_en.pdf)

## B. Analysis of the Current Situation and the National Response to mother-to-child transmission of HIV

The situation analysis is a critical step in the development of the Global Fund proposal. The main objectives of the analysis are:

- ◆ To define the magnitude of the HIV epidemic among women and children and the status of implementation of the PMTCT programme at policy, normative and service delivery levels;
- ◆ To inform the specific programme strategy for the proposal;
- ◆ To map out partners supporting the national programme and their specific contributions;
- ◆ To identify policy, programmatic and funding gaps;
- ◆ To identify health system bottlenecks in the performance of PMTCT (and other related) programmes;
- ◆ To identify gender, equity and rights issues as impediments for scaling-up PMTCT;
- ◆ To identify the level of performance and technical issues related to the implementation of previous Global Fund grants;
- ◆ To identify and analyse reasons for failure of previous Global Fund proposals;

The following programme elements should be considered in the situation and response analysis

### Box 1. Programme elements to be considered in PMTCT Service Delivery Area

1. **Clinical and immunological assessment of pregnant women** in the context of PMTCT, including in antenatal settings, to determine the ART eligibility of a pregnant woman, and provide either antiretroviral prophylaxis or treatment.
2. **Integration and of PMTCT and HIV care & treatment for women and infants** in order to ensure that pregnant women who require antiretroviral treatment either during or after their pregnancy get the services they need, and also that infants exposed to HIV infants receive appropriate care.
3. **Provider initiated testing and counselling** in antenatal, delivery and postnatal care settings delivered in the same settings using rapid test kits.
4. **Couples HIV testing** including encouraging testing of couples together
5. **Use more efficacious regimens:** Countries still using single-dose nevirapine (sd-NVP) should move to more efficacious ARV regimens, including antiretroviral treatment for pregnant women as clinically indicated and consistent with the 2010 WHO guidelines; the use of sd-NVP for PMTCT is no longer recommended
6. **Co-trimoxazole prophylaxis** for pregnant women living with HIV and all HIV-exposed infants (infants born to women living with women)
7. **Early Infant Diagnosis (EID)** of HIV-exposed infants by virological test/polymerase chain reaction (PCR), including through dried blood spot (DBS) technology.
8. **Provision of primary prevention services** in the context of PMTCT at health facilities (especially in antenatal and early postnatal care settings) as well as at community levels, in order to help HIV-negative women remain HIV-negative.
9. **Provision of family planning services to all women who need it, including those living with HIV**, in the context of PMTCT (especially in postnatal care settings) as well as at community levels, in order to help women avoid unintended pregnancies.

## B1. Baseline demographic and epidemiological data for the proposal

- ◆ Proportion of people living with HIV who are women (*please include sex ratio and show trends if any among women*)
- ◆ Number of pregnant women or annual births
- ◆ Proportion of people living with HIV on antiretroviral treatment who are women
- ◆ Proportion of people living with HIV on antiretroviral treatment who are *pregnant* women
- ◆ Background infant mortality rates
- ◆ Number of children infected with HIV and the proportion of persons living who are children
- ◆ Estimated number of pregnant women living with HIV giving birth each year
- ◆ HIV prevalence among pregnant women or women attending antenatal care
- ◆ Proportion of pregnant women attending antenatal care settings at least once
- ◆ Proportion of pregnant women attending antenatal care settings at least 4 times
- ◆ Number and proportion of children living with HIV in need of treatment
- ◆ Number and proportion of children living with HIV in need of treatment who receive it
- ◆ Proportion of deliveries assisted by a skilled birth attendant
- ◆ Rate of mother-to-child transmission of HIV in the absence of any interventions
- ◆ Proportion of women practicing exclusive breastfeeding, mixed feeding, or replacement feeding up to 6 months
- ◆ Number of health facilities providing integrated PMTCT, maternal, newborn and child health services, and reproductive health services
- ◆ Number of districts with strengthened DHMT on leadership and management of health systems

## B2. Review of the national response to mother-to-child transmission of HIV

1. Summary of the nationally adopted goals, targets and strategic priorities for PMTCT with relevant references to the major guiding documents (National strategic plans, Health sectoral programmes, national health policies, national PMTCT policies or guidelines, national PMTCT scale up plans, policies on health services integration etc.)
2. Status of PMTCT response: analysis of the current status of the national PMTCT response and trends in reaching the national targets; current response based on the following facility- and population-based indicators for PMTCT summarized in Annex 1 (see also section C9)
3. Description of the national policies, guidelines and protocols in place for PMTCT within the overarching context of the reproductive and child health programmes. These may include:
  - ◆ Antenatal, childbirth and post-partum care (including any policies on free care)
  - ◆ Postnatal care for infants and children
  - ◆ General policies and standard operational procedures for PMTCT services, including the description of the ARV regimens adopted for the national PMTCT programmes
  - ◆ HIV testing and counselling in the context of PMTCT (PITC in antenatal, delivery and postnatal care settings)
  - ◆ Human resource management including task shifting in the context of PMTCT
  - ◆ Infant and young child feeding
  - ◆ Sexual and reproductive health for women living with HIV
  - ◆ Policies on gender mainstreaming for health programmes, integration of services if any

Where relevant highlight the strengths and opportunities of the current policy and normative context, as well as the critical gaps in national policies, guidelines or protocols hindering progress of the PMTCT programme in the country.

## C. Formulating the PMTCT service delivery area section within the country application

### C1. Rationale for including PMTCT in the proposal – key messages:

#### Box 2. Basic questions to be kept in mind

1. What? (Magnitude of the problem – programmatic and financial gaps)
2. Who (Target / beneficiary populations)
3. When (Timelines)
4. Where (geographical coverage – catchments areas)
5. How (Programme strategies to address the issues)

- ◆ Women make up about half of the burden of people living with HIV globally. *Use national figures*
- ◆ HIV contributes to overall maternal mortality and morbidity. PMTCT will help countries in achieving Millennium Development Goals (MDGs) 4, 5 and 6. *Use national figure (e.g. HIV is one of the main causes of maternal mortality – HIV is the leading cause of mortality among adults)*
- ◆ Pregnant women as a group have extremely low rates of antiretroviral treatment coverage – only 15% of pregnant women in need of treatment are currently receiving it. Women who are eligible for treatment contribute more than 75% of all new paediatric infections. Thus, improving access to antiretroviral treatment for pregnant women would not only reduce maternal mortality but also markedly reduce new infections in children (see section on health systems strengthening and cross-cutting interventions)
- ◆ Over 90% of new infections in infants and young children occur through mother-to-child transmission. Without any interventions, between 20% and 45% of infants may become infected, but this risk can be reduced to less than 2% in a non-breastfeeding population by a package of evidence-based interventions. *Use national data*
- ◆ PMTCT is a critical gateway to treatment for children. In many countries, children are only half as likely to get treatment as adults. Indeed infants are only two thirds as likely as their mothers to have received their own dose of ARVS for PMTCT.
- ◆ Large scale implementation of provider-initiated testing and counselling in the context of PMTCT in most resource-limited countries is the unique opportunity for a majority of women to know their HIV status. It also provides the opportunity to recommend HIV testing and counselling to their male partners, their children and families
- ◆ PMTCT is not only about the provision of ARV prophylaxis. Through implementation of its 4 components there is a unique opportunity to address HIV prevention, care, treatment and support needs of women, their infants and families. Comprehensive PMTCT is an opportunity to improve maternal, newborn and child health and survival
- ◆ Effective integration and implementation of PMTCT interventions within MCH services will strengthen the health system and improve outcomes in all mothers and children in the community
- ◆ PMTCT is the main gateway to HIV care and treatment for women (see section on health systems strengthening cross-cutting interventions)
- ◆ Adopting and supporting the revised WHO recommendations for HIV and infant feeding can improve feeding practices among all infants and reduce serious morbidity and contribute to improved child survival in the entire population

## C2. Addressing PMTCT while describing the national prevention, treatment, care and support strategies

### 1. Guiding principles of the national programmes

- a. Improved coordination (coordination bodies and mechanisms involving key national programmes, civil society and non-governmental organizations, organizations of persons living with HIV, and other partners)
- b. Decentralization of PMTCT services to primary facilities and community level: for example scaling-up based on a district-based approach
- c. Integration of HIV prevention, care and treatment with maternal, newborn and child health services: HIV, TB, MNCH services including child health (particularly expanded program on immunization), nutrition and sexual and reproductive health services (especially family planning)

### 2. Institutional framework and national strategic orientations

Briefly describe

- a. The national coordination bodies and mechanisms
- b. The key elements of the national response focusing on the national health policy and national strategic plan – specify how PMTCT is positioned as a priority in the national strategic plan
- c. How the country is performing with respect to MDGs goals, and targets for the elimination of new HIV child infections
- d. Local and regional initiatives (how PMTCT and the broader issue of women and children needs are positioned in these initiatives)
- e. Contribution of development partners to the national response (make sure supports to PMTCT and paediatric HIV care, treatment and support are mentioned)

## C3. Linking PMTCT to the proposal objective

Under the broader proposal goal, the service delivery area should have specific that cover PMTCT and are linked to the proposed monitoring and evaluation framework (See Annex A, Indicators) – for example

- ◆ To prevent HIV infection among pregnant women, mothers, their children and families by increasing access to HIV prevention services
- ◆ To reduce maternal mortality and morbidity
- ◆ To reduce HIV transmission among children
- ◆ To reduce infant mortality related to diarrhoea and malnutrition secondary to inappropriate feeding practices
- ◆ To reduce stigma and discrimination among people living with HIV
- ◆ To increase the number of women who know their HIV status through the implementation of provider-initiated HIV testing and counselling

**Box 3. Global burden of PMTCT**

The 22 highest-burden countries for PMTCT are: Angola, Botswana, Burundi, Cameroon, Chad, Côte d'Ivoire, Democratic Republic of the Congo, Ethiopia, Ghana, India, Kenya, Lesotho, Malawi, Mozambique, Namibia, Nigeria, South Africa, Uganda, United Republic of Tanzania, Swaziland, Zambia and Zimbabwe. In these countries, accelerated PMTCT activities are needed to enable the global attainment of towards the elimination of new infections among children by 2015.

**C4. Targets for the elimination of new HIV child infections**

Over the past decade, countries have made impressive progress in rolling out programmes to stop new HIV infections among children. There is now global consensus that elimination of new HIV infections in children by 2015 is a feasible goal and one that the world must strive towards. In 2010, the WHO released new guidelines for antiretroviral drugs for PMTCT, and provided an evidence-based rationale to address not only perinatal transmission but also the large numbers of infant infections that are acquired during breastfeeding. In November 2010 WHO, UNAIDS, UNICEF and UNFPA convened a technical consultation to provide further guidance on working definitions of 'elimination', appropriate goals for elimination of new HIV infections among children, and an operational framework to scale up PMTCT in order to achieve these goals<sup>3</sup>.

The *Global Plan Towards the Elimination of New HIV Infections Among Children by 2015 and Keeping their Mothers Alive*<sup>4</sup> established strategic targets across each of the four PMTCT prongs that together would enable a national program to work towards the ambitious goal of an overall 90% reduction in the number of new child HIV infections (using end 2009 statistics as a baseline). These targets include a 50% reduction in AIDS-related maternal deaths, a reduction in the overall, population-based HIV transmission rate to 5% or less (<2% in the absence of breastfeeding or as measured at 6 weeks) and a 50% reduction in infant deaths due to HIV. While not all targets directly address the prevention of new paediatric HIV infections (although there is important overlap with Prong 3 on the provision of antiretroviral treatment to eligible pregnant women), it addresses the important linkage to maternal and child health outcomes and the need to link to long-term care and treatment beyond the time frame covered by PMTCT programmes

3 [www.who.int/hiv/pub/mtct/elimination\\_report/en/index.html](http://www.who.int/hiv/pub/mtct/elimination_report/en/index.html).

4 [http://www.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2011/20110609\\_JC2137\\_Global-Plan-Elimination-HIV-Children\\_en.pdf](http://www.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2011/20110609_JC2137_Global-Plan-Elimination-HIV-Children_en.pdf)

**Box 4. Specific elimination targets for each of the PMTCT prongs****Overall Targets:**

- ◆ Reduce the number of new HIV infections among children by 90%.
- ◆ Reduce the number of AIDS-related maternal deaths by 50%.

**Prong 1:** Reduce HIV incidence by 50% in women of reproductive age (15–49 years). Achieving significant reductions in new infections among women will help reduce the number of pregnant women living with HIV and consequently reduce the number of infants at risk of HIV acquisition

**Prong 2:** Reduce unmet family planning needs to zero among all women including women living with HIV. This is already a key MDG goal for maternal health

**Prong 3:**

- 3.1) Reduce the overall MTCT rate to <5% (<2% in the absence of breastfeeding or if assessed in infants at 6 weeks of age). The target is based on what can be achieved with high levels of coverage of both ART and ARV prophylaxis.
- 3.2) 90% of pregnant women living with HIV mothers receive perinatal antiretroviral therapy or prophylaxis.
- 3.3) 90% of breastfeeding infant-mother pairs receive antiretroviral therapy or prophylaxis

**Prong 4** - Provide 90% of pregnant women in need of antiretroviral therapy for their own health with life-long antiretroviral therapy.

- Reduce AIDS related infant deaths by >50%

A summary of the targets and indicators can be found on p.39 of the *Global Plan towards the elimination of new HIV infections among children by 2015 and keeping their mothers alive*, and more information can be found in *Global Monitoring Framework and Strategy for the Elimination of New Child HIV Infections By 2015 and Keeping Their Mothers Alive*.

## C5. Setting SMART (specific, measurable, attainable, realistic timely) targets for the PMTCT response

**Box 5. Example of a SMART target**

At least 90% of all pregnant women attending ANC (11,500) in the selected 150 health facilities serving 70 health districts will be tested for HIV and 80% of those tested positive receive ARVs (ARV prophylaxis or ART) by 2012

Keep in mind the relevant **geographic** or **population-based** indicators while setting targets for the PMTCT response within a specific time period. **Ideally national targets should be population-based. It is worthwhile to provide the geographical reach of the proposal and the size of the population**

**Box 6. Using districts as baseline units to define targets & programmatic needs**

1. Identify target districts
2. Define population-based targets for each of the selected districts
3. Conduct a mapping of partners and resources
4. Identify key programmatic and financial gaps



## C6. Defining implementation strategies – Decentralized approach to implementation

Empowering sub-national bodies as the driving forces is essential in ensuring national ownership, defining targets, improving coordination of partners and engaging communities, to ensure implementation of national programmes. Many countries have developed national scale-up plans which are used to guide and leverage and mobilize necessary resources for scaling up national programmes. In this process, health districts are required to develop district plans for implementation of PMTCT, infant feeding and paediatric HIV care, treatment and support.

The **scale-up strategy should be based on a district-driven approach and use districts as baseline units** to determine national targets, map partners and available resources, identify financial and programmatic gaps, and overall needs to be addressed through the proposal (See Box 6).

## C7. Main activities to be considered

The key principles and key entry points of the comprehensive PMTCT programmes are outlined below. Refer to Table 5, for the interventions and activities to be considered in defining the PMTCT service delivery area.

### Box 7. Principles of a comprehensive PMTCT approach

The UN promote a comprehensive approach to the prevention of HIV infection in infants and young children which addresses a broad range of HIV-related prevention, care, treatment and support needs of pregnant women, mothers, their children and families. This comprehensive approach includes:

**Prong 1:** Primary prevention of HIV infection among women, especially young women

**Prong 2:** Prevention of unintended pregnancies among women living with HIV

**Prong 3:** Prevention of HIV transmission from women living with HIV to their infants through the provision of prophylactic antiretroviral drug regimen for the woman and her newborn, safe obstetric practices, and counselling and support for the mother on the infant feeding options adopted by national authorities, and

**Prong 4:** Provision of care, support and treatment for mothers living with HIV, their infants and families

At health sector level, PMTCT services are provided in facilities targeting pregnant women, mothers and children.

- |   |   |   |
|---|---|---|
| 1. All women (including adolescents)                    | → | primary prevention of HIV infection             |
| 2. Women living with HIV                                | → | prevent unintended pregnancy                    |
| 3. Pregnant or breastfeeding women living with HIV      | → | prevent HIV transmission                        |
| 4. Women living with HIV, their infant and their family | → | provide treatment, care and support             |
| 5. Males, particularly the partner                      | → | provide prevention, treatment, care and support |

Key entry points include antenatal clinics, maternal and child health clinics, family planning facilities, as well as HIV care and treatment clinics (for adults and children), sexually transmitted infections. Additional entry points may include child immunization; gender-based violence; youth-friendly, community-based outreach; prevention and treatment for drug users; support groups of people living with HIV, tuberculosis, well-baby follow-up, post-abortion care, workplace, etc.

Although these services are primarily provided at the health facility level their full implementation requires strong linkages with communities. Some of these interventions and services will even be delivered within the communities through various approaches. Table 1 lists some key activities to be considered for inclusion within a proposal in the context of a comprehensive approach.

Table 1. Key activities to provide comprehensive PMTCT

| Prongs   | Key activities to be considered   |   |
|--|---|---|
| Primary prevention of HIV infection among women of reproductive age  | <ul style="list-style-type: none"> <li>◆ HIV information and education in antenatal, delivery and postnatal care settings</li> <li>◆ HIV testing and counselling (provider-initiated testing and counselling) – <i>This includes couple HIV testing and counselling</i></li> <li>◆ Retesting of pregnant women in high prevalence settings (and where and when feasible)</li> <li>◆ Safer sex practices, including dual protection – Prevention of HIV and other sexually-transmitted infections as well as preventing unintended pregnancies through the promotion and distribution of condoms</li> <li>◆ Screening and treatment for sexually-transmitted infections (especially in antenatal settings)</li> <li>◆ Prevention with positives (couple testing and counselling, condom promotion and distribution of condoms)</li> </ul>  |   |
| Prevention of unintended pregnancies among women living with HIV   | <ul style="list-style-type: none"> <li>◆ Family planning counselling and services (<i>Point of service provision to be considered: antenatal and post-partum care settings; family planning clinics; HIV care/ antiretroviral treatment centers/clinics</i>)</li> <li>◆ Introduction of HIV testing and counselling in reproductive health and family planning services</li> <li>◆ Safer sex practices, including dual protection (condom promotion and distribution)</li> <li>◆ Positive health, dignity and prevention programs including prevention with positives (couple testing and counselling, condom promotion and distribution of condoms)</li> </ul>   |   |
| Prevention of HIV transmission from women living with HIV to their infants   | <ul style="list-style-type: none"> <li>◆ Good quality antenatal and delivery care (all components) – including prevention and treatment of malaria, diagnosis and treatment of tuberculosis, and congenital syphilis, and isoniazid preventive therapy after excluding active TB.</li> <li>◆ Provider initiated HIV testing and counselling in antenatal and delivery care settings.</li> <li>◆ Clinical (staging) and immunological (CD4) assessment of pregnant women testing HIV-positive. (<i>Where, when and by whom services will be provided?</i>)</li> <li>◆ Antiretroviral treatment for pregnant women eligible for treatment for their own health.</li> <li>◆ Antiretroviral prophylaxis for prevention of mother-to-child transmission of HIV for women not eligible for antiretroviral treatment. It is critical to ensure that the activities noted in the proposal are in keeping with the antiretroviral prophylaxis strategy selected by the national programme. For example, programmes that chose 'Option A' in a breastfeeding population should ensure that systems to follow infants exposed to HIV and provide continuous access to nevirapene are described clearly.</li> <li>◆ Safer obstetric practices, birth planning and emergency preparedness.</li> <li>◆ Infant feeding counselling and support.</li> </ul> |   |
| Provision of appropriate treatment, care and support to women living with HIV and or syphilis, mothers, their infants and their families | <b>Package of services for mother</b>   | <b>Package of services for children exposed to HIV</b>  |
|  | <ul style="list-style-type: none"> <li>◆ Antiretroviral treatment for women eligible for treatment</li> <li>◆ Co-trimoxazole prophylaxis</li> <li>◆ Continued infant feeding counselling and support</li> <li>◆ Nutritional counselling and support</li> <li>◆ Post-natal care within 4-6 weeks</li> <li>◆ Sexual and reproductive health services including family planning</li> </ul>   | <p>Routine child health care services:</p> <ul style="list-style-type: none"> <li>◆ Routine immunization and growth monitoring and support</li> <li>◆ Continued infant feeding counselling and support</li> <li>◆ Screening and management of congenital syphilis</li> <li>◆ Screening and management of tuberculosis</li> <li>◆ Prevention and treatment of malaria</li> </ul> <p>HIV-related package of interventions:</p> <ul style="list-style-type: none"> <li>◆ Antiretroviral prophylaxis</li> </ul> |

|  |   |  |
|--|---|--|
|  | <ul style="list-style-type: none"> <li>◆ Psychosocial support</li> <li>◆ Screening for TB</li> <li>◆ Isoniazid preventive therapy after excluding active TB</li> <li>◆ HIV screening of partner and of the other children in the family</li> </ul>  | <ul style="list-style-type: none"> <li>◆ Co-trimoxazole prophylaxis starting at 6 weeks</li> <li>◆ Early diagnosis with virological tests if available</li> <li>◆ Antibody testing at 9-12-18 months where virological testing is not available</li> <li>◆ Antiretroviral treatment for eligible HIV infected children</li> <li>◆ Symptom management and palliative care if needed</li> <li>◆ Nutrition care and support</li> <li>◆ Psychosocial care and support</li> </ul> |
| <b>Health systems strengthening</b>    | Improve the organization and management of health services focusing on human resources for health, health technologies (equipment, medicines) health information, health financing, and leadership and management   |  |
| <b>Community systems strengthening</b> | <ul style="list-style-type: none"> <li>◆ Establish peer support group</li> <li>◆ Community outreach activities</li> <li>◆ Building capacity of civil society, associations of people living with HIV</li> <li>◆ Working with the media, including at local and sub-national levels</li> <li>◆ Strengthening linkage between health facilities and community-level interventions</li> <li>◆ Intervention of community-based workers at health facility level</li> </ul> <p><b>Consider involvement of community-based workers in the provision of services related to HIV testing and counselling, infant feeding and counselling, co-trimoxazole prophylaxis and early infant diagnosis</b></p> |  |

A recently developed WHO 'adaptation guide' may serve as a useful resource for proposal development. The document advocates for a more integrated approach to adapting recommendations and delivering services across all of the five recent guidelines including PMTCT. It contains frequently asked technical questions related to the guidelines, and has practical examples of adaptation and implementation of the recommendations. Several of these case studies provide examples of ways in which PMTCT recommendations have been implemented at the national level. The adaptation guide is envisaged as a 'live' document which will be updated in the light of new programmatic experience. The adaptation guide and associated case studies can be accessed at [http://www.who.int/hiv/pub/who\\_normative/en/index.html](http://www.who.int/hiv/pub/who_normative/en/index.html).

## C8. Key programme interventions

### Criteria for indication of ART in pregnant women

- ◆ Women with CD4 < 350 cells/mm<sup>3</sup> regardless of clinical stage
- ◆ Women with clinical stage 3 or 4 regardless of CD4

### Example of how to describe the regimen in the proposal

- ◆ All eligible pregnant women living with HIV (approximately 20-25% of all pregnant women living with HIV) will receive antiretroviral treatment for their own health according to the national guidelines. The first line antiretroviral therapy regimen recommended for these women is: (*insert national antiretroviral regimen*). In the case of major side-effects, the recommended alternative regimens are: (*insert national regimen*). Infants born to women living with HIV on antiretroviral therapy will receive (*insert national regimen*).

- ◆ All pregnant women living with HIV and who were already on antiretroviral treatment when they got pregnant will continue with antiretroviral treatment. Do not give efavirenz in the first trimester.
- ◆ Pregnant women living with HIV but not eligible for antiretroviral treatment yet will receive a combination prophylactic regimen for the PMTCT. The combination regimen consists of (*insert national regimen*). The child will receive (*insert national regimen*) depending on the national infant feeding policy

### Example of how to describe infant feeding counselling and support in the proposal

- ◆ All women attending antenatal clinics will be advised regarding the infant feeding practice and associated antiretroviral drug interventions that will be supported through the maternal and child health services. Mothers living with HIV will be counselled on the effectiveness of ARV interventions to reduce post-natal transmission and how breastfeeding can improve the chances for HIV-exposed infants to survive while remaining HIV-free. Mothers living with HIV will be supported to take or provide ARV interventions to prevent HIV transmission and also practice optimal infant feeding practices.

### Example how to describe co-trimoxazole prophylaxis guidelines in the proposal

According to the national guidelines, which are in line with WHO guidelines:

- ◆ All pregnant women living with HIV will receive co-trimoxazole prophylaxis (*insert national regimen*)
- ◆ All HIV-exposed children (children born to women living with HIV) will also receive co-trimoxazole prophylaxis (*insert national regimen*) starting at 4-6 weeks of age until they are no longer breastfed and their HIV infection has been definitively excluded

## C9. Key indicators and tools for programme monitoring and evaluation

Updated monitoring and evaluation guidance towards the elimination of new HIV child infections has been included in three sets of tools developed by WHO and partners<sup>5</sup>.

1. ***Global monitoring framework and strategy for the elimination of new HIV child infections by 2015:*** This outlines the global 2015 targets for elimination of new HIV child infections and related recommended indicators to report progress towards the goals. This document can be used by policy makers and other stakeholders who need a quick overview of monitoring of progress in elimination of new HIV child infections.
2. ***Monitoring and evaluating the prevention of mother-to-child transmission of HIV: A guide for national programmes*** This is a detailed guide providing a list of harmonized indicator descriptions recommended for national PMTCT programme monitoring, with details and examples of national and sub-national monitoring, data use, considerations when setting up registers and reporting forms and recommendations for revising or implementing a functional PMTCT monitoring and evaluation system. This document can be used by PMTCT and monitoring and evaluation officers who need to set up a PMTCT monitoring and evaluation system and require details of the indicators and operational issues.
3. ***Guidance on measuring the impact of national PMTCT programmes*** includes a short guide summarizing several key approaches to measure PMTCT impact, and for each approach, in the near future, a generic protocol will be developed that can be adapted at the country level. This short guide can be used by any stakeholder who needs an overview of the different ways PMTCT impact can be assessed.

<sup>5</sup> <http://www.who.int/hiv/pub/me/en/index.html>.

## C10. Addressing gender, human rights and equity issues

It is essential to increase **equitable access to prevention, treatment**, care and support services and to decrease **stigma and discrimination** in order to achieve the ultimate goals of programmes. In most settings, PMTCT interventions are provided based on the assumption that women are empowered to make an independent decision as to whether or not to take advantage of these interventions. In reality, women confront a number of obstacles, for example:

- ◆ Women often lack power to negotiate safer sexual practices (e.g. condom use)
- ◆ Women living with HIV may not be able to negotiate the use of contraceptive methods to avoid unintended pregnancies or to decide to limit their pregnancies
- ◆ Women may not be able to access antenatal, delivery and postnatal care for several reasons (e.g. lack of money to pay for transportation or to pay fees at the clinic; unable to leave young children at home in order to travel to the health center)
- ◆ Fear of repudiation, domestic violence, stigmatization and rejection may prevent women from taking an HIV test, attending extra visits and adopting safer infant feeding options (e.g. exclusive breastfeeding; replacement feeding)
- ◆ Women may not have access to intervention because of social constraints (e.g. urban versus rural), cultural practices, religion, or because of their behaviour (sex workers, injection drug users).

### Role of PMTCT in addressing gender and human rights issues

- ◆ Ensure access to basic antenatal including PMTCT-related interventions, and delivery care for all women
- ◆ Increase the ability of women to negotiate sex and safer sex; and access sexual and reproductive health services and negotiate utilization of contraceptive methods
- ◆ Support women in disclosure of their HIV status, provide couple counselling, and promote partner participation
- ◆ Promote and support engagement of communities, including male sexual partners and people living with HIV, with special attention to community outreach activities
- ◆ Provide post-test support for all and provide care, treatment and support to all mothers living with HIV, their children and families

***For example:** Improve access to antenatal care equally to rural area and urban areas, and ensure affordable access to minimum quality care including PMTCT (free testing, counselling and antiretroviral treatment and prophylaxis) services through basic benefit packages or alternative insurance mechanisms (public or private)*

## D. Health systems strengthening in the context of PMTCT and paediatric HIV care, support and treatment

Antenatal care is a unique opportunity for the delivery of a comprehensive PMTCT intervention and other programmes such as prevention of maternal and neonatal tetanus, prevention of congenital syphilis, prevention and case management of maternal malaria, prevention of maternal anaemia and malnutrition, and prevention of sexually transmitted. Inadequate care and poor patient-provider relationship during the prenatal period have a negative impact on the continuum of care during the childbirth and postnatal period and adversely affect mothers, infants and children.

Performance results from various programmes show an important drop-off of women enrolled in PMTCT from the time of their identification as living with HIV to the time of delivery. The declining trends in the uptake of PMTCT interventions (HIV testing and counselling, antiretroviral prophylaxis or treatment for mothers and infants, post-natal interventions) reflects to some extent the baseline situation where antenatal care coverage (one or more visits) is relatively high but where there is a low proportion of institutional deliveries.

Implementation of comprehensive PMTCT must contribute to:

- ◆ Improving access, quality and use of maternal, newborn and child health services through upgrading of the existing infrastructure and equipment for antenatal care, childbirth and post-partum care.
- ◆ Improving referral and data reporting systems to ensure better continuum of care.
- ◆ Addressing human resource shortage within the maternal, newborn and child health systems or in a broader national health system through strengthening of service delivery, appropriate referrals, task shifting, and so on.
- ◆ Improving the national monitoring and evaluation skills through capacity building and technical support for harmonization and integration of monitoring and evaluation indicators and systems.
- ◆ Improving procurement and supply chain management systems through upgrading and equipping the systems and capacity-building.
- ◆ Addressing health financing constraints to improve financial access and health services.

Integrated Management of Adolescent and Adult Illness (IMAI) which is a comprehensive approach to scaling up and decentralizing comprehensive HIV care, treatment and prevention within primary health care is designed to strengthen the health system in resource constrained settings. IMAI, the related Integrated Management of Childhood Illness (IMCI), and the Integrated Management of Pregnancy and Childbirth (IMPAC) support a comprehensive approach to HIV, TB, malaria, PMTCT, and broader maternal, neonatal and child health services within primary health care, covering the full life cycle. This offers a concrete blueprint for the realization of ambitious scale-up targets including those of PMTCT by integrating simplified clinical management of these key interventions into the routine work of existing health services with strong community support.

## D1. Improving basic maternal, newborn and child health care

### Box 8. Impact of HIV on maternal morbidity and mortality

- ◆ Escalating maternal mortality since the advent of the HIV epidemic (*for example. AIDS is the leading cause of death among women of reproductive age worldwide; You can note that in your country, rates of maternal mortality have increased X-fold over the past Y decades; Maternal mortality rates have increased X times in parallel with the increasing HIV/AIDS epidemic*)
- ◆ Potential direct causes include post-partum haemorrhage, puerperal sepsis and complications of caesarean sections
- ◆ Potential indirect causes include AIDS itself and opportunistic infections such as tuberculosis and toxoplasmosis and pneumonia

Improving the working conditions of health care providers within antenatal and delivery care settings and improving the quality of care will benefit all women, especially vulnerable women and pregnant women living with HIV.

The HIV epidemic has changed the pattern and cause of maternal mortality (see Box 8). HIV-related complications are now among the leading causes of maternal mortality in most high-burden countries. HIV can be the direct cause of maternal mortality through post-partum haemorrhage, puerperal sepsis and complications of caesarean sections. Indirect causes include the natural evolution of the disease itself and opportunistic infections such as tuberculosis and toxoplasmosis.

The following activities should be considered, but note that this list is not an exhaustive:

### 1. Provision of comprehensive care, treatment and support services to increase access to and uptake of maternal, neonatal and child health services:

- ◆ Facility and community-level activities including communication strategies
- ◆ Early newborn care
- ◆ Nutritional support and infant feeding support
- ◆ Care during pregnancy, labour and the postpartum period
- ◆ Screening for and management of anaemia
- ◆ Screening for and care of sexually-transmitted infections (including syphilis)
- ◆ Screening for and treatment of TB
- ◆ Prevention and treatment of malaria

### 2. Equipment of antenatal and delivery rooms

- ◆ Antenatal and delivery kits
- ◆ HIV rapid test kits and commodities
- ◆ Gloves for examination and deliveries, fetal stethoscopes
- ◆ Fetal stethoscopes
- ◆ Impregnated bed nets
- ◆ Equipment for midwifery and obstetric care including delivery and labour beds, refrigerators, chairs, light source, and delivery gowns for midwives
- ◆ Television and video equipment for health education and information
- ◆ Equipment and supplies for medical waste disposal and management
- ◆ Supplies for infant and young child feeding – for example antiretroviral drugs for preventing postnatal transmission

### 3. Upgrading or renovation of existing facilities (e.g. counselling rooms) to accommodate the delivery of PMTCT interventions

#### Box 9. Settings that might need facility improvement and equipment

- ◆ Antenatal care registration and waiting area
- ◆ Counselling and examination rooms
- ◆ Labour and delivery rooms
- ◆ Family planning unit
- ◆ Laboratory
- ◆ Infant feeding/nutrition counselling and support rooms
- ◆ Rooms for storage and distribution of diagnostics, drugs and supplies

The infrastructure necessary for group counselling and information sessions, individual HIV post-test counselling, antenatal care and examination, and delivery and postnatal care is often inadequate. Provision of equipment is also critical to improve the quality of care and uptake of the wide range of services (see Box 9). Upgrading or renovation of existing facilities is critical to:

- ◆ Ensure good quality antenatal and delivery care
- ◆ Ensure a minimum of privacy and confidentiality for HIV testing and counselling
- ◆ Provide good quality rapid testing, immunological assessment (CD4) and PCR/DBS
- ◆ Provide good quality infant feeding counselling and support

#### 4. Strengthening service delivery systems for the delivery of postnatal services for mothers and their children (see Box 10)

##### Box 10. Guidance on strengthening service delivery systems

To ensure a good continuum of care in the context of PMTCT and paediatric HIV care consider the following areas:

1. Definition of the package of services to be delivered
2. Identification of the service delivery points (consider points of immunization, well-baby clinics, and nutrition rehabilitation centers) – the purpose is to identify needs for facility improvement and equipment
3. Profile of service providers at point of service delivery – the purpose to identify quantitative (numbers) and qualitative (training) needs
4. Tools (forms, registers, cards) to ensure information-sharing among service providers, between point of service delivery, health facilities and districts.

Good quality care includes the delivery of co-trimoxazole prophylaxis, early infant diagnosis and infant feeding counselling and support as integral component of routine postnatal care for mothers, infants and children. The following activities could be considered:

- ◆ Equipment of services and improvement of facilities
- ◆ Training and clinical mentoring of service providers
- ◆ Task-shifting from physicians to nurses
- ◆ Involvement of non-medical cadres (community health workers, traditional birth attendants, persons living with HIV, community-based organizations)
- ◆ Development or revision of tools (e.g. registers, forms, cards, leaflets, brochure). Special attention should be given to activities for the inclusion of HIV information on maternal health cards and under-5 cards (e.g. revision of the cards, validation workshops, printing and dissemination, and rollout).

## D2. Improving laboratory capacity

### ***For monitoring of combination antiretroviral prophylaxis and antiretroviral treatment***

- ◆ Haemocue® for determination of haemoglobin levels in pregnant women. This is important because AZT should not be given to pregnant women and mothers with severe anaemia (haemoglobin level below 7 gm/dl).
- ◆ Building capacity or setting up systems to perform CD4 cell counts for all pregnant women living with HIV. Antiretroviral eligibility by CD4 is key to implementing the 2010 WHO recommendations.

### ***Specific activities related to early infant diagnosis to be considered***

Activities necessary for the scale-up of early infant diagnosis of HIV using PCR and DBS technologies should be considered:

- ◆ Identification of reference laboratories for PCR using DBS
- ◆ Use immunization clinic 'opt out' testing of young infants
- ◆ Facility improvement and equipment of laboratories
- ◆ Referral systems for collection and transfer of blood specimens
- ◆ Referral systems for return of test results
- ◆ Training of service providers for collection and preparation of specimens



### D3. Innovative approaches to addressing health financing issues and human resource constraints

Implementation of comprehensive PMTCT and paediatric HIV care, support and treatment involves various health services across the different levels of the health system and services. Some financial issues may impede the equitable access to health services. The following points should be considered:

- ◆ Identification of financial barriers in accessing health services
- ◆ Conducting economic viability analysis of innovative health financing approaches
- ◆ Designing safety nets to cushion poor people and vulnerable people
- ◆ Selection of innovative approaches to protect poor people and vulnerable people, and equity of services
- ◆ Supporting co-sponsorship of key activities by relevant programmes

The main platforms and key entry points for the delivery of the core PMTCT interventions are the maternal, newborn and child health service such as antenatal, delivery, postnatal (immunization, well baby clinics) and family planning services. Beyond health facilities, implementation of PMTCT requires active involvement of the civil society and communities.

At the same time, implementation of PMTCT and paediatric care, support and treatment services as integral components of maternal, newborn and child health programmes can result in increased workload for already overstretched health care workers. In general, health care workers are in insufficient number and do not have all the required skills for the implementation of the range of PMTCT and paediatric HIV care and treatment. This may require new skills and additional staff. In order to address these issues, the following activities could be considered:

- ◆ Reorganization of the service delivery system including referral for appropriate competences for each level of service;
- ◆ Orientation of existing health care workers based on assessed skill and knowledge gaps including community actors for the provision of a defined set of activities at the community and health facility level;
- ◆ Strengthening clinical mentoring and supportive supervision to allow continued learning of health workers;
- ◆ Considering task shifting as an option for filling in existing gaps of required health personnel.

Community actors and volunteers have limited resources and therefore may need financial incentives to support them in doing their work. In the long term, unavailability of financial incentives can hamper their motivation and their ability to support the process effectively.

Development of a human capacity-building plan for the health sector, or specifically for PMTCT and paediatric HIV care and treatment, could be included as an activity if the country does not have such a plan. This could help to:

- ◆ Develop a clear idea of the current number of health care workers at all levels (employed and deployed);
- ◆ identify actual needs and
- ◆ define appropriate remedial actions including exploring options for results-based financing and incentives for retention of key categories of skilled health workers and health teams essential for implementing integrated services including PMTCT

Training of health care providers to deliver PMTCT services and all the other HIV services is usually carried out separately resulting in inadequate knowledge and skills among health care workers to provide comprehensive and compassionate services to pregnant woman living with HIV. The WHO IMAI/IMPAC clinical course for integrated PMTCT services provides an integrated approach that better serves HIV pregnant women with other needs for care. The course trains health care workers in the co-management of clinical conditions for pregnant women living with HIV by providing HIV care, antiretroviral treatment, antiretroviral prophylaxis and PMTCT interventions integrated into antenatal, labour and delivery, postpartum and newborn care at primary facility.

## D4. Strengthening procurement and supply chain management systems

Comprehensive PMTCT involves a wide range of health service delivery points. Key issues include policy frameworks, forecasting, procurement, storage and distribution of commodities which should be an integral part of the existing national procurement and supply chain management system (see Box 11). Table 2 shows the supplies to be considered for the provision of PMTCT services.

### Box 11. Elements to be considered for supply chain management strengthening<sup>1</sup>

- ◆ Identify sites that will start to implement new antiretroviral regimens; and targeted sites that will roll out the programme at least in the coming year.
- ◆ Map the referral system and linkages and identify stages and settings where the woman (and the baby) is expected to get counselling, testing, treatment and care before and after delivery.
- ◆ Create the list of essential items needed, including laboratory supplies.
- ◆ Forecast the needs and identify which of these items and quantities will be provided by which source, taking into account also the contribution of partners. Other considerations include lead time in ordering and procurement; storage and distribution capacity, and buffer stock.
- ◆ Decide which items need to be supplied continuously at which sites such as antenatal care, maternity, maternal and child health clinic, antiretroviral treatment centres, paediatric antiretroviral centres, family planning centres, and laboratories.
- ◆ Analyse existing procedures for procurement, including ordering, storage, distribution, issuing, and dispensing at all levels of care.
- ◆ Identify and map processes and procedures for supplying the targeted PMTCT sites.
- ◆ Develop a package for supervisors and health workers in PMTCT sites including a brief description of the technical requirements for good storage, management and use of items for PMTCT, and description of the process for ordering, receiving, storing, recording and reporting.
- ◆ Produce job aids such as wall-charts for the staff in sites with a clear description of the PMTCT intervention, administration of ARVs for prophylaxis and linkages that need to be followed in the system.
- ◆ Introduce the supplies information package in each PMTCT site combined with a training session for the staff.
- ◆ It is suggested that the committee on HIV/AIDS supplies creates a small sub-group that will meet regularly to monitor closely and continuously all matters related to the PMTCT supplies and adapt supply strategies as appropriate.

<sup>1</sup>Adapted from: *Guidance on supply chain planning for implementation of PMTCT*. New York, United Nations Children's Fund

Supplies to be considered for the provision of PMTCT services<sup>6</sup>

Table 2. Supplies for provision of PMTCT

|                              | Description   | Supply requirement  |
|------------------------------|---|---|
| <b>Maternal components</b>   | HIV testing and counselling at antenatal clinic and delivery settings for PMTCT   | HIV rapid test kits   |
|                              | Antiretroviral treatment for mothers who need it for their own health   | Fixed-dose antiretroviral combinations for at least one year according to national treatment guidelines   |
|                              | Co-trimoxazole prophylaxis for mothers living with HIV  | Co-trimoxazole for at least 1 year following birth of child   |
|                              | Antiretroviral prophylaxis for the mother based on the 2010 WHO recommended regimen for PMTCT for pregnant women                | Maternal zidovudine for at least 7 months OR<br>Maternal triple prophylaxis for at least 18 months  |
|                              | Immunological Assessment  | CD4-reagents bundle   |
|                              | Family planning commodities   | Contraceptives <sup>7</sup>   |
| <b>Paediatric components</b> | Antiretroviral prophylaxis for the infant based on the 2010 WHO recommended regimen for infants born to mothers living with HIV | Depending on the prophylactic option chosen:<br>Nevirapine syrup - for either 6 weeks or 12 months or<br>zidovudine syrup - for 6 weeks               |
|                              | Early diagnosis of paediatric HIV infection   | PCR reagents bundle and DBS bundle  |
|                              | Diagnosis at the age of 12-18 months (if PCR not available)   | HIV rapid test kits   |
|                              | Co-trimoxazole prophylaxis for HIV exposed children   | Co-trimoxazole for 2 years where no virology testing for Infants is available; Co-trimoxazole for 3 months where virology testing for infants is done |

## D6. Monitoring and evaluation, quality assurance and operational research

The purpose of the proposal should be to strengthen the national capacity for monitoring and evaluation, quality assurance and operational research. Specific activities are related to:

- ◆ Definition and harmonization of indicators
- ◆ Development or revision of monitoring and evaluation tools and reporting mechanisms
- ◆ Training and orientation of programme managers, district management teams, and service providers

<sup>6</sup> Source: *Guidance on supply chain planning for implementation of Prevention of Mother to Child Transmission (PMTCT) of HIV Infection*. New York, United Nations Children's Fund

<sup>7</sup> In many countries there are systemic challenges to integration of sexual reproductive health and PMTCT services. Global Fund encourages the integration of family planning interventions into HIV care and treatment programs as part of a larger reproductive health program, and supports equal treatment of women living with HIV regarding their reproductive choices. Requests for contraceptive commodities may be warranted, but proposals should demonstrate that Global Fund funds will not replace other family planning donors (e.g. UNFPA and the US Government). In addition, proposals must address possible interactions with antiretrovirals and also present an analysis of current family planning commodities, utilization and uptake.

- ◆ Timely collection and analysis of data, and dissemination of results
- ◆ Identification of gaps and bottlenecks
- ◆ Development and implementation of corrective measures
- ◆ Evaluation and re-evaluation

The three interlinked patient monitoring systems for HIV care and antiretroviral treatment, maternal, newborn and child health services and PMTCT (including malaria prevention) and TB/HIV, are suited for programmes expanding PMTCT coverage by integration of PMTCT interventions with their maternal and child services. The WHO HIV care and antiretroviral treatment patient monitoring system has been expanded to support PMTCT and malaria prevention interventions integrated with maternal and newborn care and also TB-HIV interventions delivered within HIV care, linked with the TB recording and reporting system.

Table 3 below provides a set of generic activities and items to consider budgeting for in the monitoring and evaluation of PMTCT service delivery. As part of the process, identify critical operational research questions aimed at improving implementation of the programme, service delivery, quality, and uptake of services.

Note that for the Global Fund proposal, countries are recommended to use the six building block-model of the Health Systems while analysing the key bottlenecks and the health systems strengthening interventions required overcoming the barriers. The building blocks are:

1. Service Delivery
2. Health Workforce
3. Information
4. Medical Products, Vaccines and Technologies
5. Financing
6. Leadership and governance (Stewardship)

Annex 2 contains examples of the specific activities across the 3 building blocks that are considered the most relevant to health systems strengthening in the context of PMTCT programming (Service Delivery, and Health Workforce, Information).

**NOTE:** The Global Fund will accept all proposals for health systems strengthening component, **except for the two categories:** 1. Basic scientific and clinical research aimed at demonstrating the safety and efficacy of new drugs and vaccines, and 2. Large scale capital investments such as building hospitals or clinics.

As part of the process, identify critical operational research questions aimed at improving implementation of the programme, service delivery, quality and uptake of services.

**Table 3. Generic activities and items to consider budgeting for in PMTCT monitoring and evaluation service delivery area**

| Monitoring and evaluation area               | Generic activities  | Items to consider budgeting for  |
|--|---|--|
| Routine Programmatic Data collection and use | <ul style="list-style-type: none"> <li>◆ Review and revise indicators (align with 2010 WHO antiretroviral guidelines and with elimination of new HIV child infection activities such as introducing monitoring of antiretroviral coverage during breastfeeding, consider other indicators of interest)</li> <li>◆ Review and propose revisions of tools</li> <li>◆ Pilot-test new tools (and instructions) and indicators</li> <li>◆ Review of human resources and recruitment of additional staff necessary for the work planned</li> <li>◆ Printing tools</li> <li>◆ Develop operation manual and training on new tools and indicators</li> <li>◆ Other training to various programmatic and monitoring and evaluation staff at all levels</li> <li>◆ Develop systematic approaches to use data better</li> <li>◆ Feedback mechanism on data collection and reporting</li> <li>◆ Review and revise targets</li> </ul> | <ul style="list-style-type: none"> <li>◆ Existing and additional staff</li> <li>◆ Stakeholders meeting</li> <li>◆ Workshops</li> <li>◆ Travel and Per diem</li> <li>◆ Computer-related hardware</li> <li>◆ Other materials and supplies</li> <li>◆ Transport mean (e.g. car for supervision visits)</li> <li>◆ Dissemination cost</li> <li>◆ Launch (e.g. of new tools, reports)</li> <li>◆ Technical assistance; consultants</li> <li>◆ Printing cost</li> <li>◆ Tools to facilitate data use</li> <li>◆ Extra data collection</li> </ul> |
| Data quality and supervision                 | <ul style="list-style-type: none"> <li>◆ Identify problems and solutions to improving data quality; prepare and implement solutions; reassess</li> <li>◆ Develop or review data checklist to perform during routine supervision at facilities or sub-national level</li> <li>◆ Annual National PMTCT Data Stakeholders Meeting</li> </ul>   |  |
| Special studies and periodic surveys         | <ul style="list-style-type: none"> <li>◆ Identify specific topics for further data collection through special studies or operational research</li> <li>◆ Health facility survey</li> <li>◆ Population-based survey (with or without HIV testing)</li> </ul>   |  |
| Impact measurement                           | <ul style="list-style-type: none"> <li>◆ Summarize currently existing data on impact of PMTCT programs</li> <li>◆ Identify what impact to measure</li> <li>◆ Review various ways to measure impact and develop country plans and protocols (see Guidance on Measuring the Impact of National PMTCT Programmes); Budget for planned activities each year</li> <li>◆ Programme reviews</li> </ul>   |  |
| Coordination and reporting                   | <ul style="list-style-type: none"> <li>◆ Develop a monitoring and evaluation workplan and review its performance and implementation regularly</li> <li>◆ Periodic meetings to share information, coordinate and synergize work at different levels (e.g. technical working groups, national and sub-national levels; links with other stakeholders, etc.)</li> <li>◆ Periodic reports with baselines, targets, and actual results</li> <li>◆ Mid-term and end of the year review reports</li> </ul>   |  |

## E. Costing the activities

Creating a budget that is clearly linked to the workplan of activities is often a challenge for Global Fund proposals. The WHO HIV Department has developed a workplanning and budgeting tool to help countries prepare proposal budgets and workplans for Round 11. This tool was first used in Round 9, but the current version has been developed specifically for the preparation of Round 11 proposals. The tool can be used for the HIV, TB, Malaria, and health systems strengthening components of Global Fund proposals, and it has been endorsed by the Global Fund for use in preparing proposals. The tool operates on a number of preset assumptions, but also allows for input of specific assumptions relevant to the setting where the activities are planned. The tool has built in validation checks, and generates an integrated workplanning-budget, with a single master worksheet combining workplan, programmatic targets and costing data

Listed below are some of the cost elements which may be important to include in the budget depending on the nature of the PMTCT activities proposed. Costs should be based on country-specific data for selected countries from different regions of the world. These costs need to be linked to the Global Fund cost categories.

**Service delivery level costs** include the following:

- ◆ HIV testing and counselling, including distribution of condoms and test kits
- ◆ Provision of antiretroviral drugs for prophylaxis
- ◆ Provision of first-line antiretroviral drugs to eligible women and children over the age of 18 months and, in the case of clinical diagnosis of failure, provision of second line drugs
- ◆ Prophylaxis, diagnosis and treatment of opportunistic infections (OIs) and cost of Co-trimoxazole cost
- ◆ Laboratory tests for regular monitoring and suspected toxicity (for people showing clinical signs of toxicity) and switching individual drugs in cases of confirmed toxicity
- ◆ Operating costs of CD4, PCR/DBS and viral load monitoring tests
- ◆ Palliative care
- ◆ Nutrition kits
- ◆ Antenatal care and delivery kits
- ◆ Contraceptives

**Programme costs** include the following:

- ◆ Improvement of facilities
- ◆ Equipment at point of service delivery
- ◆ Training and on-going learning of health workers (doctors, nurses, midwives), peer educators, lay counsellor and community-based service provider
- ◆ Job aids and on-the-job reference materials for service providers
- ◆ Incentive and transportation fees for community actors and community health workers
- ◆ Provision of counselling sessions such as HIV, family planning, infant feeding, and nutritional support
- ◆ Recruitment and training of community health workers and lay volunteers to follow up patients for treatment and adherence support
- ◆ Supervision and monitoring across the levels of the health system (central level, provincial, district and facility levels)
- ◆ Drug distribution and storage systems
- ◆ Equipment of maternal, newborn and child health services
- ◆ Universal precautions including post exposure prophylaxis
- ◆ Laboratory equipment, supplies and management costs (CD4, PCR/DBS)
- ◆ Support to referral systems for collection and transfer of blood samples as well as return of test results
- ◆ Purchasing vehicles for transportation system

- ◆ Test kits
- ◆ Technical support in planning, management and monitoring and evaluation of the PMTCT-related systems and services (tools, workshops). Tools include health cards for mothers, infants and children, registers, forms, leaflets and brochures.

## F. Key implementing partners to be considered

In addition to the government and key stakeholders, the following should be invited and engaged in the process of the proposal writing:

- ◆ Key bilateral, nongovernmental and community-based organizations, quality improvement teams, and academic partners active in supporting or implementing scale up of PMTCT activities in the country
- ◆ Associations of health care providers including midwives or skilled birth attendants, organizations working in women's education and support groups, organizations of people living with HIV, peer educators, and community groups are important allies to be engaged both in the initial design of the proposals as well as the implementation and monitoring and evaluation of the Global Fund.

## G. Types and sources of technical assistance that may be required during implementation

**The following areas could be considered for technical assistance:**

- ◆ Training and orientation of service providers including community actors
- ◆ Development and revision of guidelines, protocols and implementation tools including monitoring and evaluation tools
- ◆ Strategic information, including monitoring and evaluation and quality assurance
- ◆ Operation research including scale-up methods
- ◆ Programme evaluation
- ◆ Establishing quality improvement teams and establishing systems for using data-for-action

Global Fund encourages costs for technical assistance from UN organizations to be estimated and included in the proposal. This may be the only way that WHO for example can provide consistent support.

## Resources

### PMTCT

Antiretroviral drugs for treating pregnant women and preventing HIV infection in infants: recommendations for a public health approach. – 2010 version. Geneva, World Health Organization 2010  
[http://whqlibdoc.who.int/publications/2010/9789241599818\\_eng.pdf](http://whqlibdoc.who.int/publications/2010/9789241599818_eng.pdf)

WHO expert consultation on new and emerging evidence on the use of antiretroviral drugs for the prevention of mother-to-child transmission of HIV, Conclusions of the consultation. Geneva, World Health Organization. 17-19 November 2008  
[http://www.who.int/hiv/topics/mtct/mtct\\_conclusions\\_consult.pdf](http://www.who.int/hiv/topics/mtct/mtct_conclusions_consult.pdf)

Antiretroviral drugs for treating pregnant women and preventing HIV infection in infants: Towards universal access - Recommendations for a public health approach. Geneva, World Health Organization. 2006  
<http://www.who.int/hiv/pub/guidelines/pmtctguidelines3.pdf>

## **Guidance on global scale-up of the prevention of mother-to-child transmission of HIV**

Towards universal access for women, infants and young children and eliminating HIV and AIDS among children. Geneva, World Health Organization. 2007  
[http://www.who.int/hiv/mtct/PMTCT\\_enWEBNov26.pdf](http://www.who.int/hiv/mtct/PMTCT_enWEBNov26.pdf)

Scale up Planning Guide for the Prevention of Mother-to-Child Transmission of HIV and Paediatric HIV Care, Treatment and Support. Geneva, World Health Organization. 2007  
**<http://www.who.int/hiv/topics/mtct/meetings/NairobiFeb07ScaleUpGuide.pdf>**

Strategic Approaches to the Prevention of HIV Infection in Infants. Report of a WHO Meeting, Morges, Switzerland, 20-22 March 2002. Geneva, World Health Organization.  
<http://www.who.int/hiv/pub/mtct/en/StrategicApproachesE.pdf>

Strategic Framework for the Prevention of HIV Infection in Infants in Europe. Geneva, World Health Organization. 2004  
<http://www.who.int/hiv/mtct/PMTCTEURO.pdf>

Glion Consultation on Strengthening the Linkages between Reproductive Health and HIV/AIDS: Family Planning and HIV/AIDS in Women and Children - 25 May 2006. Geneva, World Health Organization.  
[http://www.who.int/hiv/pub/advocacymaterials/glionconsultationsummary\\_DF.pdf](http://www.who.int/hiv/pub/advocacymaterials/glionconsultationsummary_DF.pdf)

To access WHO IMAI/IMPAC clinical training course for integrated PMTCT interventions and other IMAI/IMCI/IMPAC materials, tools, wallcharts and briefing package, – please go to [www.who.int/hiv/capacity/en/](http://www.who.int/hiv/capacity/en/). The IMAI CD or access to the IMAI EZ collaboration site provides access to unpublished material and native files for adaptation or contact [imaimail@who.int](mailto:imaimail@who.int). The IMAI/IMPAC tolls have been updated to be compatible with the new WHO normative guidelines on PMTCT. Geneva, World Health Organization.

## **Infant Feeding and HIV**

Guidelines on HIV and infant feeding. 2010. Principles and recommendations for infant feeding in the context of HIV and a summary of evidence. Geneva, World Health Organization, 2010  
[http://whqlibdoc.who.int/publications/2010/9789241599535\\_eng.pdf](http://whqlibdoc.who.int/publications/2010/9789241599535_eng.pdf)

HIV and infant feeding: new evidence and programmatic experience, Report of a technical consultation held on behalf of the Inter-agency Task Team (IATT) on Prevention of HIV infections in pregnant women, Mother and their Infants, Geneva, Switzerland, 25-27 October 2006  
[http://www.who.int/child\\_adolescent\\_health/documents/infant\\_feeding/en/index.html](http://www.who.int/child_adolescent_health/documents/infant_feeding/en/index.html)

### **HIV and Infant Feeding: Update (2007)**

Based on the Technical Consultation held on behalf of the Inter-agency Task Team (IATT) on Prevention of HIV Infection in Pregnant Women, Mothers and their Infants. Geneva, World Health Organization, 25-27 October 2006  
[http://www.who.int/child\\_adolescent\\_health/documents/infant\\_feeding/en/index.html](http://www.who.int/child_adolescent_health/documents/infant_feeding/en/index.html)

Community-based strategies for breastfeeding promotion and support in developing countries. Geneva, World Health Organization, 2003  
[http://www.who.int/child\\_adolescent\\_health/documents/9241591218/en/index.html](http://www.who.int/child_adolescent_health/documents/9241591218/en/index.html)

HIV and infant feeding: Framework for priority action (English). Geneva, World Health Organization  
[http://www.who.int/child-adolescent-health/New\\_Publications/NUTRITION/HIV\\_IF\\_Framework\\_pp.pdf](http://www.who.int/child-adolescent-health/New_Publications/NUTRITION/HIV_IF_Framework_pp.pdf)

HIV and infant feeding: Framework for priority action (French). Geneva, World Health Organization.  
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*Also available in Spanish, Portuguese, Chinese (see web site - <http://www.who.int/nutrition/publications/infantfeeding/en/index.html>)*



HIV transmission through breastfeeding: A review of available evidence. Geneva, World Health Organization, 2007  
[http://www.who.int/child-adolescent-health/New\\_Publications/NUTRITION/ISBN\\_92\\_4\\_156271\\_4.pdf](http://www.who.int/child-adolescent-health/New_Publications/NUTRITION/ISBN_92_4_156271_4.pdf)  
Also available in French, Spanish

## HIV Testing and Counselling

Guidance on provider-initiated HIV testing and counselling in health facilities. Geneva, World Health Organization and Joint United Nations Programme on HIV/AIDS, 2007  
[http://whqlibdoc.who.int/publications/2007/9789241595568\\_eng.pdf](http://whqlibdoc.who.int/publications/2007/9789241595568_eng.pdf)

Testing and Counselling for Prevention of Mother-to-Child Transmission of HIV (TC for PMTCT): Support Tools. San Francisco,  
<http://www.womenchildrenhiv.org/wchiv?page=vc-10-00>

Integrating HIV Voluntary Counselling and Testing services into Reproductive Health Settings. Stepwise guidelines for programme planners, managers and service providers. UNFPA, IPPF (2004)  
[http://www.unfpa.org/upload/lib\\_pub\\_file/245\\_filename\\_hiv\\_publication.pdf](http://www.unfpa.org/upload/lib_pub_file/245_filename_hiv_publication.pdf)

Guidelines and training for provider initiated testing and counselling integrated within antenatal, labour and delivery, and post-partum services is provided within the IMAI-IMPAC guidelines and training materials.

## Care for HIV Infected Women

### ***Nutrition Counselling, Care and Support for HIV-Infected Women***

Guidelines on HIV-related care, treatment and support for HIV-infected women and their children in resource-constrained settings  
[http://www.who.int/hiv/pub/prev\\_care/en/nutri\\_eng.pdf](http://www.who.int/hiv/pub/prev_care/en/nutri_eng.pdf)

#### Standards for Maternal and Neonatal Care

The Standards for Maternal and Neonatal Care consists of a set of user-friendly leaflets that present WHO key recommendations on the delivery of maternal and neonatal care in health facilities, starting from the first level of care.  
[http://www.who.int/making\\_pregnancy\\_safer/publications/en/](http://www.who.int/making_pregnancy_safer/publications/en/)

HIV/AIDS care and treatment: a clinical course for people caring for persons living with HIV/AIDS: facilitator's manual  
<http://www.fhi.org/en/RH/Training/trainmat/index.htm>

Hormonal Contraception and HIV: An Update. Charles Morrison and Kim Best. August 2004  
<http://www.fhi.org/en/RH/Pubs/booksReports/hcandhiv.htm>

Sexual and Reproductive Health of Women Living with HIV/AIDS: Guidelines on Care, Treatment and Support for Women Living With HIV/AIDS and their Children in Resource-Constrained Settings  
<http://www.who.int/hiv/pub/guidelines/sexualreproductivehealth.pdf>

WHO *IMAI-IMCI Chronic HIV Care with ART and Prevention* and *IMAI Acute Care* guideline modules, training materials, and other tools supports comprehensive, integrated care for HIV-infected mothers.

## Target Setting, Monitoring & Evaluation

Global Monitoring Framework and Strategy for the Elimination of New Child HIV Infections By 2015. Available at <http://www.who.int/hiv/pub/me/en/index.html>.

Monitoring and Evaluating the Prevention of Mother-to-Child Transmission of HIV: A guide for national programmes. Available at <http://www.who.int/hiv/pub/me/en/index.html>

Guidance on Measuring the Impact of National PMTCT Programmes.  
Available at <http://www.who.int/hiv/pub/me/en/index.html>

## Overall implementation of activities

WHO Operations Manual for delivery of HIV prevention, care and treatment at primary health centers in high-prevalence, resource-constrained settings.

[http://www.who.int/hiv/pub/imai/operations\\_manual/en/index.html](http://www.who.int/hiv/pub/imai/operations_manual/en/index.html)

Strengthening Health Systems to improve health outcomes.

[http://www.who.int/healthsystems/strategy/everybodys\\_business.pdf](http://www.who.int/healthsystems/strategy/everybodys_business.pdf)

The WHO integrated management tools provide a comprehensive, integrated approach to scaling up decentralized services in limited-resource settings. Many high burden PMTCT countries have already adapted IMAI and IMCI tools and begun IMAI-IMPAC integrated PMTCT training.

## Annex 1: List of Indicators for PMTCT

| Indicators                           |  |
|--------------------------------------|--|
| Health Facilities                    | Total number of facilities nationally providing antenatal care services  |
|                                      | Total number/percentage of health facilities providing antenatal care services with both HIV testing and ARVs for PMTCT on site ( <i>this indicator can be revised to <b>percentage of antenatal care facilities that also provide HIV testing</b> if there is no intention to provide ARVs at antenatal care setting</i> )  |
|                                      | Total number/percentage of facilities nationally providing antenatal care which also provide a more efficacious combination regimen for PMTCT ( <i>this indicator could be added if a country plans to introduce new regimen; the definition of 'more efficacious regimen' should be specified</i> )   |
|                                      | Total number/percentage of health facilities that provide virological testing (e.g. PCR) for infant diagnosis, on site or from Dried Blood Spots (DBS)   |
| Antenatal care / Labour and delivery | Total number/percentage of pregnant women with known HIV status (includes women who were tested for HIV and received their results)  |
|                                      | Total number/percentage of pregnant women who tested HIV positive ( <i>including those with already confirmed HIV infection</i> )  |
|                                      | Total number/percentage of pregnant women living with HIV assessed for antiretroviral treatment eligibility (CD4 cell count or clinical staging)   |
|                                      | Total number and percentage of pregnant women living with HIV who received ARVs for MTCT. <i>Broken down accordingly:</i> <ul style="list-style-type: none"> <li>◆ Antiretroviral therapy for pregnant women living with HIV who are eligible for treatment</li> <li>◆ Maternal triple ARV prophylaxis</li> <li>◆ Maternal AZT</li> <li>◆ Single-dose nevirapine only</li> </ul> |
|                                      | Total number/percentage of infants born to pregnant women living with HIV (HIV-exposed infants) provided with ARV prophylaxis to reduce the risk of early mother-to-child transmission in the first 6 weeks  |
| Postpartum / Infant follow-up        | Percentage of infants born to women living with HIV (HIV-exposed infants) who are breastfeeding provided with antiretroviral prophylaxis (to either mother or infant) to reduce the risk of HIV transmission during the breastfeeding period.  |
|                                      | Percentage of HIV-exposed infants who are exclusively breastfeeding, replacement feeding or mixed feeding at DPT3 visit ( <i>remember to pilot test if not yet collecting</i> )  |
|                                      | Total number/Percentage of infants born to pregnant women living with HIV receiving a virological test for HIV diagnosis within two months of birth  |
|                                      | Total number of infants born to pregnant women living with HIV who are started on co-trimoxazole prophylaxis within two months of birth  |
|                                      | Percentage of children living with HIV aged 0-14 who are currently receiving antiretroviral therapy  |
| Service providers                    | Number of health care providers trained on PMTCT   |
|                                      | Number of peers/lay counsellors trained for the provision of PMTCT interventions   |
|                                      | Number of peer support groups formed in the context of PMTCT   |
| Other                                | Existence of national policies and guidelines consistent with international standards for the prevention of mother-to-child transmission of HIV  |
|                                      | Percentage of women of reproductive age living with HIV attending HIV care and treatment services with unmet need for family planning services ( <i>remember to pilot test if not yet collecting</i> )   |
|                                      | Estimated percentage of child infections from women living with HIV delivering in the past 12 months – estimated transmission rate   |

## Annex 2. Building blocks of the health system and questions and activities to be considered for Global Fund support through health systems strengthening for the PMTCT service delivery area

### **Building Block 1: Service Delivery** –service packages, delivery models, infrastructure, management, safety and quality, and demand for care

#### **1. Equipment and supplies for antenatal and delivery rooms**

- ◆ Midwifery and obstetric kits or individual equipment (e.g. gloves for examination and deliveries, fetal stethoscopes, barrier gowns and goggles)
- ◆ Equipment for midwifery and obstetric care – e.g. delivery and labour beds, refrigerators, chairs, light source
- ◆ TV and video equipment for health education and information
- ◆ Equipment and supplies for medical waste disposal and management
- ◆ Supplies for infant and young child feeding – e.g. antiretroviral drugs to prevent postnatal transmission, counselling tools and job aids
- ◆ Impregnated bed nets
- ◆ Syphilis – clinic-based test with same-day treatment of positive results and follow-up of partners.

#### **2. Improving laboratory capacity for monitoring of combination antiretroviral prophylaxis and antiretroviral treatment**

- ◆ Haematocrit or haemocue for determination of haemoglobin level in pregnant women
- ◆ Building capacity or setting up systems to perform CD4 cell count for all pregnant women living with HIV – stress the importance of this for the implementation of 2010 WHO guidelines

#### **3. Upgrading or renovation of existing facilities is critical to:**

- ◆ Ensure good quality antenatal and delivery care
- ◆ Ensure a minimum of privacy and confidentiality for HIV testing and counselling
- ◆ Provide good quality rapid testing, immunological assessment (CD4) and PCR/DBS
- ◆ Provide good quality infant feeding counselling and support

#### **4. Strengthening post-natal service delivery systems for mothers and their children**

- ◆ Equipment of services and improvement of facilities
- ◆ Training and mentoring of service providers
- ◆ Task-shifting
- ◆ Involvement of non-medical cadres e.g. community health workers, traditional birth attendants, community-based organizations, people living with HIV and so on
- ◆ Development or revision of tools such as registers, forms, cards, leaflets and brochures. Special attention should be given to activities for the inclusion of HIV information on maternal health cards and under-5 cards such as revision of the cards, validation workshops, printing and dissemination, and rollout.

#### **5. Specific activities related to early infant diagnosis**

- ◆ Identification of reference laboratories for PCR using DBS
- ◆ Facility improvement and equipment of laboratories
- ◆ Referral systems for collection and transfer of blood specimens
- ◆ Referral systems for return of test results
- ◆ Training of service providers e.g. collection and preparation of specimens, PCR tests for laboratory technician, and standard operating procedures and job aids

## 6. Programme monitoring and supervision

Strengthening the programme monitoring and supportive supervision systems from the central to the sub-national level and from the provincial and district levels down to the health care facilities. Specific activities may include:

- ◆ Development and revision of the tools for supportive supervision and performance assessment
- ◆ Planning and conducting scheduled supportive supervision visits
- ◆ Training at the central and sub-national levels including at health facilities, and
- ◆ Provision of vehicles for regular monitoring and supervisory visits

Use the IMAI Operations Manual for operational guidance on how to implement the above

**Building Block 2: Health Workforce** – covering national workforce policies and investment plans, advocacy, norms, standards and data

### Consider Innovative approaches to addressing human resource constraints

- ◆ Reorganization of the service delivery system: The *WHO operations manual for delivery of HIV prevention, care and treatment at the health centre level in high-prevalence and resource-constrained setting* provide guidance on planning integrated service delivery
- ◆ Orientation of existing health care workers and community actors (e.g. community-based and other non-governmental organizations, people living with HIV, peers, lay counsellors, community health workers, and traditional birth attendants) for the provision of a defined set of activities at community as well as training mothers living with HIV as lay providers on the clinical team at the health facility level (also called ‘expert patients’ or ‘mentor mothers’). Involvement of community actors and trained and paid lay providers on the clinical team can help to take some of the work burden off health care workers. Community actors and lay providers can play critical role by identifying pregnant women in the community, providing counselling and health education, including information on healthy lifestyles, birth planning and the importance of antenatal care and skilled assistance at birth.
- ◆ Task-shifting
- ◆ Use of WHO IMAI/IMPAC training to strengthen human resource capacity to provide comprehensive PMTCT interventions for antenatal, childbirth, post natal and newborn care at the primary level
- ◆ Performance-based incentives for enhancing performance

**Building Block 3: Information** – covering facility- and population-based information and surveillance systems, global standards, and tools

**Strengthening the national capacity for monitoring and evaluation, quality insurance and operational research.** Specific activities are related to:

- ◆ Definition and harmonization of indicators
- ◆ Development or revision of monitoring and evaluation and reporting tools such as the WHO three interlinked patient monitoring systems for HIV care, antiretroviral treatment services, PMTCT, maternal, neonatal and child health services, and integrated tuberculosis-HIV services
- ◆ Training and orientation of programme managers, district management teams, and service providers
- ◆ Collection and analysis of data, and dissemination of results
- ◆ Identification of gaps and bottlenecks
- ◆ Development and implementation of corrective measures
- ◆ Measure impact
- ◆ Re-evaluation

As part of the process, identify critical operational research questions aimed at improving implementation of the programme, service delivery, quality and uptake of services

