Guidance on supply chain planning for implementation of Prevention of Mother to Child Transmission (PMTCT) of HIV infection

1. Objective
This document outlines general principles for program and supply managers on which to base supply planning for the implementation of WHO and national guidelines on the Prevention of Mother to Child Transmission (PMTCT) of HIV. It suggests a basic approach that can ensure effective and sustainable supply of PMTCT commodities.

2. Context
Every day, around 1400 infants are infected with HIV through Mother To Child Transmission of the virus (MTCT) during pregnancy, labor and delivery, or breast-feeding. In infants infected with HIV, disease progresses very quickly, around 50% will die before the age of two if they do not receive care and treatment.¹

Not every infant born of a HIV positive mother will be infected with the HIV virus. The risk of transmission of HIV infection from the mother to the infant is 20-45%. This rate of infection can be successfully and affordably reduced to less than 2% if a comprehensive intervention is applied.

In developed countries with institutionalization of PMTCT interventions as a standard of care, infection in infants has been eliminated. However, in middle and low income countries, only about 11% of HIV positive pregnant women are reached by PMTCT interventions.² Coverage rates are lowest in West and Central Africa, Asia and East and Southern Africa, reaching only 1%, 7% and 11% of HIV-infected women respectively.³

The main reasons for slow uptake of PMTCT services are:

1. Weak health care infrastructure;
2. Insufficient numbers of health workers;
3. Lack of integration of PMTCT programs into regular Mother and Child health care services;
4. Poor supply management of PMTCT drugs and HIV test kits;
5. High rate of deliveries outside mainstream health institutions;
6. Poor involvement of male partners in HIV testing;
7. Stigma and issues of disclosure by HIV positive women.

Despite many challenges, momentum is currently gaining and the efforts to scale up PMTCT are starting to make an impact.  

3. Role of UNICEF in PMTCT

UNICEF has supported PMTCT programs since their inception in 1998, starting with initial projects in 11 countries and expanding over the years to over 80 countries. It has played a critical leadership role in setting the global PMTCT agenda in scaling up national PMTCT programs in resource-limited settings. Areas of support have included policy, guideline and tool-development, capacity development including development of skills of service providers, promotion of methods to expand access to HIV testing and counseling, efficient procurement of ARVs and other essential commodities and monitoring and evaluating progress. Furthermore, UNICEF continues to be the lead agency on procurement and supplies management for HIV/AIDS commodities.

4. What is PMTCT?

PMTCT is not an isolated or parallel program; it is a comprehensive approach composed of four components to be implemented as an integral part of essential maternal, newborn and child health services. These interventions include:  

1. Primary prevention of HIV among women of childbearing age – preventing women of childbearing age from acquiring HIV infection will globally reduce the number of children that can get infected from their mothers.

2. Preventing unintended pregnancies among women living with HIV, while focusing on improving the quality of life for women living with HIV. If these women choose not to become pregnant they should receive the support through family planning programs on how to prevent pregnancies. This intervention contributes to reducing globally the number of children that can get infected from their mothers.

3. Preventing HIV transmission from a woman already infected with HIV to her infant – this consists of a core package of interventions which includes, among other things, antiretroviral (ARV) therapy, safe delivery practices, infant feeding and counseling, care and support for HIV positive mothers and their children.

4. Providing appropriate treatment, care and support to women living with HIV and their children and families – this strategy refers to the provision of essential health services and nutritional support, psychosocial support and efforts to reduce stigma and discrimination. A HIV positive mother needs to have access to ARVs for her own treatment so she is able to offer care to the newborn. The death of a mother is a high risk factor of child mortality.

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The PMTCT intervention is mainly focused on the third component of these strategies, which is preventing the already infected mother from transmitting the HIV virus to her infant in utero, around the time of delivery and in the postpartum period.

PMTCT as a set of consecutive interventions, must include: offering HIV counseling and testing; access to ARV and co-trimoxazole prophylaxis for the mother and the baby; counseling to choose an appropriate infant feeding method; provide CD4 testing for the mother and Early Infant Diagnosis for the baby; ensure that linkages with Mother and Child programs (MCH), ART centers and pediatric ARTs are functional. These interventions are more site specific strategies and are delivered through the health care system.

5. PMTCT Guidelines

The first guidelines for PMTCT intervention were issued by WHO in 2000 recommending the use of single dose Nevirapine 200mg for the mother at least 4 hours before delivery, as well as applying a single dose of 0.6ml Nevirapine to the baby within the first 72 hours after birth. Since then, considerable evidence has accumulated showing advantages of using more potent ARVs for prophylaxis, the effectiveness of ARVs, safety to use in pregnancy and resistance associated with the use of ARVs. As a result, in 2006 WHO revised the 2000 guidelines and recommended a public health approach to assist countries in developing standardized protocols. Based on the evidence, the 2006 WHO PMTCT guidelines recommend moving away from the use of single dose Nevirapine to using more efficacious ARV regimens.6

The current guidelines recommend that a HIV positive pregnant woman who is not already receiving any antiretroviral therapy (ART), should start taking Zidovudine from the 28th week of pregnancy or as soon as possible thereafter. In addition, at the onset of labor, she will take a single dose of Nevirapine, Lamivudine and an extra dose of Zidovudine. Immediately after birth, the baby has to receive a single dose of Nevirapine and then start taking Zidovudine for one week or four weeks, depending on when the mother started taking Zidovudine during pregnancy. After delivery the mother should continue taking a combination of Zidovudine and Lamivudine for one week (referred to as the “tail”). If the mother was already on ART before becoming pregnant, she will continue with her regular treatment while the infant will need to take only Zidovudine for seven days.

PMTCT intervention as recommended by WHO is illustrated below:7

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6 WHO guidelines on PMTCT can be found at [http://www.who.int/hiv/pub/mtct/pmtct/en/](http://www.who.int/hiv/pub/mtct/pmtct/en/)

If a woman comes to ANC only after the 28th week of pregnancy and starts taking AZT, then the baby will need to receive AZT for four weeks instead of one.

Following all these complex steps does not yet guarantee that the infant is not infected with HIV. Addressing properly infant feeding options is as important as applying ARV prophylaxis described above. Around one third of all infections transmitted from the mother to the baby may occur through breastfeeding. WHO recommends avoiding breastfeeding from birth only if substitute feeding is acceptable, feasible, affordable, sustainable and safe. Exclusive breastfeeding is supported in all other cases when these conditions are not met.

WHO recommends that all infants exposed to HIV should receive Cotrimoxazole prophylaxis starting at 4-6 weeks of age and continuing until HIV infection is excluded. Cotrimoxazole can reduce child mortality in HIV positive children by over 40%. However, although Cotrimoxazole is widely available and is affordable, the progress of its provision for prophylaxis in infants exposed to HIV and HIV positive mothers is still slow.

To measure the effectiveness of the PMTCT intervention and be able to offer proper care, the infant needs to be diagnosed as early as possible. The testing method that detects antibodies used to test adults can not be applied in children younger than 18 months due to the presence of antibodies from the mother in the infant’s blood. Instead, virology testing is required using the PCR method, which is the gold standard of Early Infant Diagnosis (EID). Virology testing is still not widely available in most of middle and low income countries.

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10 See Guidance Notes on Early Infant Diagnosis issued by UNICEF Supply Division. 2007.
### Supplies to provide PMTCT services

In order to support in-country health facilities transitioning to more efficacious PMTCT regimens, as recommended in WHO treatment guidelines, UNICEF has identified the following minimum supply requirements.\(^{11}\)

<table>
<thead>
<tr>
<th>Description</th>
<th>Supply Requirement</th>
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<tbody>
<tr>
<td><strong>Maternal Components</strong></td>
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<tr>
<td>HIV testing and counselling at Antenatal Clinic and delivery settings for PMTCT</td>
<td>HIV rapid test kits</td>
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<tr>
<td>Antiretroviral Treatment for mothers who need it for their own health</td>
<td>Fixed Dose ARV Combinations for at least one year according to national treatment guidelines Lamivudine, Nevirapine, Stavudine/Zidovudine FDCs</td>
</tr>
<tr>
<td>Co-trimoxazole prophylaxis for HIV positive mothers</td>
<td>Co-trimoxazole for at least one year following birth of child</td>
</tr>
<tr>
<td>Antiretroviral prophylaxis for the mother based on the current WHO recommended regimen for PMTCT for pregnant mothers</td>
<td>Zidovudine 300 mg tablet, Lamivudine 150mg + Zidovudine 300mg FDC. Nevirapine 200mg tablet</td>
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<tr>
<td>Immunological Assessment</td>
<td>CD4-reagents bundle</td>
</tr>
<tr>
<td><strong>Paediatric Components</strong></td>
<td></td>
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<tr>
<td>Antiretroviral prophylaxis for the infant based on the current WHO recommended regimen for infants born to HIV positive mothers</td>
<td>Nevirapine syrup Zidovudine syrup</td>
</tr>
<tr>
<td>Early diagnosis of paediatric HIV infection</td>
<td>PCR-reagents bundle and Dry Blood Spot bundle</td>
</tr>
<tr>
<td>Diagnosis at the age of 12-18 months (in case PCR not available)</td>
<td>HIV rapid test kits</td>
</tr>
<tr>
<td>Co-trimoxazole prophylaxis for HIV exposed children</td>
<td>Co-trimoxazole for two years (where no virology testing for infants) Co-trimoxazole for 3 months (where virology testing for infants is done)</td>
</tr>
</tbody>
</table>

**Explanations:**
- Lamivudine, Nevirapine, Stavudine/Zidovudine: first line ARVs in most national HIV/AIDS treatment guidelines
- Cotrimoxazole: antiinfective used to prevent infections
- CD4-testing: to determine stage of HIV and need for treatment
- PCR-testing: to determine HIV status in children
- ART: Antiretroviral Treatment (only when CD4-testing indicates need for full treatment)
- *Might be extended beyond 3 months if the child is breastfeeding

All ARV formulations to provide PMTCT services are commercially available and are listed in the WHO prequalification scheme. However, current pediatric formulations of Nevirapine syrup and Zidovudine syrup are still problematic with regards to the packaging and dosing of the product. For example, Nevirapine is commercially available in bottles of 240ml while one dose of 0.6ml is needed to be used only once in a newborn. Similarly, Zidovudine is also packed in larger volume than what is needed for a newborn. Moreover, for both Nevirapine and Zidovudine, measuring the right dose before administering it to the infant is a particular concern.

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\(^{11}\) For the full list of items and technical specifications, you can refer to the UNICEF Supply Catalogue available at: [http://www.supply.unicef.dk/catalogue/](http://www.supply.unicef.dk/catalogue/)
problem. Doses as small as 0.6ml are difficult to measure without a dispensing syringe/device. In some countries, Boehringer Ingelheim facilitated a complementary donation from Baxa to make available a syringe pre-filled with the single dose of Nevirapine, as part of the donation program. Nevirapine suspension is stable in this packaging for up to two months, facilitating the dispensing of the infant dose. Nevertheless, new packing and dispensing devices for infant formulations are needed and innovative approaches need to be explored.

7. Supply System for PMTCT intervention

Not all activities for PMTCT interventions are carried out in one health facility: Antenatal Care (ANC), Labor/Delivery, Mother and Child Health Care (MCH), ART centers, Laboratory diagnostics services are often separate and may be in different locations. Even when all these services are offered within one health institution, they may still be located in different buildings with different administrative arrangements. All these aspects must be taken into consideration when planning for supply system as they all represent different distribution points for commodities. In other words, ANC, labor/delivery rooms, MCH centers. ART centers, Laboratories all need to have continuous flow of supplies and have capacities to store, manage and use appropriately commodities that are needed for a PMTCT intervention.

A well functioning supply system is a prerequisite for effective PMTCT intervention. The system of forecasting, procurement and distribution of commodities needed for PMTCT needs to be streamlined with the existing supply system of HIV/AIDS commodities. It is therefore necessary to review national supply systems and policies early in the planning process of the PMTCT program in order to establish a sustainable system of supplies when starting to implement more efficacious regimens while at the same time going to scale.

Although there are different approaches that can be used, the following suggested steps are essential to be taken into consideration when developing procedures for supply management in PMTCT at a country level:

PMTCT program planers should link with the existing national or institutional committee on HIV/AIDS supplies management and managers of the respective medical stores to assess the scale up plan for PMTCT and plan for supplies accordingly:

1. Identify sites that will start to implement more efficacious regimens.
2. Identify targeted sites that will roll out the program at least in the coming year.
3. Map the referral system and linkages of the PMTCT program; “walk in the shoes of a possibly infected pregnant woman” and identify stages and settings where she (and the baby) is expected to get counseling, testing, treatment and care before and after delivery.
4. Create the list of essential items needed for the PMTCT intervention, including laboratory supplies.
5. 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: lead time in ordering and procurement; storage and distribution capacity; buffer stock.

6. Decide which items need to be supplied continuously at which sites: ANC, maternity, MCH clinic, ART centers, pediatric ART centers, family planning centers, and laboratory.

7. Analyze existing procedures for procurement, which include ordering, storage, distribution, issuing, dispensing at all levels of care.

8. Identify and map processes and procedures for supplying the targeted PMTCT sites.

9. Develop a package for supervisors and health workers in PMTCT sites which include brief description of technical requirements for good storage, management and use of items for PMTCT, as well as description of the process for ordering, receiving, storing, recording and reporting.

10. Produce job aids such as wall-charts for the staff in PMTCT sites with a clear description of the PMTCT intervention, administration of ARVs for prophylaxis and linkages that need to be followed in the system.

11. Introduce the supplies information package in each PMTCT site combined with a training session for the staff.

12. 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.

Useful resources:

Unicef Supply Division: www.unicef.org/supply
UNICEF on children and AIDS
http://www.uniteforchildren.org/knowmore/knowmore_28756.htm
WHO on PMTCT http://www.who.int/hiv/mtct/en
Procurement and Supply Management Toolbox available at http://www.psmtoolbox.org
WHO AIDS Medicines and Diagnostic Service (AMDS) accessible at www.who.int/hiv/amds/en
WHO Prequalification Program http://mednet3.who.int/prequal/