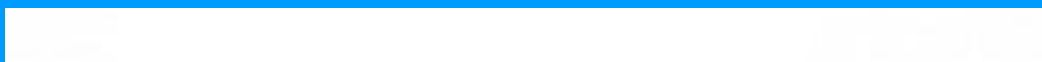




**GUIDANCE ON ENSURING  
EFFECTIVE SUPPLY CHAIN  
PLANNING FOR COMMODITIES  
NEEDED FOR IMPLEMENTATION AND  
SCALE UP OF SERVICES FOR THE  
PREVENTION OF MOTHER TO CHILD  
TRANSMISSION (PMTCT) OF HIV  
INFECTION.**

**July 2008**



## Table of contents

1. Objective .....	3
2. Context.....	3
3. Role of UNICEF in PMTCT .....	4
4. What is PMTCT? .....	4
5. Guidelines on the use of ARV for the treatment of HIV positive pregnant women and prevention of HIV infection in infants and young children .....	5
5. Recommendations on infant feeding and infant feeding.....	6
6. Recommendation on prophylaxis of opportunistic infections.....	6
7. Recommendation on early diagnosis of HIV infection in infants.....	6
8. Optimizing supply chain management to provide PMTCT services.....	6
9. Category of supplies.....	8
10. Supplies available through the pharmaceutical sector: Antiretroviral medicines.....	8
11. Outline of Annexes .....	9
ANNEX 1. ....	10
ANNEX 2 .....	12
ANNEX 3 .....	16
ANNEX 4 .....	17
ANNEX 5 .....	18

## 1. Objective

This document outlines general principles for program and supply managers on which to base supply planning for commodities needed for the implementation of current WHO and national guidelines on the Prevention of Mother to Child Transmission (PMTCT) of HIV, Cotrimoxazole prophylaxis, ARV prophylaxis and ARV treatment for pregnant women. It suggests a basic approach that can ensure effective and sustainable supply of PMTCT related commodities.

## 2. Context

Every day, around 1400 infants are infected with HIV during pregnancy, labor and delivery, or breast-feeding. HIV disease progresses very quickly in infants, with around 50% dying before the age of two if they do not receive care and treatment.<sup>1</sup>

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 ranges between 20-45%. This rate of infection can be successfully and affordably reduced to less than 2% if a comprehensive intervention is applied. The current WHO guidance includes the provision of treatment, care and support to women living with HIV/AIDS and their children and families. This means that pregnant women who are diagnosed to be HIV positive and are eligible for ARV treatment, must be enabled to obtain this treatment.

In developed countries with institutionalization of a package of evidence-based PMTCT interventions as a standard of care, infection in infants has virtually been eliminated. However, in middle and low income countries, only about 23% of HIV positive pregnant women were reached by PMTCT interventions in 2006.<sup>2</sup> Coverage rates are lowest in West and Central Africa, Asia and East and Southern Africa, reaching only 7%, 7% and 30.5% of HIV-infected women respectively.<sup>3</sup>

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 Maternal, Newborn 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.<sup>4</sup>

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<sup>1</sup> UNICEF statistics available at <http://www.childinfo.org/areas/hiv/aids/mtct.php>, last update March 2006.

<sup>2</sup> UNICEF/WHO, Report Card on PMTCT and Pediatric HIV care, 2006; WHO, UNICEF and UNAIDS. Progress report. April 2007. Available at: [http://www.unicef.org/progressforchildren/2007n6/index\\_41837.htm](http://www.unicef.org/progressforchildren/2007n6/index_41837.htm)

<sup>3</sup> UNICEF statistics available at [http://www.childinfo.org/hiv\\_aids\\_mother\\_to\\_child.html](http://www.childinfo.org/hiv_aids_mother_to_child.html) last update March 2007.

<sup>4</sup> For more information on the global response to scaling up PMTCT interventions see "Children and AIDS: A Stocktaking report" released by UNICEF in January 2007. <http://www.who.int/hiv/paediatric/stocktakingreport.pdf>

### 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. **UNICEF has now positioned itself to work within the context of national programs towards integration of PMTCT and paediatric treatment interventions into Maternal, Neonatal and Child Health (MNCH), child survival programmes national health systems.**

### 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:<sup>5</sup>

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 or to delay future pregnancies, 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, ARV prophylaxis, antiretroviral (ARV) therapy for women who are eligible for treatment, safer delivery practices, infant feeding and counseling 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 ART for her own health so she is able to offer care to the newborn. The death of a mother is a high risk factor of child morbidity and mortality.

PMTCT as a set of consecutive interventions, must include: offering HIV testing & counselling; access to ARVs and co-trimoxazole prophylaxis for the mother and the baby; counselling to choose an appropriate infant feeding method; ART eligibility screening including, WHO clinical staging and CD4 testing for the mother; Early Infant Diagnosis for the baby; ensure that linkages with Maternal, New born and Child health programs (MCNH), ART centers and paediatric ARTs are functional. These

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<sup>5</sup> World Health Organization. The strategic approaches to the HIV prevention in infants. Geneva. 2003. Available at: <http://www.who.int/hiv/mtct/StrategicApproaches.pdf>

interventions are more site specific strategies and are delivered through the health care system.

## **5. Guidelines on the use of ARV for the treatment of HIV positive pregnant women and prevention of HIV infection in infants and young children.**

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 2 hours before delivery, and a single oral dose of 0.6ml Nevirapine suspension (10mg/ml) to the infant within the first 72 hours after birth (dose is 2mg/kg, assumption of a 3kg average weight for a new born infant).

Since then, considerable evidence has accumulated showing advantages of using more potent ARVs for prophylaxis, the effectiveness of ARVs, safety in pregnancy and resistance associated with the use of ARVs. As a result, in 2004 and 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 that countries adopt the following:

- ART for all HIV infected pregnant women in need of treatment for their own health
- The use of more efficacious ARV prophylactic regimens for women who are not eligible for antiretroviral therapy, and
- Using single-dose maternal and infant Nevirapine as a practical short-term alternative though less desirable alternative in situations where combination regimens are not feasible yet.<sup>6</sup> Using single dose Nevirapine (Sd-NVP) should be considered a short-term interim measure while steps are being taken to enable more effective regimens to be delivered.
- Drugs used should be formulated in such a way as to reduce pill/liquid burden and promote adherence. Fixed Dose Combinations and co packaged products are recommended.

The current guidelines recommend that:

- a HIV positive pregnant woman who are not eligible for antiretroviral therapy (ART), should start taking Zidovudine 300mg twice a day from the 28<sup>th</sup> week of pregnancy or as soon as possible thereafter. In addition, at the onset of labor, she will take a start dose of Nevirapine 200mg , Lamivudine 150mg and Zidovudine 600mg (This translates to one Fixed Dose Combination tablet containing Zidovudine 300mg+Lamivudine150mg, plus and extra dose of Zidovudine 300mg).

-Immediately after birth, the baby has to receive a single dose of Nevirapine suspension 2mg/kg (currently formulated as 10mg/ml) and then start taking Zidovudine suspension 4mg/kg every 12 hours (currently formulated 10mg/ml) for one week or four weeks if the mother received less than four weeks of Zidovudine during pregnancy.

-After delivery the mother should continue taking a combination of Zidovudine 300mg and Lamivudine 150mg every 12 hours for 7 days (referred to as the “tail”) to reduce the risk of resistance to Nevirapine.

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<sup>6</sup> WHO guidelines on PMTCT can be found at <http://www.who.int/hiv/pub/mtct/pmtct/en/>

-If the mother was already on ART before becoming pregnant, she will continue with her regular treatment while the infant will need to take Zidovudine for seven days only.

For details of the ARV prophylaxis and treatment options for pregnant women and ARV Prophylaxis for new born infants, please see <http://www.who.int/hiv/pub/guidelines/pmtctguidelines3.pdf>

## **6. Recommendations on infant feeding and infant feeding**

Addressing infant feeding options with the mother is as important as giving 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 replacement feeding is acceptable, feasible, affordable, sustainable and safe. Exclusive breastfeeding is supported in all other cases when these conditions are not met.<sup>7</sup>

## **7. Recommendation on prophylaxis of opportunistic infections**

WHO recommends that all infants exposed to HIV (Infants born to HIV positive women) should receive Cotrimoxazole prophylaxis once a day, starting at 4-6 weeks of age and continuing until HIV infection is excluded. Cotrimoxazole can reduce child mortality in HIV infected 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 and ways should be devised to increase uptake.<sup>8</sup>

## **8. Recommendation on early diagnosis of HIV infection in infants**

To enhance prevention efforts (e.g. optimal support for exclusive breastfeeding among breastfeeding populations), be able to offer proper care, treatment and support and ultimately measure the effectiveness of the PMTCT intervention, It is important to provide access to early infant diagnostic testing for HIV.. 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 passively transmitted 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 and countries are encouraged to make efforts to make these available.<sup>9</sup>

## **9. Optimizing supply chain management to provide PMTCT services**

It is recognized that currently, not all activities for PMTCT interventions are carried out in one physical location: Maternal, Neonatal and Child health care facilities (that offer family planning, Antenatal Care (ANC) and immunization), Labor/Delivery, ART centers, Laboratory diagnostics services may often be in different physical localities.

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<sup>7</sup> UNICEF and WHO. Planning Guide for National Implementation of the Global Strategy for Infant and Young Child Feeding. Geneva. 2007. Available at: [http://www.who.int/child-adolescent-health/New\\_Publications/NUTRITION/ISBN\\_978\\_92\\_4\\_159519\\_3.pdf](http://www.who.int/child-adolescent-health/New_Publications/NUTRITION/ISBN_978_92_4_159519_3.pdf)

<sup>8</sup> World Health Organization. Guidelines on co-trimoxazole prophylaxis for HIV-related infections among children, adolescents and adults: Recommendations for a public health approach. Geneva. 2006. Available at: <http://www.who.int/hiv/pub/guidelines/ctxguidelines.pdf>

<sup>9</sup> See Guidance Notes on Early Infant Diagnosis issued by UNICEF Supply Division. 2007.

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 and they all need to have continuous flow of supplies with capacities to store, manage and use these commodities appropriately.

A well functioning supply chain system is a prerequisite for effective PMTCT intervention. This should include agreement on what specific items are required, quantities required over a given period in time, available finances, procurement methods, storage, distribution and appropriate use. It is recommended that the supply chain system PMTCT commodities be aligned with those for the wider HIV/AIDS commodities and, ultimately, the national health commodity supply chain. 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, the pharmacy department within the Ministry of health and managers of the respective medical stores to assess the unmet needs and the scale up plan for PMTCT and plan for supplies. For more details, please see procurement and supply management for HIV/AIDS (CF/PD/PRO/2006-11)

<http://www.intranet.unicef.org/PD/PDC.nsf/f983eca69fad0f9285256c760051e9bf/7b1f6c5f995b43648525723c005c1bdc?OpenDocument>

1. Identify sites that will start to implement new or more PMTCT services and/or implement the use of the 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 PMTCT intervention, including laboratory supplies.
5. Identify all partners working with PMTCT in the country
6. 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. Forecasting and quantification should be done as part of a national effort.
7. 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.
8. Analyze existing procedures for supply chain, which include planning, forecasting, procurement, storage, distribution, MIS and reporting, and dispensing at all levels of care.
9. Identify and map processes and procedures for supplying the targeted PMTCT sites, identify and analyze gaps, and develop an action plan how the gaps can be filled.
10. 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.

11. 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.
12. Introduce the supplies information package in each PMTCT site combined with a training session for the staff.
13. It is suggested that the committee responsible for 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.

## 10. Category of supplies

In order to support in-country health facilities initiating, scaling up PMTCT services or transitioning to more efficacious PMTCT, the following categories of supplies must be considered:

- Items supplied through the sexual and **reproductive health system** (condoms, reproductive health commodities).
- Items supplied through **laboratory services** (Pregnancy test kits, rapid HIV test kits, Syphilis, Hb test facilities and consumables, PCR, CD4, laboratory equipment).
- Items supplied through the **pharmaceutical sector** (basic essential drugs, such as iron and folate, supplements, commodities for IPT, antibiotics for infections, ARVs, vaccines as per vaccination schedule).
- **Medical equipment** such as basic midwifery delivery packs and medical consumables.
- **Nutritional support** (replacement feeds, when appropriate).

## 11. Supplies available through the pharmaceutical sector: Antiretroviral medicines

ARV medicines required for PMTCT interventions are commercially available and are listed in the WHO prequalification programme website (<http://healthtech.who.int/pq/>), if prequalified by WHO. However, current available pediatric suspensions of Nevirapine syrup and Zidovudine syrup are available in pack sizes that are designed for treatment and therefore, not suitable for the lower quantities required for PMTCT. For example, Nevirapine 10mg/ml is commercially available in bottles of 100ml and 240ml while only a single dose of 0.6ml (based on 2mg/kg) is needed for a newborn. Similarly, Zidovudine 10mg/ml in bottles of 100ml-240ml and can be a challenge when the larger volume bottles is what is accessible to countries. Doses as small as 0.6ml are difficult to measure without a suitably graduated dispensing syringe/device. Some countries have access to a complementary donation of Nevirapine suspension in 20-25ml bottles, accompanied with an oral syringe that has a closure cap. This oral syringe can be prefilled/prepacked with the required quantity of Nevirapine suspension at the health facility and be taken home by the mother for administration to an infant on delivery, with a current recommended shelf life of two months. It is recommended that prefilled syringes be packed in suitable Aluminium pouches to decrease moisture loss. Mothers must be adequately counseled on the at-home storage and use requirement. The oral syringe can also be used to measure and administer Nevirapine to a new born infant directly, as needed. It is hoped that such products will soon be available beyond the donation programme. Nevertheless, new packing and dispensing devices for infant

formulations are needed and UNICEF is exploring innovative approaches to meet this demand.

## **12. Outline of Annexes**

Annex 1: A list of commodities needed to provide PMTCT services within the context of a minimum package of care in Maternal, Newborn and Child health services.

Annex 2: A stepwise process for assessing readiness of supply chain for PMTCT commodities.

Annex 3: A proposed process for introducing supply management procedures.

Annex 4: A summary of recommended actions for programmes planning to scale up services.

Annex 5: Key resource documents and technical briefing notes provided by United Nations agencies and other organisations.

## ANNEX 1

### COMMODITIES NEEDED TO PROVIDE PMTCT SERVICES WITHIN THE CONTEXT OF A WHO RECOMMENDED SCHEDULE FOR MOTHER AND CHILD CARE

When?	What happens in terms of intervention?	Implications for supply planning
<b>Antenatal visit 1</b> Between 16 and 34 weeks	<ul style="list-style-type: none"> <li>• HIV/STD counselling</li> <li>• Promotion of condom use</li> <li>• HIV testing</li> <li>• Syphilis screening</li> <li>• TT Immunisation</li> <li>• Hb Screening</li> <li>• Anaemia prophylaxis</li> <li>• Malaria prophylaxis as needed</li> </ul>	Ensure access to/ availability of: <ul style="list-style-type: none"> <li>• Condoms</li> <li>• HIV tests/consumables needed in testing</li> <li>• Syphilis test/consumables needed in testing</li> <li>• Vaccine/ consumables for administration</li> <li>• Hb testing facilities</li> <li>• Cotrimoxazole prophylaxis</li> <li>• Iron and folate supplements</li> <li>• Malaria prophylaxis if needed</li> </ul>
<b>Antenatal visit 2</b> Two weeks after the first ante-natal visit, between 18 and 36 weeks	<ul style="list-style-type: none"> <li>• Syphilis treatment</li> <li>• Confirmation of HIV positive tests</li> <li>• Post-test counselling</li> <li>• Consent for ARV prophylaxis/initiation of treatment for HIV positive women if eligible</li> <li>• HIV positive women referred to support groups and services</li> <li>• Promotion of exclusive breast-feeding to all pregnant women with HIV</li> <li>• Infant feeding counselling for HIV positive mothers</li> </ul>	Ensure access to/ availability of: <ul style="list-style-type: none"> <li>• HIV tests/consumables needed for testing</li> <li>• Antibiotics for STD treatment</li> <li>• HIV tests for confirmation and tie breakers</li> <li>• Consumables needed in testing</li> <li>• ARVs for prophylaxis as needed</li> <li>• ARVs for ART as needed</li> <li>• Cotrimoxazole prophylaxis</li> <li>• Hb monitoring facilities</li> </ul>
<b>Antenatal visit 3</b> 34- 36 weeks	<ul style="list-style-type: none"> <li>• Initiation of ARV treatment if eligible/prophylaxis if regimen recommended includes a pre-natal component</li> <li>• Counselling and testing of partner</li> </ul>	Ensure access to/ availability of: <ul style="list-style-type: none"> <li>• ARVs for Prophylaxis as needed</li> <li>• ARVs for ART as needed</li> <li>• HIV tests/consumables needed for testing</li> <li>• Cotrimoxazole prophylaxis</li> <li>• Hb monitoring facilities</li> </ul>

<b>Labour/delivery</b>	<ul style="list-style-type: none"> <li>• Intra-partum ARV component</li> <li>• Avoidance of unnecessary invasive procedures</li> <li>• Universal precautions</li> </ul>	<p>Ensure access to/ availability of:</p> <ul style="list-style-type: none"> <li>• ARVs for Prophylaxis</li> <li>• Basic midwifery pack</li> </ul>
<b>Immediate post-partum</b>	<ul style="list-style-type: none"> <li>• Support to infant feeding (as per choice of the mother)</li> <li>• BCG, polio 0</li> <li>• Family planning, promotion of condom use</li> <li>• Initiation of ART if eligible</li> <li>• Referral to support groups/care services.</li> </ul>	<p>Ensure access to/ availability of:</p> <ul style="list-style-type: none"> <li>• Vaccines as per schedule</li> <li>• ARV prophylaxis for infant</li> <li>• ARV prophylactic “tail” for mother and infant.</li> <li>• ARVs for ART as needed</li> <li>• Cotrimoxazole prophylaxis</li> </ul>
<b>According to EPI Plus schedule</b>	<ul style="list-style-type: none"> <li>• DPT1, DPT2, DPT3, measles (hepatitis B)</li> <li>• Support to adequate feeding and infant caring practices</li> <li>• Growth monitoring</li> <li>• Referral to support groups/ care services</li> </ul>	<p>Ensure access to/ availability of:</p> <ul style="list-style-type: none"> <li>• Products for nutritional support when needed</li> <li>• Products for replacement feeding if needed</li> <li>• Cotrimoxazole prophylaxis</li> <li>• Vaccines as per schedule</li> <li>• Equipment for growth monitoring</li> </ul>
<b>As needed for illness</b>	<ul style="list-style-type: none"> <li>• Treatment of infections</li> <li>• Nutritional and caring counselling</li> </ul>	<p>Ensure access to/ availability of:</p> <ul style="list-style-type: none"> <li>• Basic essential drugs</li> <li>• Cotrimoxazole prophylaxis</li> <li>• Drugs for opportunistic infections</li> <li>• Products for nutritional support when needed</li> </ul>
<b>According to HIV screening schedule</b> (e.g. Elisa at 12 and 18 months of age)	<ul style="list-style-type: none"> <li>• HIV testing of the baby</li> <li>• Referral for paediatric care if child HIV positive</li> </ul>	<p>Ensure access to/ availability of:</p> <ul style="list-style-type: none"> <li>• HIV testing facility for the infant</li> <li>• Co-trimoxazole prophylaxis</li> <li>• Drugs for opportunistic infections</li> <li>• Products for nutritional support when needed</li> </ul>

Adapted from UNICEF Technical Guidance Note on PMTCT (October 2002) and WHO Guideline on Scaling up ARV treatment in Resource Poor Settings (December 2003, 2006)

## **ANNEX 2**

### **STEPWISE PROCESS FOR ASSESSING READINESS OF SUPPLY CHAIN FOR PMTCT COMODITIES**

#### **STEP 1: Ensuring that supply management is appropriately coordinated.**

Has a coordinating body, committee/task team or person, been appointed to be responsible for developing the overall supply strategy?	? Yes	? In preparation	? No
Are all relevant persons represented (AIDS national Program, Medical Store,...)? Do they have optimal opportunity to provide inputs?	? Yes	? In preparation	? No
Have supply objectives been developed regarding the provision of medical equipment and consumables, reproductive health commodities, laboratory requirements, pharmaceuticals and nutritional products as needed, as outlined in annex 1?	? Yes	? In preparation	? No
Is there a subcommittee/task team member responsible for assessing the opportunity costs and financial viability of this intervention, from a supply perspective?	? Yes	? In preparation	? No
Is there a management information system/framework for reporting procurement and utilization data at regular intervals? Is there a person/ task team responsible for analyzing the information and reporting it to the coordinating body?	? Yes	? In preparation	? No
Is there a schedule of meetings linked to the implementation of the overall intervention?	? Yes	? In preparation	? No

**STEP 2: Ensuring that appropriate PMTCT equipment and consumable commodities are selected, following recognized criteria for inclusion in procurement lists.**

Is there a government structure, such as an EML committee, governing the selection of health commodities to be provided in the health care setting affected by this intervention ?	? Yes	? In preparation	? No
Was the core package of services to be provided in the intervention reviewed, and is there a list of commodities required to provide these services? (see annex 1)	? Yes	? In preparation	? No
<ul style="list-style-type: none"> <li>i. Is there a VCCT or Provider Initiated testing and counselling (PITC) policy with a universally agreed testing algorithm?</li> <li>ii. Are there a policy on pharmaceuticals to be provided in the minimum care package, including an ARV regimen for PMTCT?</li> <li>iii. Is there a policy on the supply of breast milk substitute?</li> </ul>			
Was a facility review performed to assess the infrastructural requirements for implementing the intervention, and is there a list of basic facilities and/or equipment required to provide the services?	? Yes	? In preparation	? No
Is there agreement among all stakeholders on which commodities are to be supplied, and is there a list of items with quantities needed and indications of who will procure/donate them?	? Yes	? In preparation	? No

**STEP 3: Ensuring that PMTCT equipment and consumable commodities are procured through reliable, cost-effective mechanisms.**

Has a procurement strategy (who will buy what) been defined for both the pilot and the expanded phase of the project?	? Yes	? In preparation	? No
Are there minimum quality criteria for the commodities to be supplied?	? Yes	? In preparation	? No
Is there a list of pre-qualified potential suppliers for all equipment and consumables? How is local and international competition ensured?	? Yes	? In preparation	? No
Have the regulatory requirements for procuring these items been considered, e.g. registration status of drugs?	? Yes	? In preparation	? No
Have the legal implications been considered? E.g. patent situation, prescribing restrictions of certain drugs and/or loopholes in maintenance contracts for equipment?	? Yes	? In preparation	? No
Is there a supply plan with quantities and delivery dates for initial orders, follow up orders, emergency orders/contingency stocks?	? Yes	? In preparation	? No
Was an orientation/training module developed for procurement staff, and is there a schedule for implementing this training?	? Yes	? In preparation	? No
Is there a monitoring and evaluation strategy that includes monitoring the quantities procured/distributed and linking it to the number of clients enrolled in the intervention ?	? Yes	? In preparation	? No

#### STEP 4: Ensuring appropriate storage and reliable, cost-effective distribution of PMTCT equipment and consumable commodities

Is customs clearance arranged for the supplies, and responsibility? Cost and payment by who?	? Yes	? In preparation	? No
Has a storage and inventory management strategy been defined?			
Has the means for In country distribution/transport and Delivery to Facility been determined and arranged (using government facility or outsourcing, contracting to private sector)? What is the cost structure?			
Is management information system implemented? At what interval, disseminated to whom? Is it possible to generate reports to track consumption against budgets at various levels?			
Is it possible to generate reports on specific programme issues, such as PMTCT (for example, based on the PMTCT report card)?			
Is there a contingency strategy to ensure a reliable supply when off-take and supply needs are erratic, e.g. in the first phase of implementation? Are stock levels monitored in facilities initiating with redistributing as necessary?	? Yes	? In preparation	? No
Have the supply systems affected in this intervention been reviewed for its efficiency and effectiveness, and are there recommendations for improvements/alternatives to be assessed?	? Yes	? In preparation	? No
Is there a workplan with timelines and responsibilities for setting up storage areas, placing opening orders, defining ordering intervals, developing ordering procedures, etc? (see annex 2)	? Yes	? In preparation	? No
Is there a monitoring and evaluation strategy that includes monitoring the quantities ordered/distributed and linking it to the number of clients enrolled in the intervention?	? Yes	? In preparation	? No
Was an orientation/training module developed for supply management of PMTCT commodities at facility level, and is there a schedule for implementing this training?	? Yes	? In preparation	? No

**STEP 5: Ensuring appropriate use of PMTCT commodities, not only to streamline supply chains but also to ensure appropriate patient care in the context of ANC**

Are there clinical guidelines for/training materials on providing PMTCT services within the context of ANC?	? Yes	? In preparation	? No
Is good dispensing practice included in the training modules?	? Yes	? In preparation	? No
Is there a training strategy with timelines that will govern, for example, the number of counsellors trained per reporting period?	? Yes	? In preparation	? No
Is there a monitoring and evaluation strategy that monitors the use of products and, for example, links the number of clients enrolled to commodities consumed?	? Yes	? In preparation	? No

**ANNEX 3**

**PROPOSED PROCESS FOR DEVELOPING PROCEDURES FOR SUPPLY MANAGEMENT**

- Review existing procedures for procurement, which includes product selection, quantification, procurement, ordering, receipt, storage, distribution, issuing, dispensing etc., at all levels of care, and draft a set of generic procedures.
- Develop a training package for supervisors and health workers in pilot sites, which include technical background as well as generic procedures.
- Develop, during the training, a strategy to adapt generic procedures for application in the facility.
- Ask supervisors to report on progress on a monthly basis.
- Review appropriateness after one month, three months and six months, and adapt as needed.
- Revise the generic procedures and use that as a basis for training in the roll-out/scale up

## ANNEX 4

### RECOMMENDED ACTIONS FOR PMTCT PROGRAMMES GOING TO SCALE AND IMPLEMENTING THE MORE EFFICACIOUS REGIMENS.

Essential Service Component	Recommended Actions	Other Options
<b>Supply Planning</b>		
Review past programme experiences focusing on supplies	<p>Assess/re-assess the appropriateness of commodities and functioning of various supply components of the programme:</p> <p><b>Reproductive Health (Prong 1, 2)</b> (Condoms, reproductive health commodities)</p> <p><b>Laboratory Services (Prong 1, 2, 3)</b> (Test kits for -HIV, -syphilis, and consumables)</p> <p><b>Pharmaceutical Sector (Prong 1, 2, 3, 4)</b> (Basic essential drugs, such as iron and folate, supplements, antibiotics for treating infections, ARV's. Vaccines as per vaccination schedule)</p> <p><b>Medical Equipment (Prong 1, 2, 3, 4)</b> (Basic midwifery delivery packs and medical consumables)</p> <p><b>Nutritional Support (Prong 3, 4)</b> (replacement feeds when appropriate)</p>	Review activity reports of partners involved in pilot studies and/or delivering services, current PMTCT activities and analyze supply successes and/or breakdowns.
Define a revised list of core commodities that includes appropriate technologies	<p>Review amendments to policies, scale up strategies and programming frameworks.</p> <p>Perform a market survey and assess the need for and feasibility of introducing new products and technologies.</p>	Review commodity procurement lists used by national programs and partners Share experiences nationally and internationally
Develop a supporting supply strategy for scaling up of PMTCT services in the context of mother and child health	Prepare a supply plan linked to the implementation plan of the expansions strategy; covering selection, procurement, distribution and storage, and training on the use of commodities. Develop a strategy for the introduction of new products; phase out of obsolete. Define a framework for monitoring and evaluating supply aspects of PMTCT	Assess consequences of supply breakdowns

## **ANNEX 5**

### **CORE RESOURCE DOCUMENTS**

- Quick et al (eds): Managing Drug Supply Second Edition. Kumarian Press, 1997
- Family Health International (FHI): Module 7: Managing the supply of drugs and commodities. In: Strategies for an expanded and comprehensive response to a national HIV/AIDS epidemic: a handbook for designing and implementing HIV/AIDS Programs. See: <http://www.fhi.org> - new publications
- WHO HIV/AIDS Guidelines <http://www.who.int/hiv/pub/guidelines/en/index.html>
- WHO: HIV and Infant Feeding. Framework for priority action 2003  
<http://www.who.int/hiv/pub/mtct/en/HIVandInfantFeeding.pdf>
- ? HIV/AIDS Care and Support Programme Guidance Note, October 2003
- Supply Division Briefing Note on HIV/AIDS and products required for PMTCT, January 2004

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#### **Additional useful websites**

UNICEF on children and AIDS

[http://www.uniteforchildren.org/knowmore/knowmore\\_28756.htm](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](http://www.who.int/hiv/amds/en)

WHO Prequalification Program <http://healthtech.who.int/pq/>