Preventing Mother-to-Child Transmission (MTCT)

Background

In sub-Saharan Africa, where up to 40 percent of pregnant women are now HIV-infected, the HIV/AIDS pandemic has eroded hard-won gains in infant and child survival and threatens to have catastrophic effects on the family and on normal population dynamics. In contrast, the U.S. and other developed countries are on the verge of eliminating HIV MTCT.

Without intervention, there is a 15 to 30 percent risk of MTCT during pregnancy and delivery (most transmission occurs close to the time of delivery), and an additional 10 to 20 percent risk postpartum via breastfeeding. The single most important risk factor for transmission is maternal viral load in plasma, cervico-vaginal secretions, and breast milk.

The technology now exists to substantially reduce MTCT in developing countries, based on simplified interventions that are feasible, although still challenging to implement in resource-poor settings. Recent international clinical trial results have demonstrated that the risk of MTCT could be reduced by 30 to 50 percent by administering short-course antiretroviral prophylaxis in the last weeks of pregnancy or at labor and delivery, and by changing breastfeeding practices in HIV-infected women. The urgent challenge is to translate research findings into public health intervention programs, and to link MTCT to surveillance, primary prevention, and care.

Apart from choice of antiretroviral regimen, key issues related to the ability to implement short-course MTCT interventions include 1) access to voluntary HIV counseling and testing (VCT), 2) community support and acceptance, and 3) integration of MTCT interventions into local maternal-child health (MCH) services. In addition, the breastfeeding dilemma remains complex. Although breastfeeding should remain the cornerstone of MCH programs, replacement feeding from birth or exclusive breastfeeding followed by early weaning should be encouraged for HIV-infected women. Concerns about replacement feeding include safety, stigma, and negative spillover effects on HIV-negative women, and must be weighed carefully in the local setting.

Following the results of the short-course zidovudine (ZDV) studies, international health agencies have developed a series of guidelines and strategic options for MTCT interventions in developing countries, and UNICEF has taken a leading role in promoting pilot MTCT programs in developing countries. However, only a few programs are currently operational, and these are at early stages.

Recognized Best Practices

UNAIDS, WHO and UNICEF have taken the lead in developing best practice guidelines for MTCT intervention programs based on voluntary counseling and testing (VCT), short-course antiretrovirals, and options related to breastfeeding.
Recommendations and strategic options will need to be updated as new data and experience become available.

**Key interventions**

- Routine, simplified voluntary counseling and testing (preferably rapid testing)
- Antenatal, whenever possible (e.g., routine, group pre-test counseling), or
- At labor/delivery or immediately postpartum.
- Antiretroviral prophylaxis.

For women with ANC

- Short-course ZDV (beginning at ~36 weeks’ gestation), or
- Single-dose nevirapine ("NVP", single dose to the mother at onset of labor and single dose to the infant at 2-3 days of life), or
- AZT/3TC intrapartum to the mother and one week postpartum to the infant.

For women with no ANC

- Immediate postpartum ZDV (6 weeks) to the infant, or
- Immediate postpartum nevirapine (1-2 doses) to the infant (no efficacy data available).

Counseling and alternatives to breastfeeding (status quo: early, exclusive breastfeeding) Replacement feeding from birth Early exclusive breastfeeding, followed by early weaning at 4-6 months.

**Related interventions**

- A successful HIV MTCT prevention program needs to be integrated into and strengthen basic antenatal MCH services, be linked to other key HIV primary prevention and care programs, be easily monitored and evaluated. It should include these elements:
- Community IEC mobilization (information, education, and communication).
- Primary prevention in adolescents and young adults.
- Basic ANC services (multivitamins with iron, syphilis screening and treatment, tetanus immunization, etc.).
- Family planning counseling.
- Maternal and infant HIV care--OI prophylaxis (eg. co-trimoxazole and INH) or antiretroviral therapy (if and when available).
- Basic data system and technical capacity for monitoring and evaluation--Maternal HIV prevalence, intervention acceptance and coverage, effectiveness (in targeted subpopulations).
• Infant laboratory testing (EIA and/or PCR, in a subset, for focused evaluations)

Applying Best Practice Guidelines to Real-World Settings

Capacity for implementing MTCT HIV intervention programs will vary considerably, based on level of antenatal care, whether births occur mostly in medical facilities or at home, and potential for replacement feeding. Although the goal should be to raise the level of care and infrastructure to setting 1 (below), which represents current best practice, pilot evaluations and operational research are needed for other settings common in Africa (settings 2-4 represent common scenarios).

Best practice

Setting 1) Good ANC, acceptance of antenatal HIV interventions, safe water supply, and safe alternatives to breastfeeding (largely urban Africa): Routine antenatal VCT, short-course ZDV, AZT/3TC or NVP, and replacement feeding for women who choose not to breastfeed. Data suggest that NVP is probably the most appropriate option in many developing countries.

Potential strategies for pilot evaluation

Setting 2) Fairly good but limited ANC (>75% access), low level obstetric services (predominantly home deliveries with traditional birth attendants), no safe water supply, and/or maternal decision to breastfeed (common scenario for rural Africa): Active IEC and routine VCT to support intervention, ZDV or NVP self-administered or by some form of directly observed therapy, promotion of early weaning where possible.

Setting 3) Weak ANC, stigma and barriers associated with ART and replacement feeding: Rapid testing at delivery, targeted NVP to mother in labor (if possible) and to infant immediately after birth.

Setting 4) Weak ANC, very high prevalence (>20-30%): Routine nevirapine to all delivering women and newborns, followed by testing and counseling where possible, and recommendations on feeding options.

CDC Experience and Capabilities

CDC has substantial experience and capability in both MTCT research and implementation. Its expertise is based on domestic and international work and includes surveillance, cohort studies defining risk factors for transmission, clinical trials to evaluate efficacy of short-course regimens transmission, and behavioral science issues. In the U.S., CDC has lead responsibility for U.S. Public Health Service recommendations and for monitoring their implementation, and is now leading a domestic perinatal HIV elimination initiative. Internationally, CDC has conducted collaborative, state-of-the-art perinatal HIV research in Zaire, Côte d'Ivoire, and Thailand. These efforts culminated in the successful efficacy trials of short-course ZDV in Thailand and Côte d'Ivoire.
CDC is now working actively to help implement and evaluate MTCT programs internationally. In Thailand, CDC worked with local collaborators to implement short-course ZDV in Bangkok, and has been working closely with the MOPH to help implement a regional MTCT program that recently became the basis for a national program. In Côte d'Ivoire, CDC is working with the MOH and FSTI to help establish short-course ZDV and ongoing care at selected clinical sites.

CDC is also actively collaborating in the international MTCT implementation effort in the following ways:

- Participating in UNAIDS MTCT working groups.
- Providing technical assistance to UNAIDS to develop monitoring and evaluation guidelines for MTCT pilot intervention programs.
- Providing technical assistance to UNICEF to help in implementing and evaluating MTCT pilot projects (e.g., Botswana, Rwanda and Zimbabwe).
- Consulting with Global Strategies for HIV Prevention and Pediatric AIDS Foundation.

**CDC Approach**

The objective of the MTCT initiative is to help implement feasible, sustainable interventions to decrease HIV MTCT in developing countries, and to assure that these interventions are integrated within MCH programs, strengthen antenatal care, promote the health of the mother, and enhance HIV prevention programs at the family and community level.

The Global AIDS Program (GAP) MTCT technical strategies will be based insofar as possible on best practice guidelines. In some cases, however, pilot interventions and operational research may be warranted to evaluate innovative approaches, where accepted best practice cannot be implemented.

GAP MTCT support to specific countries will vary, based on the country-specific MTCT strategy, its specific needs and requests from CDC, CDC capacity in-country, and commitments and support from other partners (e.g., UNICEF, WHO, FSTI, EU). The CDC approach for GAP MTCT support will emphasize coordination within a national AIDS plan, local leadership and capacity-building, integration within and strengthening of MCH services and expansion to scale beyond the pilot phase.

As first priority, individual country assessments are needed to review, help strengthen, or help develop national MTCT plans. Elements to address include 1) appropriate local MTCT strategy, 2) current activities and capacity, 3) key MTCT collaborators and stakeholders, 4) priorities, and 5) best opportunities for CDC assistance. This assessment should be updated periodically and would be used by the host MOH and CDC to determine how CDC can best assist in the implementation and/or monitoring and evaluation of the MTCT plan, and how best to coordinate work with other bilateral, international and NGO partners working on MTCT. Although a national plan is needed, in most developing countries MTCT intervention programs
should start as local demonstration projects which could serve as models for rapid expansion to scale.

To assist with overall planning, CDC will work with international agencies to finalize a MTCT implementation manual.

**Illustrative Activities**

1. Help develop and review MTCT pilot and national plans.
2. Help develop, implement and monitor antenatal or labor/postpartum VCT program.
3. Help develop and implement core database for basic monitoring of MTCT program.
4. Provide training in basic MTCT intervention components.
5. Assist in monitoring and evaluation, and plans for expansion.
7. Assist with establishing essential laboratory capacity and quality assurance (QA) (e.g., rapid testing, EIA and infant PCR testing in selected situations).
8. Assist with community IEC to promote understanding and support for MTCT program.
9. Infrastructure support - personnel: Support and training for national and/or local MTCT personnel.
10. Infrastructure support -- physical plant: Help build/renovate key facilities needed for MTCT (e.g., group counseling rooms with video, private counseling rooms, ANC exam rooms, simple laboratory in antenatal clinics and labor and delivery wards for rapid testing). Support local computer capacity/networking/Internet access.
11. Procure reagents, commodities, supplies needed for intervention (e.g., laboratory test kits, antiretroviral drugs, infant formula).
12. Facilitate training and linkages with NGOs and CBOs to mobilize social support and care.
13. Assist with breastfeeding and replacement-feeding counseling.

**Technical Considerations**

Although the primary interventions for MTCT might appear relatively straightforward, clear guidelines and appropriate training are needed to ensure that the interventions are offered in a reliable, consistent and locally acceptable manner. Standardizing each phase of the intervention is critical, as is assuring a realistic personnel plan for program management and delivery.

**Priorities:**

- Local guidelines for each phase of the intervention (based on implementation manual).
- Support and education materials for both clinic and community (posters, pamphlets, radio, videos etc.).
- Basic data monitoring system (simple, integrated with other local data, locally manageable, able to provide timely feedback).
- Quality assurance for HIV testing, including rapid testing and, where applicable, PCR testing of infants to determine outcome.
- A realistic personnel plan including training, refresher programs, and support.
- A realistic management plan to implement and sustain the intervention.
- Develop primary prevention plan to support HIV-negative women and reduce risk of incident infections during pregnancy and postpartum during breastfeeding.
- Screening, treatment, and prevention of STIs during pregnancy.

**Operational Considerations**

- Support full-time or part-time in-country MTCT advisor, with technical back-up from CDC-based consultants or supervisors.
- Integrate MTCT plan in-country as part of a national AIDS plan, since it impacts directly on primary prevention, surveillance, VCT and care as well as priority-setting and resource allocation.
- Promote collaborative efforts where UNICEF- or PAF-supported MTCT pilot projects have begun; clearly define specific roles to assure coordination and maximum effect.
- Develop a strong IEC strategy.
- Where possible, integrate the MTCT intervention within existing health care systems. If additional personnel are needed (e.g., laboratory technicians, counselors, outreach workers), identify needs and plan for integration within current systems.
- Assess the feasibility of replacement feeding for HIV-infected women, and address concerns related to safety and stigma.
- As new MTCT data become available, reassess intervention strategies.

**Resources**

The GAP MTCT program will draw upon the expertise of a wide range of CDC staff already working on MTCT projects and participating in CDC’s Informal International Perinatal Working Group. Atlanta-based experts will be available to provide support to in-country GAP assignees, collaborators from other agencies, and directly to local MTCT leadership. CDC may also contract with other groups to provide additional expertise and capacity.

**Key partners**

- UNICEF, UNAIDS, WHO
- Ministries of Health (MOH)
- National AIDS Control Programs (NACP)
Monitoring and Evaluation

Substantial efforts already have been undertaken to define key indicators, and a draft document on MTCT M&E has been issued by UNAIDS (See ref 2, p. 100). General M&E guidelines also have been summarized in the "Measure" project (see ref 5, p. 100).

GAP monitoring and evaluation will focus most on performance and outcome markers for programs. The highest priority will be monitoring of coverage and uptake. The second priority will be medical and social impact ("program effectiveness"), which could be assessed in selected samples (e.g., transmission rate, outcome, mortality in a sub-sample), and by focused, qualitative assessments (e.g., community support, feeding practices, stigma).

Evaluation of MTCT pilots and programs should be based on program objectives, defined as part of the review and development of country programs. Suggested MTCT program objectives:

- Antenatal care to >75% of childbearing women.
- HIV VCT to >95% of women seen in antenatal care settings.
- Provide >75% of HIV-infected women with an effective MTCT antiretroviral regimen.
- Reduce early MTCT HIV transmission (as measured at 2-4 months) to <10-15%
- Final rate (at 18-24 months) of <10-15% in areas offering replacement feeding.
- Final rate of <20-25% in areas that cannot offer replacement feeding, and in the absence of other interventions.

Key program indicators (coverage and uptake): Number of women registering for antenatal care, number offered VCT, number receiving HIV test, number receiving MTCT intervention.

Key outcome indicators: Early and late transmission rates, mortality, drug resistance.
Key social and program impact indicators: Acceptability, social impact, effect on infant feeding practices, costs and cost effectiveness, ability to provide local data for policy and decision-making.

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**Suggested Readings**

International Guidelines

1. Guidelines for the implementation of the prevention of mother to child transmission of HIV integrated in MCH and primary health care services. UNICEF/UNAIDS/WHO. May 1999 (draft).


6. UNAIDS. Guidelines for evaluating HIV voluntary counseling and testing. UNAIDS (Dept. of Policy, Strategy and Research), Geneva, 2000 (being finalized).


Other key references:


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