PREVENTING MOTHER-TO-CHILD TRANSMISSION OF HIV IMPLEMENTATION STARTER KIT

MOVING EVIDENCE INTO ACTION
This implementation starter kit describes and provides access to all the materials used in the Prevention of Mother-to-Child HIV Transmission (PMTCT) component of FHI 360's Zambia Prevention, Care and Treatment Partnership (ZPCT). The program resulted in a significant increase in the use of PMTCT services as well as significant reductions in the mother-to-child transmission of HIV among ZPCT clinic clients. It now serves as a model for other countries. This kit is designed to be used by program designers to replicate the success of the ZPCT PMTCT program in other settings.

This starter kit:

- Describes components of the ZPCT PMTCT intervention and the evidence of its effectiveness
- Discusses the core elements that contribute to the intervention's positive impact
- Provides links to program materials — such as training materials and job aids — with descriptions of how they are used
- Includes appendices with the latest World Health Organization PMTCT guidelines and general guidance on replicating effective programs
ZPCT I was a cooperative agreement between FHI 360 and the U.S. Agency for International Development (USAID) through the President’s Emergency Plan for AIDS Relief (PEPFAR). ZPCT I was in operation from 2004 to 2009 and worked to strengthen and expand HIV and AIDS services — including PMTCT services — in partnership with Zambia’s Ministry of Health (MOH) and the National AIDS Council. ZPCT I was implemented in five of Zambia’s nine provinces: Northern, Luapula, Copperbelt, Central and North-Western. With the exception of Copperbelt, these provinces have the highest poverty index in Zambia [1].

The key role of ZPCT I was to build capacity in the public health care system. It supported the implementation and scale-up of HIV services by the MOH through training, mentorship, structural refurbishments, strengthening of monitoring and evaluation systems, and the provision of equipment and medical supplies [1]. Most of the programmatic evidence compiled here is based on ZPCT I. (The program has been renewed through 2014 — as ZPCT II — to further replicate and expand its activities.)

The project now supports all four “prongs” of the United Nations’ 2001 strategy for PMTCT (see box). Nevertheless, this implementation kit focuses on Prong 3 because early efforts — and the available evidence — from ZPCT I focused primarily on Prong 3 efforts.

The ZPCT program integrates PMTCT services at all levels of health care. The integration takes place at several entry points of service [1]:

- antenatal care (ANC) settings
- labor and delivery wards
- maternal, newborn and child health clinics
- family planning clinics
- clinics for sexually transmitted infections (STI)

One of ZPCT’s strengths is its ability to respond to new programmatic evidence and to shifting global guidance and priorities. Like most PMTCT programs, ZPCT’s early years strongly emphasized the provision of antiretroviral (ARV) drugs to pregnant women living with HIV to prevent transmission of the virus to infants. However, as programmatic evidence and global guidelines increasingly recognized other PMTCT strategies, ZPCT increased its efforts to implement a comprehensive approach to address all four prongs of the United Nations’ strategy for PMTCT:

1. Prevention of HIV among women of reproductive age.
2. Elimination of unmet need for family planning and spacing of births for women living with HIV.
3. Expansion of access to HIV counseling and testing (CT) for pregnant women. Ensured access to antiretrovirals for pregnant women living with HIV to prevent the transmission of HIV to infants during pregnancy, birth and breastfeeding.
4. Provision of HIV care, treatment, and support to women living with HIV, their children and their families.

ZPCT II focuses significant efforts and resources on Prong 2; further details can be found in this 2012 document, created by FHI 360.
The program also supports a strategy in which health care workers (HCWs) provide ANC and PMTCT services to communities that are far from a health facility [1].

CASCADE OF SERVICES
ZPCT sites provide a cascade of services to increase HIV testing among pregnant women and prevent transmission to their infants:

1. **PMTCT activities during antenatal care.** Women typically enter the cascade of PMTCT services through routine antenatal care.

2. **Pre-test counseling.** Health care workers, lay counselors or both give motivational talks to groups of women in waiting rooms. Doing so reduces the time needed for one-on-one counseling.

3. **Opt-out HIV testing.** ZPCT uses same-day opt-out HIV testing. Testing is offered to all pregnant women as part of routine ANC care; women may opt out of HIV testing and still receive ANC. Testing is performed by either HCWs or trained PMTCT lay counselors.

4. **Results and post-test counseling.** “Testing corners” within some ANC clinics facilitate rapid HIV testing by nurses or lay counselors without relying on a lab. Women receive counseling, are tested and receive their results. Testing in the ANC clinics encourages women to remain on-site to receive their results.

5. **CD4 count testing.** All 210 health facilities supported by ZPCT I have access to CD4 testing for all pregnant women attending an ANC who test positive for HIV. CD4 testing is conducted on-site if the site has a laboratory with such capacity. For smaller health facilities with no such capacity, testing is conducted off-site through a sample referral system.

6. **ARV prophylaxis for mother, baby or both.** The Zambian National PMTCT Guidelines stipulate that women with CD4 counts equal to or less than 350 cells per milliliter should receive highly active antiretroviral therapy (HAART), whereas those with a CD4 of more than 350 should receive zidovudine (AZT) from 14 weeks gestational age with intrapartum single-dose nevirapine (sdNVP) and in postpartum a seven-day AZT + lamivudine (3TC). Single dose is offered as the last option for women unable to get AZT short-course prophylaxis [2].

7. **PMTCT interventions in labor and delivery services.**

8. **Postnatal follow-up of the mother and baby with counseling on infant feeding.** Exclusive breastfeeding is promoted to six months; no formula is provided for mothers who decide not to breastfeed. Family planning is offered to promote birth spacing and prevent unintended pregnancies. The baby is tested for HIV, and mother and child are linked to continuing services and support. This process is facilitated by the mother-baby tracking tool.

COMPONENTS OF PMTCT INTERVENTION
To establish and scale-up the cascade of services into all ZPCT I sites, the Prong 3 PMTCT intervention included these components [1]:

9. **Training for HCWs and lay counselors in HIV counseling and testing, PMTCT and commodity management.** Because of a severe shortage of qualified HCWs, the program did not hire new HCWs. Instead, program staff built the capacity of MOH employees and recruited volunteer lay workers — including some people living with HIV/AIDS — to support HCWs.
Lay workers were trained to provide some PMTCT services and conduct community engagement. Additionally, HCWs were allowed to work extra shifts and given an additional transport allowance.

- **Training of antiretroviral therapy (ART) nurse prescribers.** To strengthen the provision of the most efficacious ART regimens, nurse practitioners were trained in collaboration with the ZPCT training unit. This included training on provision of HAART for those eligible within the maternal, newborn and child health care (MNCH) services where feasible.

- **Creation of job aids for HCWs and lay counselors.**

- **Dissemination of relevant policy guidelines to all health centers.**

- **Intensive on-site mentorship for HCWs by ZPCT technical officers.** To operationalize and ensure quality PMTCT services, HCWs were trained in partnership with staff from the district medical offices.

- **Community mobilization targeting both women and men.** Community education was used to stimulate demand for PMTCT services. Activities involved traditional and religious leaders where possible to reduce stigma against HIV and related services.

- **System strengthening as the overarching approach for ZPCT I.** This component was guided by site assessments at each facility and included actions such as addressing training needs, refurbishing infrastructure, procuring necessary equipment and products, and training in ongoing management of PMTCT commodities.

The program was extended with USAID’s ZPCT II project through 2014 to further replicate and scale-up the intervention. Among other updates to comply with global guidelines on PMTCT, ZPCT II increased its focus on reducing unmet needs for family planning for women, including women living with HIV [3].

**THE INTERVENTION’S EFFECTIVENESS: RESEARCH RESULTS**

Research shows that the ZPCT PMTCT intervention was effective in several dimensions: It increased uptake of PMTCT services, and it successfully reduced mother-to-child transmission of HIV among ZPCT clinic clients.

Male involvement is an important part of an effective PMTCT intervention. Involving men has been shown to increase community acceptance and awareness of PMTCT services and increase the support that male partners give to PMTCT clients.

To encourage male partners to be involved at the clinic level, ZPCT I developed information targeted toward men, encouraging them to accompany their partners to ANC and to be actively involved in their care.

ZPCT I instituted a policy that allowed women attending clinics with their male partners to be seen first. Additionally, community-level “Safe Motherhood Action Groups” and “Mother Support Groups” led by lay counselors promoted male involvement in antenatal care, including PMTCT.
Moreover, evidence shows that the program’s approach effectively addressed barriers such as a shortage of qualified health care workers and resource constraints. Its use of lay counselors contributed to the program’s impact and efficiency. Research suggests that the ZPCT PMTCT intervention is a prime candidate for replication and scale-up.

A study of service data from the first three years of the ZPCT intervention at 38 sites across five provinces found that uptake of PMTCT services increased significantly throughout the cascade (Figure 1). At baseline (July 2005 to September 2005), 9,723 pregnant women were counseled about PMTCT, 4,630 (45 percent) were tested for HIV and received their results, 890 tested positive for HIV, 549 seropositive pregnant women were enrolled or referred to clinical care beyond PMTCT, and 258 seropositive pregnant women (29 percent) received a complete course of ARV prophylaxis.

A year later (July 2006 to September 2006), 7,509 pregnant women were counseled about PMTCT, 6,758 (90 percent) were tested for HIV and received their results, 1,057 tested positive for HIV, 967 seropositive pregnant women were enrolled or referred to clinical care beyond PMTCT, and 701 seropositive pregnant women received a complete course of ARV prophylaxis (66 percent).

The trend was sustained in years two and three, with the percentage of pregnant women counseled, tested and receiving results increasing to 99 percent and the percentage of women who tested HIV positive receiving a complete course of prophylaxis reaching 100 percent [1].

The increased CD4 testing was partially responsible for the uptake of ARV treatment among women who tested HIV positive. A study of service data from all 60 sites of the PMTCT intervention found that across 12...
months of observation (April 2007 through March 2008), there were increases in the proportion of HIV-positive pregnant women assessed for CD4 count, the proportion of CD4 count results available at primary health clinics and the proportion of HIV-positive women eligible for treatment who initiated ART. Factors positively associated with uptake of CD4 enumeration included (1) blood-draw for CD4 count occurring on the same day as determination of HIV-positive status, (2) CD4 count results sent back to the health facilities within seven days, (3) facilities without providers being trained to offer ART, and (4) health facility being located in an urban area.

The PMTCT intervention also reduced rates of transmission among clients. Observational data from ZPCT sites showed an HIV acquisition rate of 6.5 percent among children, ages 0 to 6 weeks, where the where the mother and infant received interventions, compared with 20 percent where no intervention was given to either mother or baby. In the same study of infants, 0 to 12 months old, 52 percent of women were exclusively breastfeeding, whereas 25 percent were mixed-feeding and 20 percent were feeding formula.

A costing study showed that the PMTCT services in ZPCT facilities cost between $113 to $126 per mother, depending on whether the services were provided in a hospital or health center.

The intervention’s low cost was due in part to the use of trained lay counselors to support HCWs. A qualitative and quantitative study assessing the quality of services provided by lay counselors — using semi-structured interviews of counselors and supervisors, analysis of counseling and testing record books, and focus groups with health care providers — found that lay counselors carry a significant load of the work at PMTCT sites. Among counseling and testing clients interviewed at study sites, 70.5 percent received CT from a lay counselor rather than a health care worker. With an average of 2.4 lay counselors at each facility visited (ranging from one to four counselors), lay counselors were available to provide CT services almost all of the time. Further, the study found the quality of lay counselors’ work to be high and comparable to the CT services provided by HCWs. Health facility managers interviewed in the study highly valued lay counselors and reported that lay counselors contributed significantly to reducing the workload of HCWs. Managers even described lay counselors as having a “tremendous” and “overwhelming” impact.

As beneficial as using lay counselors has proven to be in the PMTCT intervention, the sustainability of relying on workers who devote significant amounts of time to their work with minimal compensation for transportation remains questionable. In the study conducted on lay counseling, health center managers expressed concern about lay counselor retention. Lay counselors, however, reported that they were rewarded with more than financial compensation: They were dedicated to their work, considered themselves professionals and found their work rewarding. When asked about their main motivation for being a counselor, the most common response given was the ability to “help people” and serve their community. Many also alluded to how HIV and AIDS had touched them personally.

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1 HCWs suggested that this may be due to HIV stigma: Clinics offering CD4 enumeration were likely to do so in a separate area, where HIV and AIDS services are provided. Some women may avoid these facilities for fear of being seen in those areas.
CORE ELEMENTS

The following section describes the core elements of the ZPCT PMTCT program. Core elements are intervention components that represent the theory and internal logic of the program and that most likely produce the program’s main effects. To replicate this program faithfully, a program designer would incorporate all of the core elements without changing or adapting them. Practically speaking, however, a program designer may need to tailor the program for different contexts.

Although the intervention was evaluated, the core elements of the ZPCT program have not been individually tested to show they are essential to outcomes. Nevertheless, the following main components are those that ZPCT staff consider to be critical to the program’s impact [6]:

- **Intensive training for health care workers.** Health care workers were trained by ZPCT technical officers, who had been trained by the MOH to be master trainers. Training for HCWs included on-site mentorship until they achieved the relevant competencies. As previously noted, the program did not hire additional staff but built the capacity of HCWs. Training was conducted during afternoons and evenings in the same health facilities where clinicians worked, so they were not removed from their stations while clinics were open. This was also more cost-effective than a residential training program.

- **Data use as a management tool.** In this process, ZPCT staff were trained to enter quality data on a regular basis. Monitoring and evaluation (M&E) officers conducted monthly audits at the clinic level and then presented results to the technical officers responsible for CT and PMTCT, clinical care, and pharmacy and laboratory. Technical officers reviewed the indicators in relation to targets and collaboratively planned how to meet those targets.

- **Facilitating referrals between different kinds of services.** For example, this included referrals between ANC and PMTCT to family planning services; between ANC and psychosocial support groups; between rural health centers and ART clinics; and between departments within the health facility. ZPCT formed referral networks in each district, including a referral coordinating unit (managed by District Health Management Teams or District AIDS Task Forces). The program also developed referral forms, registers, a directory of services and a referral operations manual.

- **Task shifting from HCWs to lay workers.** To support the intervention efficiently, ZPCT employed community volunteers as lay counselors, adherence support workers and PMTCT motivators. Each community volunteers had
to meet certain criteria to be considered for the position of lay counselor. Volunteers had to be able to read and write in English, reside within the facility catchment area and have volunteer experience with the health facility for at least one year. Lay counselors were thoroughly trained by the same trainers who trained the HCWs. The six-day curriculum included topics such as adherence and support counseling and community mobilization, as well as simplified versions of the medical information provided to HCWs. The lay counselors were certified after the practicum. A study found that lay counselors perceived the intensive training to be of high quality [5].

- **Lay counselors conduct HIV tests.** Lay counselors were initially trained to provide only pre- and post-test HIV counseling because, at the time, the MOH permitted only HCWs to perform HIV testing. In May 2006, however, after certification of an original cohort of lay counselors, the Zambian National HIV VCT guidelines were changed to allow non-healthcare workers to conduct HIV testing using the finger-prick method. As a result, ZPCT began training all new and previously certified lay counselors in HIV testing as well as counseling [5].

- **Certified lay counselors provided services in health facilities two to three days per week.** ZPCT furnished a stipend of 100,000 Zambian kwacha per month (approximately US$25) to cover travel expenses for days worked at the facility [5].

- **Partnership with key stakeholders.** Partnerships among nongovernmental organizations (NGOs), government, the community, civil society and HCWs were initiated at the beginning of the project and sustained throughout. Sustained partnership allows for coordination of PMTCT efforts between programs and for sharing of skills, knowledge, challenges and lessons learned. The partnership was coordinated with the Facility Site Action Plans tool, which defined roles for different stakeholders to avoid creating parallel structures or systems. The partnership used MOH policies and guidelines but allowed for the integration of improvements into systems at the district and facility levels. For example, the creation of a multi-sector PMTCT technical working group in Zambia facilitated timely updates to national PMTCT policies when new global recommendations were issued.

- **Systems strengthening.** System strengthening was the overarching approach for the ZPCT program. Baseline site assessments conducted in each facility determined the type of support required, including identifying the number of staff in each facility who needed to be trained in PMTCT. Further support included refurbishing facilities, procuring equipment and commodity management training.
INTERVENTION MATERIALS

This section describes each of the materials included in the intervention package and provides basic guidance for how these materials could be used in replicating the program. (Click on the underlined orange text below for links to these documents.)

All of the materials were developed in accordance with the latest World Health Organization (WHO) and Government of Zambia guidelines for the context of Zambia. Though the core medical components should apply to any context, some small adaptations may be necessary for other settings with different cultural contexts or resource or infrastructure situations.

TRAINING MATERIALS

The largest component of the intervention is training HCWs and lay counselors. All training materials were developed by the PMTCT Technical Working Group under the leadership of the Zambian Ministry of Health. They were closely adapted from standard WHO training materials for PMTCT health care workers.

TRAINING OF HEALTH CARE WORKERS

The HCW training is a six-day workshop with three days of theory and three days of guided practice. The theory portion of the workshop includes participatory learning exercises, extensive participant background readings and PowerPoint presentations. The practice sessions are role plays guided by learning guides — with information about how to perform tasks, such as counseling at a woman’s first antenatal visit — and checklists for participants to use to make sure they perform all the necessary tasks. Participants practice the role plays under the facilitator’s supervision. The facilitator scores their performance using a skills-development matrix.

Training materials include modules on primary HIV prevention and family planning; HIV testing; counseling women living with HIV on PMTCT — which includes counseling on infant feeding, provision of ARV prophylaxis to pregnant women living with HIV, management of the antenatal, labor and postnatal periods in HIV-positive pregnant women as it relates to PMTCT, and linkages to care, treatment and support for women living with HIV, their children and families; and early infant diagnosis of HIV (EID). The training materials consist of these tools:

- A facilitator’s notebook provides guidance on adult learning and participatory training methodology; participant registration forms; and pre-, mid- and post-workshop assessment forms.
TRAINING OF LAY COUNSELORS

The lay counselor training program consists of a workshop followed by a practicum. The six-day classroom component of the lay counselor training includes instruction as well as role plays and case studies to ensure that trainees understand the concepts and methods of HIV counseling and testing. In the four-week practicum, each trainee practices counseling and testing under the supervision of an experienced CT provider. This ensures that each trainee is able to practice and refine his or her counseling skills. Each counselor is certified only after successfully completing the classroom and the practicum components of the training.

Training materials for lay counselors include basic information on these topics: HIV and the four prongs of PMTCT; counseling and testing for HIV; referrals for family planning services; group health education; adherence to ARV regimens; community mobilization; and linkages to care, treatment and support for women living with HIV, their children and families. The training materials for lay counselors consist of these tools:

- **PowerPoint presentations** for use during the workshop:
  - Module 1: Introduction
  - Module 2: Primary prevention of HIV and prevention of unintended pregnancies in HIV positive women
  - Module 3: Specific interventions to prevent mother-to-child transmission of HIV
  - Module 4: Maternal, infant and young child nutrition in PMTCT
  - Module 5: HIV testing
  - Module 6: Counseling for PMTCT
  - Module 7: Linkages, treatment, care and support for mothers, infants and families with HIV
  - Module 8: Monitoring and evaluation and logistics management

- **Participant reference manuals** for each training module provide all the information needed to conduct the PMTCT course and serves as the text for participants and a reference source for trainers.

- **A participant handbook** provides pre-, mid- and post-workshop assessment forms; background readings; workshop exercise instructions; learning guides and checklists to be used in the practicum; and a skills development matrix to assess participant performance during the practicum.
• A facilitator’s manual provides guidance for trainers of lay counselors.

• PowerPoint presentations for use during the workshop.
  - Module 1: Basic HIV/AIDS information
  - Module 2: PMTCT information
  - Module 3: Counseling
  - Module 4: HIV testing
  - Module 5: Community mobilization and record keeping
  - Module 6: Adherence counseling and support
  - References

• Participant reference manuals for each training module provide all the information needed to conduct the PMTCT course and serves as the text for participants and a reference source for trainers.
  - Cover page
  - Acknowledgements
  - Foreward
  - Module 1: Basic HIV/AIDS information
  - Module 2: PMTCT information

• A participant handbook includes pre- and post-workshop assessment forms; background readings; workshop exercise instructions; learning guides and checklists to be used in the practicum; and a skills development matrix to assess participant performance during the practicum.

DATA TOOLS
Client data collection is critical to any health care program. The ZPCT program’s M&E unit collects detailed data about women’s experiences in the PMTCT program and uses it to

• Algorithm of care for women presenting in labor ward
• “Opt-out” HIV testing for PMTCT

JOB AIDS
ZPCT developed a set of job aids to support HCWs and lay counselors in performing their duties in clinics. Workers should be familiar with how to use the job aids, and the job aids should be easily accessible at the clinics.

• Algorithm for care of the HIV-positive pregnant woman
• Antiretroviral prophylaxis regimen to prevent mother-to-child transmission of HIV

• Dried blood spot (DBS) technique
• Infant dosing recommendations for simplified infant NVP and co-trimoxazole
• HIV CT for couples
• HIV diagnosis in exposed infants less than 18 months old
• PMTCT cue card for maternal and child health care providers

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monitor the performance of HCWs and lay counselors on an ongoing basis. All of the following data tools are filled out by HCWs and lay counselors and reviewed at facility, district and provincial levels before being sent to PMTCT headquarters in Lusaka.

- **PMTCT patient register** (includes data sheets for general counseling, integrated counseling, delivery and mother-baby follow-up)
  - Instructions for integrated PMTCT and counseling register
  - Instructions for mother-baby follow-up register
  - Instructions for labor ward register
- **Antenatal patient card**
- **Mother-baby tracking tool**
- **Agenda for managing information and improving data quality**
  - Monthly M&E data validation and quality guide
- **SMARTCare PMTCT tracking tool**
  - PMTCT register
  - PMTCT register, with sample coding for confidentiality
- **Maternal and child health delivery register**
- **Maternal and child health delivery register, with sample coding for confidentiality**

**MANAGEMENT AND PLANNING TOOLS**

As noted in the Core Elements section, it is critical from the beginning that government, NGOs and community stakeholders work together to coordinate services and prevent duplication. ZPCT used a tool called the “Facility Site Action Plan” to enable multiple stakeholders to determine and agree upon roles and responsibilities as well as to identify and begin addressing any cultural and community-level barriers to implementing PMTCT services. HCWs learn how to fill in the Facility Site Action Plan during the training workshop and take the tool back to their clinics to complete in collaboration with other stakeholders.

As noted, the ZPCT program trained staff in PMTCT facilities about commodities management. ZPCT facilities developed forms to help staff monitor, forecast and order supplies, including ARV drugs. The program also developed a position description used in the recruitment of lay counselors.

The following management and planning tools are available:

- **Facility Site Action Plan**
- **ARV drug supply management forms**
- **Lay counselor position description**

**SYSTEMS STRENGTHENING TOOLS**

Systems strengthening efforts are guided by facility site assessments, which are conducted at baseline at every PMTCT facility. Facility site assessments are conducted collaboratively by all ZPCT technical units. Once an assessment is complete, the ZPCT program unit, in consultation with the director of finance and the director of technical support, make decisions about what actions to prioritize and how to go about making the designated changes. Depending on the site, ZPCT systems strengthening includes these efforts:

- **Identifying and addressing training needs.** This includes tracking the number of staff in each facility who need to be trained in PMTCT and the number of HCWs who have been trained. It also includes referring and sponsoring ART nurse prescribers to participate in the MOH General Nursing Council training on providing the most efficacious drug regimens,
including provision of HAART for those eligible within the MNCH services where feasible.

- **Refurbishments needed to create more space in PMTCT settings and assure privacy during service provision.** This is done within USAID regulations. For example, where the facility has a foundation, ZPCT II supports completing the structure or partitioning rooms using particleboard.

- **Procurement of medical and laboratory equipment** needed to support HIV services (such as blood pressure machines, scales, CD4 machines).

- **Commodity management training.** This training is completed through ZPCT’s Laboratories and Pharmacy Unit. A person in each facility is selected to receive commodity management training: This person could be a HCW trained in PMTCT, a laboratory and pharmacy technician, or a facility management staff member. ZPCT laboratory and pharmacy staff conduct the three-day training, which includes skills on how to forecast, quantify and order PMTCT logistics (HIV test kits, ARVs for PMTCT and DBS kits including other PMTCT related logistics) from medical stores and how to manage logistics at the facility level, including requisition and reporting from facility level to district level.

These systems strengthening tools are available online:

- **Facility Site Assessment Tool**

- **A commodities management tool** is currently under review and will be posted soon.

The *Moving Evidence into Action* series was developed by the FHI 360 Research Utilization unit, with funding from the Technical Quality & Technical Assistance Initiative and the Scientific & Technical Strategic Initiative. It was prepared in 2012 by Elizabeth Doggett, Joyce Mwale, and Prisca Kasonde, with contributions from Eva Canoutas, Justin Mandala, and Kwasi Torpey.
REFERENCES


APPENDIX 1: INTERNATIONAL GUIDELINES FOR PMTCT

The following summaries offer the latest clinical guidelines for PMTCT. Please see the linked documents for full details.

**WHO 2010 PMTCT GUIDELINES**


**WHO INFANT FEEDING GUIDELINES**

http://www.who.int/maternal_child_adolescent/documents/9789241599535/en

**ELIGIBILITY FOR TREATMENT**

The 2010 recommendations promote starting lifelong ART for all pregnant women with severe or advanced clinical disease or with a CD4 count at or below 350 cells/mm³, regardless of symptoms.

**ARV PROPHYLAXIS DURING PREGNANCY**

HIV-positive pregnant women who are not eligible or are not receiving lifelong ART should be given ARVs as prophylaxes to prevent transmission to their children.

The 2010 recommendations include two options, both of which should start earlier than previously recommended in pregnancy — at 14 weeks or as soon as possible thereafter:

1. Daily AZT for the mother and infant prophylaxis for six weeks after birth. Infant prophylaxis should be continued until the end of the breastfeeding period.

   OR

2. A three-drug regimen for the mother, taken during pregnancy and throughout the breastfeeding period, as well as infant prophylaxis for six weeks after birth.

The 2010 guidelines incorporate evidence that providing ART to either mother or child can significantly reduce postnatal transmission of HIV through breastfeeding.

WHO advises countries to choose a single infant feeding practice to advocate to all mothers with HIV, based on local conditions, instead of relying on individual health workers to counsel women to choose the PMTCT method they prefer. The guidelines advise governments to choose between counseling HIV-positive mothers to breastfeed and receive ART interventions or to avoid all breastfeeding as the strategy most likely to give infants the greatest chance of HIV-free survival.

The guidelines further specify that even when ART is not available, breastfeeding may provide infants of HIV-positive mothers with the greatest chance of HIV-free survival. In countries that choose to promote breastfeeding but where ART is not available, WHO recommends the following if an infant's HIV status is negative or unknown:

- Mothers with HIV should be counseled to exclusively breastfeed for the first six months of the child's life

- After six months, mothers with HIV should continue breastfeeding, introducing complementary foods, for the first 12 months of life unless environmental and social conditions are safe for and supportive of replacement feeding.
WHO 2012 USE OF ANTIRETROVIRAL DRUGS FOR TREATING PREGNANT WOMEN AND PREVENTING HIV INFECTION IN INFANTS

http://www.who.int/hiv/PMTCT_update.pdf

THREE OPTIONS FOR ARV REGIMENS IN PMTCT PROGRAMS

<table>
<thead>
<tr>
<th>Woman receives</th>
<th>Infant receives</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Treatment</strong> (for CD4 count ≤350 cells/mm³)</td>
<td><strong>Prophylaxis</strong> (for CD4 count &gt;350 cells/mm³)</td>
</tr>
<tr>
<td>Option A&lt;sup&gt;a&lt;/sup&gt;</td>
<td>Option B&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>Triple ARVs starting as soon as diagnosed, <em>continued for life</em></td>
<td><em>Same initial ARVs for both</em>&lt;sup&gt;b&lt;/sup&gt;</td>
</tr>
<tr>
<td>Antepartum: AZT starting as early as 14 weeks gestation. Intrapartum: at onset of labour, sdNVP and first dose of AZT/3TC Postpartum: daily AZT/3TC through 7 days postpartum</td>
<td>Triple ARVs starting as soon as 14 weeks gestation and <em>continued intrapartum and through childbirth if not breastfeeding or until 1 week after cessation of all breastfeeding</em></td>
</tr>
<tr>
<td>Daily NVP from birth through 1 week beyond complete cessation of breastfeeding; or, if not breastfeeding or if mother is on treatment, through age 4–6 weeks</td>
<td>Daily NVP or AZT from birth through age 4–6 weeks regardless of infant feeding method</td>
</tr>
</tbody>
</table>

Note: "Triple ARVs" refers to the use of one of the recommended three-drug fully suppressive treatment options.

<sup>a</sup> Recommended in WHO 2010 PMTCT guidelines

<sup>b</sup> True only for EFV-based first-line ART; NVP-based ART not recommended for prophylaxis (CD4 >350)

<sup>c</sup> Formal recommendations for Option B+ have not been made, but presumably ART would start at diagnosis.
APPENDIX 2: IMPLEMENTING EVIDENCE-BASED PROGRAMS

To maximize results and return on donor investment, a prominent guiding principle of donor initiatives is to implement programs that have been proven to be effective. It can be challenging, however, to stay abreast of the research that contributes to evidence-based programming and to weigh the programs for appropriateness in particular settings. An additional question is how to adapt proven programs to local conditions while maintaining the essence of what makes them effective.

The following text is a synthesis of a CDC framework prepared by FHI 360’s Research Utilization team to assist country programs on how to replicate evidence-based programs in local settings.

GUIDANCE ON HOW TO IMPLEMENT EVIDENCE-BASED PROGRAMS

Replicating Effective Programs (REP) is a framework developed by the U.S. Centers for Disease Control to guide the implementation of evidence-based, health care interventions. The framework is described in the article, “Implementing evidence-based interventions in health care: application of the replicating effective programs framework” by Kilbourne et al. in Implementation Science.

Based on a systematic literature review and community input, the REP process derives from action anthropology, principles of health promotion, diffusion of innovation theory and social learning theory. The framework specifies steps needed to maximize fidelity to the original intervention that was proven effective, while allowing opportunities for tailoring the intervention to local conditions. REP consists of four phases:

1. Pre-conditions — identifying need, target population and suitable intervention
2. Pre-implementation — intervention packaging and community input
3. Implementation — package dissemination, training, technical assistance and evaluation
4. Maintenance and evolution — preparing the intervention for sustainability

An outline of the REP appears below.

REPLICATING EFFECTIVE PROGRAMS

A CDC FRAMEWORK

1. Pre-conditions
   - Identify the appropriate at-risk populations for the intervention.
   - Identify a suitable effective intervention.
   - Ensure the intervention fits the local setting — examine whether the intervention has been successful in similar populations.
• Assess potential barriers to implementation with local participating organizations and other relevant stakeholders.

• Compile the intervention package¹ — include setup procedures, training and TA plans, curricula and other guides/job aids and promotional materials, and flag core elements² of original intervention that are essential for the program to work.

2. Pre-implementation

• Create a community working group — stakeholders from organizations serving the target population.

• Refine intervention package based on community working group input.

• Pilot test the intervention package for clarity and functionality in a few intervention sites.

• Further refine intervention package based on pilot test.

• Orient implementing organizations to package intervention and identify “champions” at each implementing organization to facilitate adoption of the package.

3. Implementation

• Train implementing organization on implementing and sustaining intervention.

• Provide technical assistance after training, and include assistance on discerning core elements from options, integration with existing services, and troubleshooting implementation process.

• Evaluate — gather information on and analyze how the intervention was implemented, whether core elements were successfully implemented, client-level outcomes and cost-benefit.

• Feedback and refine — run results of evaluation by community working group for input and suggestions on how to refine the package for further dissemination and implementation.

4. Maintenance and evolution

• Sustain intervention through organization and financial changes — e.g., incorporate new program into job duties, securing funding, training of additional personnel.

• Re-customize intervention delivery as circumstances change.

• Prepare refined package for national dissemination and implementation.

¹ If the effective intervention is not fully packaged for replication, it is important to involve the researchers, or others who were part of the original intervention, to explain all the inputs and core components that led to the intervention’s positive outcomes during the study. Often, details about tested interventions are only available in research protocols, which do not provide enough information for replication.

² Core elements are critical features of the intervention’s design and intent that are thought to be responsible for its effectiveness. While the core elements should be standard, the way they are implemented can be adapted to the local setting. If the core elements are not evident, program managers should consult with the original researchers of the proven intervention.

REFERENCES