World Health Organization

RAPID ADVICE

Use of antiretroviral drugs for treating pregnant women and preventing HIV infection in infants

Version 2

WHO Library Cataloguing-in-Publication Data

Rapid Advice: use of antiretroviral drugs for treating pregnant women and preventing HIV infection in infants, November 2009.
Revised June 2010

1.Antiretroviral agents - pharmacology. 2.HIV infections - therapy. 3.HIV infections - prevention and control. 4.Disease transmission, Vertical - prevention and control.
5.Pregnant women. 6.Guidelines. 7.Developing countries. I.World Health Organization.

ISBN 978 92 4 159893 4 (NLM classification: WC 503.2)

Printed in Switzerland

RAPID ADVICE

Use of antiretroviral drugs for treating pregnant women and preventing HIV infection in infants

VERSION 2 JUNE 2010

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1. Overview

1.1 Background

The World Health Organization (WHO) worked on the revision of *Antiretroviral Drugs for Treating Pregnant Women and Preventing HIV Infection in Infants: Recommendations for a public health approach*, 2006, through a series of coordinated efforts to review and synthesize emerging evidence. The key areas of review are:

a. when to start and what antiretroviral therapy (ART) to give to pregnant women living with HIV who are eligible for ART; and

b. when to start and what antiretroviral (ARV) prophylaxis to give to pregnant women who do not need ART for their own health, but need ARVs to reduce the risk of mother-to-child transmission (MTCT) of HIV.

This evidence was assembled following systematic reviews, GRADE profile analysis, consultation with key implementers, cost review, and peer review.

Various individuals were involved in the development of these recommendations: the Core Writing Group consisting of WHO staff and external experts, the full Guidelines Review Committee, and the Peer Review Group. The members are listed in Annex 1.

The aim was to identify evidence-based recommendations that would be likely to deliver high quality care and more effective PMTCT ARV interventions. The evidence and its quality, risks and benefits, acceptability, feasibility, cost and financial implication, were considered by the Guidelines Review Committee and the Peer Review Group, who agreed on a series of updated recommendations.

In advance of the release of the full revised guidelines, WHO is releasing this *Rapid Advice*, which summarizes the key recommendations.

1.2 Why a revision?

The availability of a significant amount of new evidence on ARV prophylaxis to prevent MTCT, as well as new information on optimal timing for ART initiation (treatment eligibility) warrants development of revised 2010 guidelines. Particularly important is the evidence indicating the benefits of increasing the number of pregnant women started on lifelong ART, and new data indicating that extended ARV prophylaxis to mothers or infants is effective in substantially decreasing the risk of HIV transmission through breastfeeding. Revision of the guidelines provides an important opportunity to simplify and standardize current recommendations, and to provide updated normative guidance for more effective PMTCT interventions in both resource-limited settings and globally. Once implemented, these recommendations can reduce MTCT risk to less than 5% in breastfeeding populations (from a background risk of 35%) and to less than 2% in non-breastfeeding populations (from a background risk of 25%), and will help promote improved maternal and child health and survival. More effective interventions in resource-limited settings make it possible for low and middle income countries to target the virtual elimination of MTCT and paediatric HIV/AIDS, as has already been achieved in many countries.

These recommendations provide guidance to policy-makers and programme managers responsible for national PMTCT programmes, and is a resource document for health care workers involved in the prevention, care and treatment of pregnant women and their infants. The guidance also provides a normative framework to international and bilateral funding and implementation and support agencies.

This Rapid Advice focuses on two key areas:

1. When to start and what ART to give to pregnant women living with HIV who are eligible for ART; and

2. When to start and what ARV prophylaxis to give to pregnant women who do not need ART for their own health, but need ARVs to reduce the risk of MTCT.

1.3 Guiding principles

The WHO guidelines on the use of ARV drugs for treating pregnant women and preventing HIV infection in infants were revised in accordance with the following guiding principles:

1. Women (including pregnant women) in need of ARV drugs for their own health should receive life-long ARV treatment (ART).

2. A CD4 cell count available antenatally is critically important for decision-making with regard to maternal ART eligibility.

3. Recommended interventions should be aimed at maximizing the effectiveness of reducing vertical HIV transmission, minimizing the side effects for both mothers and infants, and preserving future HIV care and treatment options.

4. Effective postpartum ARV-based interventions will allow safer breastfeeding practices.

5. Simple unifying principles for different country settings are needed.

2. Recommendations at a glance

The PMTCT recommendations refer to two key approaches:

1. Treatment: lifelong ART for HIV-positive women in need of treatment.
2. Prophylaxis: short-term provision of ARVs, to prevent HIV transmission from mother to child.

This provides the basis for:

1. Earlier ART for a larger group of HIV-positive pregnant women to benefit both the health of the mother and prevent HIV transmission to her child during pregnancy
2. Longer provision of antiretroviral ARV prophylaxis for HIV-positive pregnant women with relatively strong immune systems who do not need ART for their own health. This would reduce the risk of HIV transmission from mother to child
3. Provision of ARVs to the mother or child to reduce the risk of HIV transmission during the breastfeeding period. For the first time, there is enough evidence for WHO to recommend ARVs while breastfeeding.

3. The revision process

3.1. Retrieving, summarizing and presenting the evidence

WHO convened an expert consultation in November 2008 to review new evidence accumulated since the 2006 guidelines. This consultation helped WHO to compile the evidence and make a decision that there was enough new evidence to warrant the revision of the 2006 guidelines.

Following this initial meeting, WHO drafted the scope of work and developed PICO[1] questions for the key areas of review. GRADE profiles were prepared for four PICO questions:

a. when to start ART in pregnant women and what to give to pregnant women eligible for ART
b. when to start ARV prophylaxis in pregnant women, and what to give pregnant women for ARV prophylaxis
c. what to give newborn infants in the immediate postpartum period; and
d. what to give breastfeeding-exposed infants beyond the immediate postpartum period.

Based on the PICO questions, systematic review of peer-reviewed literature and abstracts was performed through a collaborative effort between UCSF, CDC and WHO. The HIV/AIDS Cochrane Collaborative Review Group search strategy was used for each of the four key questions.

An informal two day meeting with key stakeholders, cohosted by PEPFAR, was held in Washington in September 2009. This meeting helped assess the feasibility of potential new recommendations and the challenges that countries may face in revising their national guidelines.

A second feasibility assessment was done through a rapid assessment in the form of a structured questionnaire to WHO country offices.

Additional considerations on the feasibility of relevant PMTCT interventions were provided through a presentation on the health systems considerations of PMTCT programmes presented during the Guidelines review meeting.

Cost information and implications were prepared by WHO for key ART regimens and ARV prophylaxis regimens taking into account the different pricing in low-income, lower-middle income and upper-middle income countries. Pricing information was based on the Global Price Reporting Mechanism (GPRM) http://apps.who.int/hiv/amds/price/hdd/. Cost implications of the proposed recommendations were presented and discussed during the Guidelines review meeting.

GRADE evidence profiles will be included in the full guideline.

3.2 Consensus, external review and updating

The Guidelines review meeting on the *Use of Antiretroviral Drugs for Treating Pregnant Women and Preventing HIV Infection in Infants* was held in Geneva from October 19-21, 2009. The meeting reviewed evidence around the four key areas in different sessions. Each of the sessions included presentations on the related GRADE evidence, current and proposed recommendations, cost implications, and the risk-benefit analysis of the key questions. Discussions were held both in plenary and in group work sessions.

The proposed recommendations were reviewed and the final recommendations were formulated taking into consideration the quality of evidence, the balance between benefits and harms, the balance between values and preferences, cost, feasibility, and other factors. If outcomes of the GRADE analysis were inconclusive, other factors as listed above were taken into consideration in making a recommendation. To reach consensus, the group took into account each of the factors listed above and went through the risk-benefit tables to make decisions on recommendations. In a

1 PICO is an acronym that describes the elements of a well-formed clinical question. The structure includes: 'P' for the patient or population; 'I' for the intervention of interest; 'C' for comparison; and 'O' for outcome

few cases where there was no initial consensus, there was further discussion and decisions were reached by voting. The key recommendations were summarized in «recommendation tables» according to the four main questions, and included a summary of key factors that were considered in making the recommendations.

The summary recommendations were sent for peer review to six independent peer reviewers and the six WHO regional offices. They also received the risk-benefit tables that included the strength of the evidence and the strength of the recommendation and were asked to provide feedback on whether they agreed with the recommendations or not, and if not why; and whether there were any key points that were not addressed that would be important to include. Feedback was received in writing from all of the reviewers. Representing different regions, countries and perspectives, the peer review process confirmed overall strong support for the proposed recommendations.

Comments received from peer review were shared with the core writing group by teleconference. The draft recommendations and recommendation tables were reviewed again, and finalized.

Based on all of the above mentioned steps, the summary recommendations were finalized and submitted to the WHO Guideline Review Committee for approval in early November 2009.

The current guidelines are to be reviewed in 2012, unless significant new evidence warrants a review process earlier.

3.3 Publication and timing

This Rapid Advice on *Use of Antiretroviral Drugs for Treating Pregnant Women and Preventing HIV Infection in Infants* will be published online in English and French.

Two guideline writers are assisting in developing the revised guidelines. After final clearance, publication and dissemination is exepted to start in June or July 2010. The guidelines target national-level policy and decision-makers, programme managers and managers responsible for designing and implementing PMTCT programmes, including ART for women.

4. Adaptation, implementation and evaluation

WHO is working closely with UN and other implementing partners, as part of the IATT (InterAgency Task Team), the PEPFAR PMTCT/Peds technical working group, and WHO regional offices to plan for rapid dissemination and implementation of the new guidelines. Much experience has been obtained from the dissemination of the previous guidelines, and active support for guideline revision at country level is needed. Key steps in the dissemination include:

1. Translation into at least 3 other languages (French, Spanish and Russian). This will be in both hard copies and web documents.
2. Development of an adaptation guide, in conjunction with implementing partners. This adaptation guide will include a process feedback document that will provide WHO with important information on the quality, usefulness and impact of the guidelines.
3. Briefings, support and joint planning for dissemination with IATT partners, PEPFAR, Global Fund, etc.
4. Regional workshops to disseminate the guidelines and support country adaptation. (Nearly all WHO regions have included this in their workplans for 2010, and PEPFAR has provided specific support for joint regional workshops.)
5. Rapid country adaptation - WHO will work directly with 2-3 high burden countries to support the rapid adaptation and implementation of the new guidelines, in order to learn first-hand how to accelerate the process.

5. Companion documents

Simple tools to accompany the full guidelines are being developed in collaboration with key implementing partners. These tools are designed to:

- assist countries in the revision of the national PMTCT guidelines and
- support the choice of regimen taking into account the resources and limitations within the country.

The first of these important tools is this rapid advice document.

6. Declarations of interest

Declaration of interest forms were collected from every member of each group. All individuals attending the Guidelines review meeting completed the required

declaration of conflict of interest form. Altogether five individuals declared some conflict of interest: L Kuhn, S Luchters, R Shapiro, and L Guay each declared receiving research support in the past and present. None of the participants received funding from pharmaceutical companies. The support is mainly as research grants from universities and government funding. The WHO Secretariat felt that the declarations did not represent significant conflicts (standard publicly-funded research support) and would not unduly affect the individual's judgment or the outcome of the meeting. The declaration from E Nyankesha was not seen as a conflict of interest. A Mushavi from the Peer review group declared some conflict but the WHO Secretariat did not feel that the magnitude of the disclosure warranted any further clearance.

7. Collaboration with external partners and funding

There are no external collaborators specific to this *Rapid Advice*. However, several partners have been engaged in the development of the guideline. All collaborations will be detailed in the full guideline.

Funding to support this work comes from PEPFAR and UNAIDS.

8. Key recommendations

8.1 ART for HIV-infected pregnant women who need treatment for their own health

RECOMMENDATION 1

In pregnant women with confirmed HIV serostatus, initiation of antiretroviral therapy for her own health is recommended for all HIV-infected pregnant women with CD4 cell count ≤350 cells/mm^3, irrespective of WHO clinical staging; and for all HIV-infected pregnant women in WHO clinical stage 3 or 4, irrespective of CD4 cell count.

(Strong recommendation, moderate quality evidence)

Remarks: *The criteria for initiating ART for pregnant women are the same as for non-pregnant women. The recommendation places a high value on the health of the woman and a relatively low value on the potential risks and increased cost. Available data show that maternal ART during pregnancy and continued during breastfeeding is efficacious in reducing HIV transmission or infant death, and is the most effective intervention for promoting the HIV-infected mother's health and decreasing HIV transmission risk, in this group with the highest risk of mother-child HIV transmission.*

Table 1. Eligibility criteria for ART or ARV prophylaxis in HIV-infected pregnant women

CD4 cell count available	
CD4 ≤350 cells/mm^3	CD4 >350 cells/mm^3
ART Regardless of clinical stage	ART If symptomatic (stage 3 or 4)

WHO clinical stage	
Stage 1	ARV prophylaxis
Stage 2	ARV prophylaxis
Stage 3	ART
Stage 4	ART

RECOMMENDATION 2

HIV-infected pregnant women in need of ART for their own health should start ART irrespective of gestational age and continue throughout pregnancy, delivery and thereafter. (See table 2)

(Strong recommendation, moderate quality evidence)

Remarks: *The timing of ART initiation for HIV-infected pregnant women is the same as for non-pregnant women, i.e. as soon as eligibility is established. The recommendation places a high value on the health of the woman. It places relatively low value on the potential risks for the mother and unborn infant.*

RECOMMENDATION 3

In pregnant women in need of ART for their own health, the preferred first-line ART regimen should include an AZT + 3TC backbone: AZT + 3TC + NVP or AZT + 3TC + EFV. Alternative regimens that are recommended include TDF + 3TC (or FTC) + EFV and TDF + 3TC (or FTC) + NVP[2].

(Strong recommendation, low quality evidence)

Remarks: *The preferred ART regimens recommended for HIV-infected pregnant women are the same as for non-pregnant women. The recommendation places a high value on the health of the mother and the benefit for reducing MTCT. It places relatively low value on the potential drug toxicity risks for the mother and unborn infant. The decision should be guided by the experience, availability and potential toxicity of these regimens in pregnancy. EFV-based regimens should not be newly initiated during the first trimester of pregnancy (see also adult ART guidelines).*

2 AZT: zidovudine; 3TC: lamivudine; NVP: nevirapine; EFV: efavirenz; TDF: tenofovir; FTC: emtricitabine

RECOMMENDATION 4
Infants born to HIV-infected women receiving ART for their own health should receive
a) for breastfeeding infants: daily NVP or AZT from birth until 4 to 6 weeks of age
(Strong recommendation, moderate quality evidence)

b) for non-breastfeeding infants: daily AZT or NVP from birth until 4 to 6 weeks of age
(conditional recommendation, low quality evidence)

Remarks: *The recommendation places a high value on preventing perinatal transmission of HIV and providing protection to the newborn infants in addition to the protection received from the mother's ART regimen. Among breastfeeding infants, there is evidence that daily NVP for 6 weeks is efficacious in reducing HIV transmission or death and infant mortality. Among non-breastfeeding infants, there is no evidence assessing the efficacy of daily NVP for any duration beyond a single dose. However, there is high quality of evidence that 6 weeks of daily infant AZT prophylaxis in conjunction with maternal antepartum AZT prophylaxis for more than 4 weeks significantly prevents MTCT of HIV. There is additional evidence that AZT for 6 weeks to the infant provides significant protection when mothers have received less than 4 weeks of antepartum prophylaxis. For mothers on ART, infant prophylaxis provides added early postpartum protection, especially for mothers who start ART late, have less than optimal adherence and have not achieved full viral suppression.*

8.2 ARV prophylaxis for all HIV-infected pregnant women who do not need treatment for their own health

RECOMMENDATION 5
All HIV-infected pregnant women who are not in need of ART for their own health require an effective ARV prophylaxis strategy to prevent HIV transmission to the infant. ARV prophylaxis should be started from as early as 14 weeks gestation (second trimester) or as soon as possible when women present later in pregnancy or in labour or delivery.
(Strong recommendation, low quality of evidence)

Remarks: *Despite the lack of direct evidence showing that starting prophylaxis earlier (than 28 weeks) is associated with lower rates of intrauterine transmission, the panel placed a high value on reducing the potential lost to follow-up and delayed start of prophylaxis by waiting until the third trimester, and recognized that there is some risk of intrauterine transmission throughout pregnancy. Available observational studies show the benefits of the early start of prophylaxis. This will minimize delays between HIV testing in pregnancy and initiation of ARV prophylaxis. Given the median time of the 1st antenatal visit in most settings, most women would not start ARV prophylaxis at 14 weeks, but the goal is for a majority of women to start during the 2nd trimester, rather than the middle of the 3rd trimester*

RECOMMENDATION 6
For the mother
For all HIV-infected pregnant women who are not in need of ART for their own health, ARV prophylaxis option A consists of:
- antepartum daily AZT;
- sd-NVP at onset of labour*;
- AZT + 3TC during labour and delivery*;
- twice daily AZT + 3TC for 7 days postpartum*.

(Strong recommendation, low quality of evidence)
** sd-NVP and AZT+3TC intra- and post-partum can be omitted if the mother receives more than 4 weeks of AZT during pregnancy*

For the infant
In breastfeeding infants, maternal ARV prophylaxis should be coupled with sd-NVP at birth and then daily administration of NVP to the infant from birth until one week after all exposure to breast milk has ended.
(Strong recommendation, moderate quality of evidence)

In non-breastfeeding infants, maternal ARV prophylaxis should be coupled with sd-NVP at birth and then daily administration of NVP or AZT from birth until 4 to 6 weeks of age.
(Conditional recommendation, low quality of evidence)

Remarks: *The maternal component of this ARV prophylaxis strategy is the same as the one recommended in the 2006 guidelines, although the revised recommendation is to start earlier during pregnancy (See Recommendation 5).*

For breastfeeding infants, the panel placed a high value on an intervention that would allow safer breastfeeding practices as long as the child is exposed to breast milk in settings where breastfeeding is the norm. Although data are only available for the provision of NVP up to 6 months of age, the panel felt there is a need to provide ARV prophylaxis throughout the breastfeeding period to minimize the risk of transmission. The panel also felt that the PMTCT ARV guidelines should not put a target duration for breastfeeding; WHO will provide separate guidelines on HIV and infant feeding, in the context of ARVs.

As in Recommendation 4, for non-breastfeeding infants, there is no evidence assessing the efficacy of daily NVP for any duration beyond a single dose. However, there is high quality of evidence that 6 weeks of daily infant AZT prophylaxis in conjunction with maternal antepartum AZT prophylaxis for more than 4 weeks significantly prevents HIV MTCT. There is additional evidence that AZT for 6 weeks to the infant provides significant protection when mothers have received less than 4 weeks of antepartum prophylaxis. This conditional recommendation was primarily based on programmatic issues that would facilitate its implementation in the field: countries should have the

option of using NVP or AZT prophylaxis in infants; 6 weeks is also the first immunization visit for children in most settings, which implies that they will be seen on site at that age.

RECOMMENDATION 7

For the mother

For all HIV-infected pregnant women who are not eligible for ART, ARV prophylaxis option B consists of triple ARV drugs provided to the pregnant women starting from as early as 14 weeks of gestation until one week after all exposure to breast milk has ended. The recommended regimens include:

- AZT + 3TC + LPV/r [3]
- AZT + 3TC + ABC[4]
- AZT + 3TC + EFV
- TDF + 3TC (or FTC) + EFV

(Strong recommendation, moderate quality of evidence)

[3] *LVP/r: lopinavir/ritonavir;*

[4] *ABC: abacavir*

For the infant

In breastfeeding infants, the maternal triple ARV prophylaxis should be coupled with the daily administration of AZT or NVP from birth until 4 to 6 weeks of age.

(Strong recommendation, low quality of evidence)

In non-breastfeeding infants, the maternal triple ARV prophylaxis should be coupled with the daily administration of AZT or NVP from birth until 4 to 6 weeks of age.

(Conditional recommendation, very low quality of evidence)

Remarks: *The provision of maternal triple ARV prophylaxis during pregnancy in women who are not eligible for ART results in very low intrauterine and peripartum transmission rates. A high value is also placed on the simplicity of the intervention as it contains only one maternal and one infant regimen and may be available as a single daily fixed-dose combination.*

For breastfeeding infants, available data suggest that maternal triple ARV prophylaxis started in pregnancy and continued during breastfeeding is efficacious in reducing HIV transmission and HIV transmission or infant death. The panel placed a high value on providing an intervention that would allow safer breastfeeding practices for as long as the child is exposed to breast milk.

For non-breastfeeding infants, the conditional recommendation was primarily based on programmatic issues that would facilitate its implementation in the field: 6 weeks is also the first immunization visit for children, which implies that they will be seen on site at that age.

Table 2 summarizes the two recommended ARV prophylaxis options for HIV-infected women who are eligible for ART:

- *Option A: Maternal AZT*
- *Option B: Maternal ARV prophylaxis*

There is a strong benefit of providing effective and sustained prophylaxis to women not eligible for ART during pregnancy, labour and delivery, as well as throughout breastfeeding in settings where breastfeeding is the preferred practice. Both recommended options provide significant reduction of the MTCT risk. There are advantages and disadvantages for both options, in terms of feasibility, acceptability and safety for mothers and infants, as well as cost. The choice for a preferred option should be made at a country level, bearing in mind these advantages and disadvantages.

Table 2. ARV prophylaxis options recommended for HIV-infected pregnant women who do not need treatment for their own health

Option A: Maternal AZT	Option B: Maternal triple ARV prophylaxis
MOTHER	MOTHER
• Antepartum AZT (from as early as 14 weeks gestation) • sd-NVP at onset of labour* • AZT + 3TC during labour and delivery* • AZT + 3TC for 7 days postpartum* ** sd-NVP and AZT+3TC can be omitted if mother receives >4 weeks of AZT antepartum*	Triple ARV from 14 weeks until one week after all exposure to breast milk has ended • AZT + 3TC + LPV/r • AZT + 3TC + ABC • AZT + 3TC + EFV • TDF + 3TC (or FTC) + EFV
INFANT	INFANT
Breastfeeding infant Sd-NVP at birth plus daily NVP from birth until one week after all exposure to breastmilk has ended *Non-breastfeeding infant* Sd-NVP at birth plus AZT or NVP from birth until 4 to 6 weeks	*Breastfeeding infant* AZT or NVP from birth until 4 to 6 weeks *Non-breastfeeding infant* AZT or NVP from birth until 4 to 6 weeks

9. Annex 1

WORLD HEALTH ORGANIZATION

Guidelines Committee Review Meeting on the Use of Antiretroviral Drugs for Treating Pregnant Women and Preventing HIV Infection in Infants - 2009 version

Château de Penthes, Geneva, Switzerland,
19-21 October 2009

LIST OF PARTICIPANTS

CONTENT (PMTCT) EXPERTS

Elaine Abrams
The International Center for AIDS Care and Treatment Programs
Mailman School of Public Health
722 West 168th Street
New York, NY 10032, USA
eja1@columbia.edu

François Dabis
Unité INSERM 330
Institut de Santé Publique, Epidémiologie et Développement (ISPED)
Université Victor Segalen Bordeaux 2,
33076 Bordeaux Cedex, France
Francois.Dabis@isped.u-bordeaux2.fr

Laura A. Guay
Elizabeth Glaser Pediatric AIDS Foundation
1140 Connecticut Ave. NW, Suite 200
Washington, DC 20036, USA
lguay@pedaids.org

Louise Kuhn
Gertrude H. Sergievsky Center
College of Physicians and Surgeons
Columbia University, New York, USA
lk24@columbia.edu

Marc Lallemant
Programs for HIV Prevention and Treatment (PHPT)
29/7-8 Samlan Road, Soi 1 - Prasing, Muang, Chiang Mai 50200, Thailand
marc3@phpt.org

James McIntyre
Perinatal HIV Research Unit
University of the Witwatersrand
Chris Hani Baragwanath Hospital
PO Bertsham, Johannesburg 2013
South Africa
mcintyre@pixie.co.za

Lynne M. Mofenson
National Institutes of Health
6100 Executive Boulevard, Room 4B11
Rockville, MD 20852, USA
LM65D@nih.gov

Roger Shapiro
Harvard Medical School
110 Francis Street, Suite GB
Boston, MA 02215, USA
rshapirosph.harvard.du

Jeffrey S. A. Stringer
University of Alabama at Birmingham
Center for Infectious Disease Research in Zambia (CIDRZ), Lusaka, Zambia
jeff.stringer@cidrz.org

COUNTRY REPRESENTATIVES/ PROGRAMME EXPERTS

Marcelo Araújo de Freitas
Care and Treatment Division
STD and Aids Department
Ministry of Health, Brazil
SAF Sul Trecho 02, Bloco F, Torre 1,
Edifício Premium, Térreo, Sala 12
CEP: 70070-600 - Brasília DF
Brazil
marcelo.freitas@saude.gov.br

Kevin M. De Cock
Centers for Disease Control and Prevention (CDC)
KEMRI, Mbagathi Road
Off Mbaganthi Way, Nairobi
Kenya
kdecock@ke.cdc.gov

Nonhlanhla Rosemary Dlamini
Deparment of Health
Private Bag X 828 Pretoria 0001
Hallmark Building, Room 1513
235 Proes street, Pretoria 0002
South Africa
DlamiR@health.gov.za

Svitlana Komar
Centre «Clinic for Treatment of HIV-infected Children»
Chornovola str., 28/1, Kiev, 01135
Ukraine
skomar@yandex.ru

Dorothy Mbori-Ngacha
University of Nairobi (Kenya)
Dept. of Pediatrics & Child Health
P.O. Box 19676, Nairobi
Kenya
Dngacha@cdcnairobi.mimcom.net
dngacha@ke.cdc.org

Elevanie Munyana
Clinical Prevention Department
PMTCT at TRAC Plus Ministry of Health
P.O. Box 84, Kigali
Rwanda
MunyanaE@tracrwanda.org

Sarah Shalongo
Paediatric ARV
Ministry of Health and Social Services
Harvey Street, Windhoek
Namibia

Florence Soroses
Global Fund
Ministry of Health and Social Services
Harvey Street, Windhoek
Namibia
FSoroses@globalfund.com.na

Nipunporn Voramongkol
Maternal and Child Health Group
Department of Health
Ministry of Public Health
Tivanon Rd., Muang District
Nonthaburi 11000
Thailand
job8018@yahoo.com

METHODOLOGISTS

Health systems:
Pierre Barker
Department of Paediatrics
University of North Carolina
Chapel Hill, NC 27516, USA
Pierre_barker@med.unc.edu

GRADE expert:
Nancy Santesso
Department of Clinical Epidemiology and Biostatistics, McMaster University
1200 Main Street West
Hamilton, ON L8N 3Z5
Canada
santesna@mcmaster.ca

IMPLEMENTING PARTNERS

Omotayo Bolu
PMTCT Team,
Global AIDS Program, CDC
1600 Clifton Road
Atlanta, GA 30333
USA
obb3@cdc.gov

Margaret Brewinski
USAID Office of HIV/AIDS
1300 Pennsylvania Ave, NW
Washington, D.C. 20523-3600
USA
mbrewinski@usaid.gov

René Ekpini
PMTCT - Pediatric care and treatment
Health Section, Program Division
UNICEF
3 United Nations Plaza
New York, NY 10017
USA
rekpini@unicef.org

CIVIL SOCIETY / PLWHA

Jane Mwirumubi
ICW East Africa Tagore Crescent
Plot 15, Kamwokya, Kampala
Uganda
jane_mwirumubi@yahoo.co.uk

Portia Nomzuzu Ngcaba
7.16 Goodhope Road
Vuyo Gardens , Amalinda
East London 5247
South Africa
portia@tac.org.za

GRADE REVIEWERS

Jaco Homsy
Institute for Global Health
University of California, San Francisco
50 Beale St
San Francisco, CA 94105
USA
jhomsy@psg.ucsf.edu

Jennifer S. Read
National Institutes of Health (NIH)
Executive Building, Room 4B11C
6100 Executive Boulevard MSC 7510
Bethesda, MD 20892-7510
USA
jennifer_read@nih.gov

George Rutherford
Institute for Global Health
University of California, San Francisco
50 Beale St, San Francisco, CA 94105
USA
grutherford@psg.ucsf.edu

Amy Sturt
Stanford University
300 Pasteur Drive, S-101
Stanford, CA 94305
USA
amysturt@gmail.com

WHO SECRETARIAT

20 Avenue Appia
CH-1211 Geneva 27
Switzerland

Boniface Dongmo Nguimfack
Strategic Information
Department of HIV/AIDS
dongmonguimfackb@who.int

Siobhan Crowley
Antiretroviral Treatment and HIV Care
Department of HIV/AIDS
crowleys@who.int

Isseu Diop-Toure (AFRO)
Regional Office for Africa
Brazzaville, Republic of Congo
diopi@afro.who.int

Ying-Ru Lo
Prevention in the Health Sector
Department of HIV/AIDS
loy@who.int

Eleonora Marini
marinie@who.int

Françoise Renaud-Théry
Systems Strengthening and HIV
Department of HIV/AIDS
theryf@who.int

Nigel Rollins
Newborn and Child Health and Development
Department of Child and Adolescent Health and Development
rollinsn@who.int

Charles Sagoe-Moses (AFRO)
Regional Office for Africa
Brazzaville, Republic of Congo
sagoemosesc@whoafr.org

Nathan Shaffer
Prevention in the Health Sector, PMTCT
Department of HIV/AIDS
shaffern@who.int

Tin Tin Sint
Prevention in the Health Sector, PMTCT
Department of HIV/AIDS
sintt@who.int

Isabelle de Vincenzi
Control of Sexually Transmitted and
Reproductive Tract Infections
Department of Reproductive Health and Research
devincenzii@who.int

Marco Vitoria
Antiretroviral Treatment and HIV Care
Department of HIV/AIDS
vitoriam@who.int

RAPPORTEURS (Guideline writers)

Renaud Becquet
INSERM, Unit 897
Research Centre in Epidemiology and Biostatistics
Université Victor Segalen Bordeaux 2
146, rue Léo Saignat
33076 BORDEAUX Cedex
France
Renaud.Becquet@isped.u-bordeaux2.fr

Stanley Luchters
International Centre for Reproductive Health
Department of Obstetrics and Gynaecology
Ghent University
De Pintelaan 185– P3, 9000 Ghent
Belgium
stanley.luchters@ugent.be

EXTERNAL PEER REVIEWERS

Sostena Romana
Global PMTCT Initiative
Clinton Foundation HIV/AIDS Initiative
Boston, USA
sromano@clintonfoundation.org

Angela Mushavi
PMTCT and Pediatric Treatment
CDC - Namibia and Namibia MOH
mushavia@na.cdc.gov

Suna Balkan
Médecins Sans Frontières
Medical Department MSF Paris
8, rue Saint-Sabin
75011 Paris, France
sbalkan@msf.org

Mary Glenn Fowler
Makere University
Johns Hopkins University Research Collaboration
Kampala, Uganda
mgfowler@mujhu.org

Marc Bulterys
CDC China
Beijing, China
Zbe2@cdc.gov

Landry Tsague
UNICEF - Rwanda
ltsague@unicef.org

CORE WRITING GROUP

James McIntyre (Expert)
François Dabis (Expert)
Lynne M. Mofenson (Expert)
Ying-Ru Lo (WHO)
Nathan Shaffer (WHO)
Tin Tin Sint (WHO)
Marco Vitoria (WHO)
Siobhan Crowley (WHO)
Isabelle de Vincenzi (WHO)
Stanley Luchters (Writer)
Renaud Becquet (Writer)