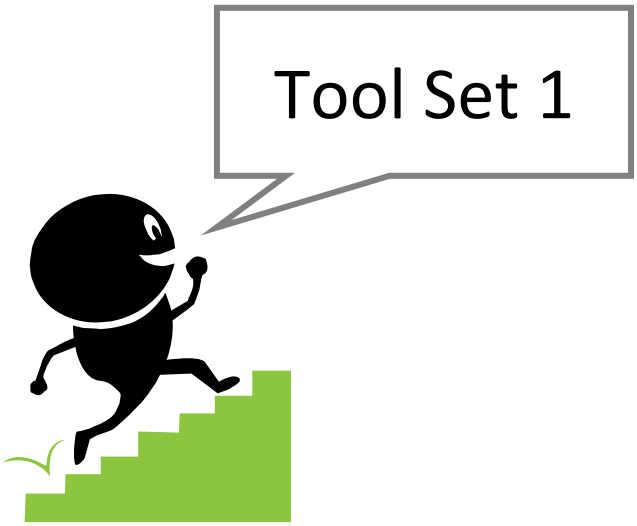

TOOL SET 1: REVISED NATIONAL GUIDELINE IMPLEMENTATION PLANNING

The tools in Tool Set 1 are intended to serve as a framework to facilitate implementation planning by highlighting key issues and considerations regarding potential guideline changes, and the implications of their implementation. To assist in this effort, smaller tools are included (e.g., a summary of the new guidelines and comparison with existing national guidelines, and support tools for decision making and planning for national roll-out).

SECTION CONTENTS

- 1.1 Supporting Implementation Planning
- 1.2 Guideline Adaptation Planning Tool for PMTCT
- 1.3 Guideline Adaptation Planning Tool for IYCF
- 1.4 Guideline Adaptation Planning Tool for ART in Infants and Children
- 1.5 Guideline Adaptation Planning Tool for ART in Adults and Adolescents
- 1.6 Inventory of Clinical Tools, Job Aids, and IEC Materials to Be Updated

1.1 SUPPORTING IMPLEMENTATION PLANNING

PART A: Checklist For Planning

The following is a checklist to support the planning processes by program or district implementation planners. Generic questions have been drawn up in some of the key implementation areas that may need further consideration when planning how to implement the revised guidelines in a program or district. Not all of the implementation areas will require significant changes, depending on the extent of the existing program. This is not an exhaustive list, but many of the questions remain relevant to whichever guidelines are adopted and/or changed.

Use of this tool should generate a list of specific activities that can form part of an implementation plan, a template of which is outlined below (see Part B). These activities can then be given specific timeframes and budget lines, along with clearly designated roles and responsibilities.

Note: Broad consultation will be required with different stakeholders to develop a comprehensive plan. However, certain activities may still need to be prioritized and implemented immediately, hence the need to link this checklist with an overall implementation plan. This should at least serve to identify the broader activities that need to be undertaken as the guidelines are revised or adapted.

Key Implementation Areas	Key Questions To Support Decision Making And Planning Process
Policy/Laws/Regulations	▪ What revisions need to be made to national PMTCT, IYCF, Adult and Pediatric HIV Care and Treatment, human resources, protocols and algorithms, etc.? ▪ What are the implications for decentralization of services? ▪ Will task shifting be required (e.g., prescribing of drugs, etc.)?
Human Resources	To increase and strengthen capacity of a multi-disciplinary team to deliver new regimens, including doctors, nurses, pharmacy, lab, counselors, etc.: ▪ Who will be trained in what? ▪ How many and over what period of time? ▪ What resources are there to do this?

Protocols and Tools	▪ What revisions need to be made to existing clinical protocols, guidelines, job aides, IEC, and training materials?
Infrastructure	▪ What additional infrastructure is required to implement these new guidelines (e.g., counseling, laboratory, equipment, pharmacy, etc.)?
Commodities	▪ What additional coordination or integration of supply chain management systems to deliver BOTH drugs and reagents to BOTH MCH and ART sites will be required? ▪ What adjustments to national forecast and procurement plans will need to be made? ▪ What additional adjustments to LMIS, order forms, and other logistics tools will be needed? ▪ What additional Pre-position commodities are necessary to support roll-out (e.g., supply newly trained sites with starter kits and appropriate order forms)?
Laboratory Services	▪ What type(s) and number of CD4 machine(s), particularly point-of-care (POC) machines, are required for scale-up? ▪ Which cadre(s) of health care worker(s) is/are authorized to order or conduct CD4 testing? ▪ Are regulations regarding quality assurance in place? ▪ What increase and strengthening of capacity are needed for the following: – Lab technician – Doctors – Nurses – Midwives – Counselors ▪ Will task shifting be required if POC machines are introduced? If so, how, for whom, etc.? ▪ What revisions to training activities and materials will be needed —

	particularly for POC CD4 testing? ▪ What revisions should be made to diagnostic monitoring protocols depending on the ART regimen to be used? ▪ What additional demand will there be for laboratory baseline and monitoring tests (e.g., LFTs, CD4, etc.)? ▪ Can on-site capacity to carry out laboratory testing — for example, hemoglobin tests using hand-held hemocue — be implemented?
Monitoring	Monitoring a national system—particularly if switching ARV regimens over a transition period, or using more than one type of ARV regimen within the national program—will be more complex. ▪ How will it be done? ▪ What national indicators/tools will be used? ▪ How will long-term follow-up of mother/infant pairs be managed? ▪ How will integration of monitoring systems be managed (e.g., MCH/ART)? ▪ What training and tools will be required?
MCH/RH/HIV Linkages	▪ Will approach to implementation be phased or immediate? ▪ Which sites will be considered to introduce regimens first (and will criteria need to be introduced to assist in site selection, etc.?) or will there be a general overall switch? ▪ How will this be coordinated during initial roll-out? ▪ Will all the new recommendations (e.g., IYCF guidelines) be introduced at the same time?
Local Leadership/Advocacy	How will the following be done: ▪ Coordination mechanisms at all levels between ART/PMTCT/Lab, etc. (e.g., identification of focal persons, building capacity to manage the overall implementation) ▪ Sensitization of all MOH leadership from national to local level ▪ Sensitization of donors (e.g., changes in national regimens may

	require additional funding) ▪ Sensitization of implementing partners/stakeholders ▪ Sensitization of community and beneficiaries
Community	▪ Will additional IEC materials and support of community treatment literacy initiatives need to be developed? ▪ How will these new initiatives overcome ongoing issues with stigma and disclosure (e.g., promotion of couples testing, male involvement, etc.)? ▪ Are community-based patient tracking systems in place through partnerships/existing networks? Can these be developed? ▪ What additional counseling capacity exists from community health workers, peer counselors, etc.?
Resource Mobilization	▪ What existing and additional short- and long-term resources for additional infrastructure, tools, drugs, monitoring, training, clinical mentorship are available? ▪ Are there existing national donor proposals that could be revised or re-prioritized to include additional requirements (e.g., Global Fund)?
Partnerships	What potential partnerships can be identified for: ▪ UN agencies ▪ Funding: Global Fund, USG, DFID, EU, etc. ▪ Clinical mentorship partners: Baylor, CHAI, JSI, UCSF, ICAP, etc. ▪ Logistics: JSI, CHAI, etc. ▪ Implementation partners: international NGOs — EGPAF, ICAP, PATH, MSF, CHAI, etc., as well as national NGOs ▪ Community: local NGOs and CBOs for tracking ▪ What needs to be done to strengthen partnerships?

PART B: Generic Template for Roll-out Plan

Insert MOH Logo

Plan for Roll-out of the 2010 WHO Recommendations for [PMTCT/ Infant and Young Child Feeding (IYCF)/ Pediatric HIV Care and Treatment (PEDS)/ Adult HIV Care and Treatment (ADULT)]

Currently the national PMTCT/IYCF/PEDS/ADULT program is preparing to adapt the *2010 World Health Organization's Recommendations for* PMTCT/IYCF/PEDS/ADULT. The following is a proposed draft plan to support rollout of revised national PMTCT/IYCF/PEDS/ADULT guidelines.

Activity	Timeframe	Key Person(s) Responsible	Requirements or Inputs	Output Indicator	Budget
Policy					
Local Leadership/Advocacy					
Human Resources					

Protocols and Tools					
Training					
Infrastructure					
Commodities					

Lab Services					
Monitoring					
MCH/RH/HIV Linkages					
Community					

Resource Mobilization					
Partnerships					
Other Comments/Considerations					

1.2 GUIDELINE IMPLEMENTATION PLANNING TOOL FOR PMTCT

Recommended Approach to Using this Tool:

1. Review the key changes in the revised WHO recommendations for ARV drugs for the treatment of pregnant women living with HIV and prevention of HIV infection in infants in PMTCT Table 1

2. For each of the key changes, use Section A-E 1 (comparing key changes inherent in the revised WHO recommendation to revised national policies) to examine whether these changes differ from current implementation practice.

3. For each of the key changes in the revised WHO recommendations that differ from current implementation practice:

    a. Use Section A-E 2 to list the country-specific issues for the program/district to consider in relation to implementation of each of the potential key changes in accordance with revised national policy

    b. Use Section A-E 3 to analyze the resource implications of implementing each key change

Antiretroviral Drugs for the Treatment of Pregnant Women Living with HIV and Prevention of HIV Infection in Infants

PMTCT Table 1: Key Changes in the Revised WHO Recommendations

Recommendation	Key Changes
WHO recommendations 1	Wider access to CD4 count
WHO recommendation 2	Treatment threshold for ART in pregnant women with HIV
WHO recommendations 3&4	Option A/ triple ART regimen for treatment in eligible pregnant women (CD4 <350 or clinical stage 3 & 4) and infant prophylaxis
WHO recommendations 5&6	Option B: combination ARV prophylaxis for non- treatment eligible pregnant women (CD4 >350 or clinical stage 1&2) or pregnant women with HIV for whom eligibility in unknown and infant prophylaxis
WHO recommendation 4, 5 & 7	Option B: Triple ARV prophylaxis for pregnant women ineligible for ART starting in antenatal care (ANC) and continued during breastfeeding period and infant prophylaxis

PMTCT SECTION A: WHO RECOMMENDATION 1: WIDER ACCESS TO CD4 COUNT		
PMTCT Section A1. Describe Revised National Policy in the Context of the Revised WHO Guidelines		
WHO 2006	**WHO 2010**	**Revised National Policy**
CD4 for all HIV-positive adolescents and adults	Same policy but aggressively implemented to increase coverage of CD4 testing for all HIV-positive patients	Please describe revised national policy to assist in identifying likely changes in implementation:

PMTCT Section A2. Key Considerations For Implementing WHO Recommendation 1: Wider access to CD4 count

Implementation of new recommendations may require:

- Additional resources to prioritize CD4 count for all pregnant women — for procurement of machines, additional reagents, logistics and support to human resources
- Improved and expanded lab-based CD4 capacity — additional infrastructure, logistics and human resources likely to be required to overcome bottlenecks
- Possible expansion of point-of-care CD4 testing using new technologies within maternal and child health (MCH) or decentralized settings to ensure outreach to all pregnant women with HIV — additional resources, HR capacity, infrastructure
- Strengthened sample transport systems with feedback of results between MCH and/or ART site centralized laboratory

Implementation issues to consider:

PMTCT Section A3. Estimating Resource Implications of Implementing WHO Recommendation 1: Wider access to CD4 count				
Program Area	**Approximate Resources Required to Implement Policy**	**Approximate Resources Available**	**Are Existing Resources Sufficient to Implement Policy?**	**Additional Resources That Could Be Mobilized**
Policy/Laws/Regulations				
Human Resources				
Protocols and Tools				
Infrastructure				
Commodities				
Laboratory Services				
Monitoring				
MCH/reproductive health (RH)/HIV Linkages				
Local Leadership/Advocacy				
Community				

PMTCT SECTION B: WHO RECOMMENDATION 2: RAISE TREATMENT THRESHOLD FOR ART FOR PREGNANT WOMEN WITH HIV		
PMTCT Section B1. Describe Revised National Policy in the Context of the Revised WHO Guidelines Policy		
WHO 2006	**WHO 2010**	**Current National Policy**
ART for all pregnant women with HIV and CD4 <250 and/or Clinical Stage III or IV	ART for all pregnant women with HIV and CD4 less than or equal to 350 and/or Clinical Stage III or IV	Please describe current national policy to assist in identifying likely changes in implementation:

PMTCT Section B2. Key Considerations for Implementing WHO Recommendation 2: Raising treatment threshold for ART in pregnant women with HIV to 350 cells/mm^3

Implementation of new recommendations may require:

- Review of the ability / feasibility to prioritize pregnant women for treatment
- Identification of more pregnant women as requiring ART
- Decentralization of laboratory and ART services into MCH or stronger linkages between MCH and ART — monitoring and logistic implications
- Increased human resource capacity to initiate treatment — training, supervision, mentorship
- Increased funding to treat more pregnant women with HIV

PMTCT Section B3. Estimating Resource Implications of Implementing WHO Recommendation 2: Raising treatment threshold for ART in pregnant women with HIV to 350 cells/mm^3				
Program Area	**Approximate Resources Required to Implement Policy**	**Approximate Resources Available**	**Are Existing Resources Sufficient to Implement Policy?**	**Additional Resources That Could Be Mobilized**
Policy/Laws/Regulations				
Human Resources				
Protocols and Tools				
Infrastructure				
Commodities				
Laboratory Services				
Monitoring				
MCH/RH/HIV Linkages				
Local Leadership/Advocacy				
Community				

PMTCT SECTION C: MATERNAL ART FOR PREGNANT WOMEN ELIGIBLE FOR TREATMENT FOR THEIR OWN HEALTH AND PMTCT *WHO RECOMMENDATIONS 3 AND 4: TRIPLE ART REGIMEN FOR TREATMENT IN ELIGIBLE PREGNANT WOMEN (CD4 <350 OR CLINICAL STAGES 3 AND 4) AND INFANT PROPHYLAXIS*		
PMTCT Section C1. Describe Revised National Policy in the Context of the Revised WHO Guidelines Policy		
WHO 2006	**WHO 2010**	**Current National Policy**
Maternal ART Current ART regimen for eligible pregnant women varies across countries	**Maternal ART** Revised recommended ART regimen for eligible pregnant women to start at any gestation age: AZT+3TC+NVP or AZT+3TC+EFV or TDF+X*TC+NVP (*X=3 or F) or TDF+X*TC+EFV (*X=3 or F) Note: EFV only after first trimester	Please describe current national policy to assist in identifying likely changes in implementation:
HIV-exposed infant prophylaxis sdNVP and 4 weeks AZT to infant	**HIV-exposed infant** In breastfeeding HIV-exposed infants, NVP or AZT daily for four to six weeks; OR In non-breastfeeding HIV-exposed infants, either NVP or AZT daily for four to six weeks	Please describe current national policy to assist in identifying likely changes in implementation:

PMTCT Section C2. Key Considerations for Implementing WHO Recommendations 3&4:
Triple ART regimen for treatment in eligible pregnant women (CD4 <350 or clinical stage 3 and 4) and infant prophylaxis

Implementation of new recommendations may require:

MATERNAL ISSUES:

- Consideration of cost implications of different ARV regimens; AZT and TDF more costly than many existing regimens in widespread use
- Substantive changes in national drug procurements, stocks and management to ensure sufficient availability — phased transition period while existing buffer stocks in use
- Decentralization of ART in MCH and strengthened linkages between ANC and MCH
- Increased health system capacity to initiate and maintain delivery of new regimens including human resource complement, additional training, etc.
- Increased capacity to monitor safety and effectiveness — limited data on TDF use in pregnancy
- Changes to national monitoring systems (e.g., national indicators, databases, registers etc.)

INFANT ISSUES:

- Strengthened follow-up systems for mothers/infants
- Increased adherence support needs for mother/infant pairs
- Strengthened linkages between MCH and ART
- Strengthened monitoring of safety — possible clinical toxicity if infant and mother taking NVP-based regimen during breastfeeding
- Consideration of the availability and cost implications of drugs needed to cover six-week period either NVP or AZT
- Changes in drug procurements, stocks, and management — phased transition from AZT to NVP and utilization of existing AZT stocks

• Increased health system capacity to implement — HR, training, tools • Changes to national monitoring systems; e.g., national indicators, databases, registers etc.
Implementation issues to consider:

PMTCT Section C3. Estimating Resource Implications of Implementing WHO Recommendations 3&4: Triple ART regimen for treatment in eligible pregnant women (CD4 <350 or clinical stages 3 and 4) and infant prophylaxis				
Program Area	**Approximate Resources Required to Implement Policy**	**Approximate Resources Available**	**Are Existing Resources Sufficient to Implement Policy?**	**Additional Resources That Could Be Mobilized**
Policy/Laws/Regulations				
Human Resources				
Protocols and Tools				
Infrastructure				
Commodities				
Laboratory Services				
Monitoring				
MCH/RH/HIV Linkages				
Local Leadership/Advocacy				
Community				

PMTCT SECTION D: ARV PROPHYLAXIS FOR NON-TREATMENT-ELIGIBLE PREGNANT WOMEN WITH HIV OR FOR WHOM ELIGIBILITY IS UNKNOWN AND INFANT PROPHYLAXIS

WHO RECOMMENDATIONS 5 AND 6:
OPTION A: COMBINATION ARV PROPHYLAXIS FOR INELIGIBLE PREGNANT WOMEN (CD4 >350 AND CLINICAL STAGES 1 AND 2) OR PREGNANT WOMEN WITH HIV WHOSE ELIGIBILITY IS UNKNOWN, AND INFANT PROPHYLAXIS

PMTCT Section D1. Describe Revised National Policy in the Context of the Revised WHO Guidelines

WHO 2006	WHO 2010	Current National Policy
Maternal Prophylaxis AZT from 28 wks with or without Combivir tail post delivery for non-eligible women or for women whose eligibility is unknown	**Maternal Prophylaxis** Antenatal AZT (from 14 weeks gestation) sdNVP at onset of labor AZT+3TC during labor and Delivery AZT+3TC for seven days postpartum	Please describe current national policy to assist in identifying likely changes in implementation:
HIV-Exposed Infant Prophylaxis sdNVP and four weeks AZT to infant	***HIV-Exposed Infant Prophylaxis*** In breastfeeding, HIV-exposed infants, daily NVP from birth until one week after all exposure to breast milk has ended **OR** In non-breastfeeding HIV-exposed infants, daily AZT or NVP for four to six weeks	Please describe current national policy to assist in identifying likely changes in implementation:

PMTCT Section D2. Key Considerations for Implementing WHO Recommendations 5&6:
Option A: Combination ARV prophylaxis for ineligible pregnant women (CD4 >350 or clinical stages 1 and 2) or pregnant women with HIV whose eligibility is unknown and infant prophylaxis

Implementation of new recommendations may require:

MATERNAL ISSUES

- Revisions to national adult ART and PMTCT guidelines
- Transitioning of sites using sdNVP or different prophylaxis protocols — phased approach or immediate switch in all sites
- Changes in national drug costs, procurements, stocks, and management — additional AZT in ANC required
- Consideration of the availability and cost implications of a longer course of AZT
- Steps to offset increased risk of AZT-related maternal anemia — improved clinical and diagnostic monitoring
- Increased health system capacity to implement — additional training, HR, job aides, tools
- Increased adherence support needs for mothers
- Changes to national monitoring systems (e.g., national indicators, databases, registers, etc.)

INFANT ISSUES

- Strengthened follow-up services for mother/infants
- Stronger integration into child-health programs to support long-term follow-up requirements - improved linkages between ANC, PNC and child health clinics
- Increased adherence support needs for mother/infant pairs
- Improved referral system from MCH into ART

• Changes in national drug procurements, stocks and management e.g. when to phase out procurement of AZT syrup and phase in procurement of additional stocks of NVP syrup • Consideration of availability and cost implications for prolonged ARV use • Consideration of potential drug toxicity from long-term use of NVP • Increased health system capacity to implement — additional training, HR, job aides, tools • Changes to national monitoring systems (e.g., national indicators, databases, registers, etc.) • Revisions to national ART, PMTCT and IYCF guidelines including pediatric ART first-line treatment protocols
Implementation issues to consider:

PMTCT Section D3. Estimating Resource Implications of Implementing WHO Recommendations 5 and 6:
Option A: Combination ARV prophylaxis for ineligible pregnant women (CD4 >350 or clinical stages 1 and 2) or pregnant women with HIV whose eligibility is unknown and infant prophylaxis

Program Area	Approximate Resources Required to Implement Policy	Approximate Resources Available	Are Existing Resources Sufficient to Implement Policy?	Additional Resources That Could Be Mobilized
Policy/Laws/Regulations				
Human Resources				
Protocols and Tools				
Infrastructure				
Commodities				
Laboratory Services				
Monitoring				
MCH/RH/HIV Linkages				
Local Leadership/Advocacy				
Community				

PMTCT SECTION E: WHO Recommendation 4, 5 & 7: **OPTION B:** Triple ARV prophylaxis for pregnant women ineligible for ART starting in ANC and continued during breastfeeding period and infant prophylaxis		
PMTCT Section E1. Describe Revised National Policy in the Context of the Revised WHO Guidelines		
WHO 2006	**WHO 2010**	**Current National Policy**
	Mother Triple ARV from 14 weeks and until one week after cessation of breastfeeding AZT+3TC+LPV-r AZT+3TC+ABC AZT+3TC+EFV TDF+XTC+EFV	Please describe current national policy to assist in identifying likely changes
	Breastfeeding Infant: ▪ NVP for 6 weeks ***Non-breastfeeding infant:*** ▪ AZT or NVP for 4 to 6 weeks	Please describe current national policy to assist in identifying likely changes

PMTCT Section E2. Key Considerations for Implementing WHO Recommendations 4, 5 and 7:
Option B: Triple ARV prophylaxis for pregnant women ineligible for ART starting in ANC and continued during breastfeeding period and infant prophylaxis

Implementation of new recommendations may require:

MATERNAL ISSUES:

- MAJOR revisions to national policy guidelines including for adult first and second line drugs that complement the triple ARV prophylaxis regimen
- Consideration of SIGNIFICANT cost implications of providing triple ARV prophylaxis in both the antenatal and breastfeeding period with substantial increase in price of triple ARV regimens to be used
- Decentralization and strengthened linkages between multiple different entry points (e.g., to ensure delivery of ARV regimens in ANC, PNC, child health services, ART)
- Improved methods to handle increased complexity of assessing women who require ART for their own health
- Strengthened long-term follow-up mechanisms to tailor prescribing triple ARV prophylaxis according to length of breastfeeding
- Changes in national drug procurements, stocks, and management — phased transition period to implement new regimen and utilization of previous ARV prophylaxis stocks
- Increased health system capacity to implement new ARV regimens — additional training, HR, job aides, tools
- Changes to national monitoring systems (e.g., national indicators, databases, registers, etc.)

INFANT ISSUES — similar to prophylaxis for eligible women on ART

- Strengthened follow-up systems for mothers/infants
- Increased adherence support needs for mother/infant pairs

- Strengthened linkages between MCH and ART
- Strengthened monitoring of safety — possible clinical toxicity if infant and mother taking NVP-based regimen during breastfeeding
- Adaptations to national pediatric first-line ART protocols and infant feeding guidelines
- Consideration of the availability and cost implications for drugs to cover six-week period either NVP or AZT
- Changes in national drug procurements, stocks, and management — phased transition from AZT to NVP and utilization of existing AZT stocks
- Increased health system capacity to implement — HR, training, tools
- Changes to national monitoring systems (e.g., national indicators, databases, registers, etc.)

PMTCT Section E3. Estimating Resource Implications of Implementing WHO Recommendation 4, 5 and 7:
Option B: Triple ARV prophylaxis for pregnant women ineligible for ART starting in ANC and continued during breastfeeding period and infant prophylaxis

Program Area	Approximate Resources Required To Implement Policy	Approximate Resources Available	Are Existing Resources Sufficient to Implement Policy?	Additional Resources That Could Be Mobilized
Policy/Laws/Regulations				
Human Resources				
Protocols and Tools				
Infrastructure				
Commodities				
Laboratory Services				
Monitoring				
MCH/RH/HIV Linkages				
Local Leadership/Advocacy				
Community				

1.2 GUIDELINE IMPLEMENTATION PLANNING TOOL FOR PMTCT

Recommended Approach to Using this Tool:

1. Review the key changes in the revised WHO recommendations for ARV drugs for the treatment of pregnant women living with HIV and prevention of HIV infection in infants in PMTCT Table 1

2. For each of the key changes, use Section A-E 1 (comparing key changes inherent in the revised WHO recommendation to revised national policies) to examine whether these changes differ from current implementation practice.

3. For each of the key changes in the revised WHO recommendations that differ from current implementation practice:

   c. Use Section A-E 2 to list the country-specific issues for the program/district to consider in relation to implementation of each of the potential key changes in accordance with revised national policy

   d. Use Section A-E 3 to analyze the resource implications of implementing each key change

Antiretroviral Drugs for the Treatment of Pregnant Women Living with HIV and Prevention of HIV Infection in Infants

PMTCT Table 1: Key Changes in the Revised WHO Recommendations

Recommendation	Key Changes
WHO recommendations 1	Wider access to CD4 count
WHO recommendation 2	Treatment threshold for ART in pregnant women with HIV
WHO recommendations 3&4	Option A/ triple ART regimen for treatment in eligible pregnant women (CD4 <350 or clinical stage 3 & 4) and infant prophylaxis
WHO recommendations 5&6	Option B: combination ARV prophylaxis for non- treatment eligible pregnant women (CD4 >350 or clinical stage 1&2) or pregnant women with HIV for whom eligibility in unknown and infant prophylaxis
WHO recommendation 4, 5 & 7	Option B: Triple ARV prophylaxis for pregnant women ineligible for ART starting in antenatal care (ANC) and continued during breastfeeding period and infant prophylaxis

PMTCT SECTION A: WHO RECOMMENDATION 1: WIDER ACCESS TO CD4 COUNT		
PMTCT Section A1. Describe Revised National Policy in the Context of the Revised WHO Guidelines		
WHO 2006	**WHO 2010**	**Revised National Policy**
CD4 for all HIV-positive adolescents and adults	Same policy but aggressively implemented to increase coverage of CD4 testing for all HIV-positive patients	Please describe revised national policy to assist in identifying likely changes in implementation:

PMTCT Section A2. Key Considerations For Implementing WHO Recommendation 1: Wider access to CD4 count

Implementation of new recommendations may require:

- Additional resources to prioritize CD4 count for all pregnant women — for procurement of machines, additional reagents, logistics and support to human resources
- Improved and expanded lab-based CD4 capacity — additional infrastructure, logistics and human resources likely to be required to overcome bottlenecks
- Possible expansion of point-of-care CD4 testing using new technologies within maternal and child health (MCH) or decentralized settings to ensure outreach to all pregnant women with HIV — additional resources, HR capacity, infrastructure
- Strengthened sample transport systems with feedback of results between MCH and/or ART site centralized laboratory

Implementation issues to consider:

PMTCT Section A3. Estimating Resource Implications of Implementing WHO Recommendation 1: Wider access to CD4 count				
Program Area	**Approximate Resources Required to Implement Policy**	**Approximate Resources Available**	**Are Existing Resources Sufficient to Implement Policy?**	**Additional Resources That Could Be Mobilized**
Policy/Laws/Regulations				
Human Resources				
Protocols and Tools				
Infrastructure				
Commodities				
Laboratory Services				
Monitoring				
MCH/reproductive health (RH)/HIV Linkages				
Local Leadership/Advocacy				
Community				

PMTCT SECTION B: WHO RECOMMENDATION 2: RAISE TREATMENT THRESHOLD FOR ART FOR PREGNANT WOMEN WITH HIV		
PMTCT Section B1. Describe Revised National Policy in the Context of the Revised WHO Guidelines Policy		
WHO 2006	**WHO 2010**	**Current National Policy**
ART for all pregnant women with HIV and CD4 <250 and/or Clinical Stage III or IV	ART for all pregnant women with HIV and CD4 less than or equal to 350 and/or Clinical Stage III or IV	Please describe current national policy to assist in identifying likely changes in implementation:

PMTCT Section B2. Key Considerations for Implementing WHO Recommendation 2: Raising treatment threshold for ART in pregnant women with HIV to 350 cells/mm^3

Implementation of new recommendations may require:

- Review of the ability / feasibility to prioritize pregnant women for treatment
- Identification of more pregnant women as requiring ART
- Decentralization of laboratory and ART services into MCH or stronger linkages between MCH and ART — monitoring and logistic implications
- Increased human resource capacity to initiate treatment — training, supervision, mentorship
- Increased funding to treat more pregnant women with HIV

PMTCT Section B3. Estimating Resource Implications of Implementing WHO Recommendation 2: Raising treatment threshold for ART in pregnant women with HIV to 350 cells/mm^3				
Program Area	**Approximate Resources Required to Implement Policy**	**Approximate Resources Available**	**Are Existing Resources Sufficient to Implement Policy?**	**Additional Resources That Could Be Mobilized**
Policy/Laws/Regulations				
Human Resources				
Protocols and Tools				
Infrastructure				
Commodities				
Laboratory Services				
Monitoring				
MCH/RH/HIV Linkages				
Local Leadership/Advocacy				
Community				

PMTCT SECTION C: MATERNAL ART FOR PREGNANT WOMEN ELIGIBLE FOR TREATMENT FOR THEIR OWN HEALTH AND PMTCT *WHO RECOMMENDATIONS 3 AND 4: TRIPLE ART REGIMEN FOR TREATMENT IN ELIGIBLE PREGNANT WOMEN (CD4 <350 OR CLINICAL STAGES 3 AND 4) AND INFANT PROPHYLAXIS*		
PMTCT Section C1. Describe Revised National Policy in the Context of the Revised WHO Guidelines Policy		
WHO 2006	**WHO 2010**	**Current National Policy**
Maternal ART Current ART regimen for eligible pregnant women varies across countries	**Maternal ART** Revised recommended ART regimen for eligible pregnant women to start at any gestation age: AZT+3TC+NVP or AZT+3TC+EFV or TDF+X*TC+NVP (*X=3 or F) or TDF+X*TC+EFV (*X=3 or F) Note: EFV only after first trimester	Please describe current national policy to assist in identifying likely changes in implementation:
HIV-exposed infant prophylaxis sdNVP and 4 weeks AZT to infant	**HIV-exposed infant** In breastfeeding HIV-exposed infants, NVP or AZT daily for four to six weeks; OR In non-breastfeeding HIV-exposed infants, either NVP or AZT daily for four to six weeks	Please describe current national policy to assist in identifying likely changes in implementation:

PMTCT Section C2. Key Considerations for Implementing WHO Recommendations 3&4:
Triple ART regimen for treatment in eligible pregnant women (CD4 <350 or clinical stage 3 and 4) and infant prophylaxis

Implementation of new recommendations may require:

MATERNAL ISSUES:

- Consideration of cost implications of different ARV regimens; AZT and TDF more costly than many existing regimens in widespread use
- Substantive changes in national drug procurements, stocks and management to ensure sufficient availability — phased transition period while existing buffer stocks in use
- Decentralization of ART in MCH and strengthened linkages between ANC and MCH
- Increased health system capacity to initiate and maintain delivery of new regimens including human resource complement, additional training, etc.
- Increased capacity to monitor safety and effectiveness — limited data on TDF use in pregnancy
- Changes to national monitoring systems (e.g., national indicators, databases, registers etc.)

INFANT ISSUES:

- Strengthened follow-up systems for mothers/infants
- Increased adherence support needs for mother/infant pairs
- Strengthened linkages between MCH and ART
- Strengthened monitoring of safety — possible clinical toxicity if infant and mother taking NVP-based regimen during breastfeeding
- Consideration of the availability and cost implications of drugs needed to cover six-week period either NVP or AZT
- Changes in drug procurements, stocks, and management — phased transition from AZT to NVP and utilization of existing AZT stocks

• Increased health system capacity to implement — HR, training, tools • Changes to national monitoring systems; e.g., national indicators, databases, registers etc.
Implementation issues to consider:

PMTCT Section C3. Estimating Resource Implications of Implementing WHO Recommendations 3&4: Triple ART regimen for treatment in eligible pregnant women (CD4 <350 or clinical stages 3 and 4) and infant prophylaxis				
Program Area	**Approximate Resources Required to Implement Policy**	**Approximate Resources Available**	**Are Existing Resources Sufficient to Implement Policy?**	**Additional Resources That Could Be Mobilized**
Policy/Laws/Regulations				
Human Resources				
Protocols and Tools				
Infrastructure				
Commodities				
Laboratory Services				
Monitoring				
MCH/RH/HIV Linkages				
Local Leadership/Advocacy				
Community				

PMTCT SECTION D: ARV PROPHYLAXIS FOR NON-TREATMENT-ELIGIBLE PREGNANT WOMEN WITH HIV OR FOR WHOM ELIGIBILITY IS UNKNOWN AND INFANT PROPHYLAXIS

WHO RECOMMENDATIONS 5 AND 6:
OPTION A: COMBINATION ARV PROPHYLAXIS FOR INELIGIBLE PREGNANT WOMEN (CD4 >350 AND CLINICAL STAGES 1 AND 2) OR PREGNANT WOMEN WITH HIV WHOSE ELIGIBILITY IS UNKNOWN, AND INFANT PROPHYLAXIS

PMTCT Section D1. Describe Revised National Policy in the Context of the Revised WHO Guidelines

WHO 2006	WHO 2010	Current National Policy
Maternal Prophylaxis AZT from 28 wks with or without Combivir tail post delivery for non-eligible women or for women whose eligibility is unknown	**Maternal Prophylaxis** Antenatal AZT (from 14 weeks gestation) sdNVP at onset of labor AZT+3TC during labor and Delivery AZT+3TC for seven days postpartum	Please describe current national policy to assist in identifying likely changes in implementation:
HIV-Exposed Infant Prophylaxis sdNVP and four weeks AZT to infant	***HIV-Exposed Infant Prophylaxis*** In breastfeeding, HIV-exposed infants, daily NVP from birth until one week after all exposure to breast milk has ended **OR** In non-breastfeeding HIV-exposed infants, daily AZT or NVP for four to six weeks	Please describe current national policy to assist in identifying likely changes in implementation:

PMTCT Section D2. Key Considerations for Implementing WHO Recommendations 5&6:
Option A: Combination ARV prophylaxis for ineligible pregnant women (CD4 >350 or clinical stages 1 and 2) or pregnant women with HIV whose eligibility is unknown and infant prophylaxis

Implementation of new recommendations may require:

MATERNAL ISSUES

- Revisions to national adult ART and PMTCT guidelines
- Transitioning of sites using sdNVP or different prophylaxis protocols — phased approach or immediate switch in all sites
- Changes in national drug costs, procurements, stocks, and management — additional AZT in ANC required
- Consideration of the availability and cost implications of a longer course of AZT
- Steps to offset increased risk of AZT-related maternal anemia — improved clinical and diagnostic monitoring
- Increased health system capacity to implement — additional training, HR, job aides, tools
- Increased adherence support needs for mothers
- Changes to national monitoring systems (e.g., national indicators, databases, registers, etc.)

INFANT ISSUES

- Strengthened follow-up services for mother/infants
- Stronger integration into child-health programs to support long-term follow-up requirements - improved linkages between ANC, PNC and child health clinics
- Increased adherence support needs for mother/infant pairs
- Improved referral system from MCH into ART

• Changes in national drug procurements, stocks and management e.g. when to phase out procurement of AZT syrup and phase in procurement of additional stocks of NVP syrup • Consideration of availability and cost implications for prolonged ARV use • Consideration of potential drug toxicity from long-term use of NVP • Increased health system capacity to implement — additional training, HR, job aides, tools • Changes to national monitoring systems (e.g., national indicators, databases, registers, etc.) • Revisions to national ART, PMTCT and IYCF guidelines including pediatric ART first-line treatment protocols
Implementation issues to consider:

PMTCT Section D3. Estimating Resource Implications of Implementing WHO Recommendations 5 and 6:
Option A: Combination ARV prophylaxis for ineligible pregnant women (CD4 >350 or clinical stages 1 and 2) or pregnant women with HIV whose eligibility is unknown and infant prophylaxis

Program Area	Approximate Resources Required to Implement Policy	Approximate Resources Available	Are Existing Resources Sufficient to Implement Policy?	Additional Resources That Could Be Mobilized
Policy/Laws/Regulations				
Human Resources				
Protocols and Tools				
Infrastructure				
Commodities				
Laboratory Services				
Monitoring				
MCH/RH/HIV Linkages				
Local Leadership/Advocacy				
Community				

PMTCT SECTION E: WHO Recommendation 4, 5 & 7: **<u>OPTION B:</u> Triple ARV prophylaxis for pregnant women ineligible for ART starting in ANC and continued during breastfeeding period and infant prophylaxis**		
PMTCT Section E1. Describe Revised National Policy in the Context of the Revised WHO Guidelines		
WHO 2006	**WHO 2010**	**Current National Policy**
	Mother Triple ARV from 14 weeks and until one week after cessation of breastfeeding AZT+3TC+LPV-r AZT+3TC+ABC AZT+3TC+EFV TDF+XTC+EFV	Please describe current national policy to assist in identifying likely changes
	Breastfeeding Infant: ▪ NVP for 6 weeks ***Non-breastfeeding infant:*** ▪ AZT or NVP for 4 to 6 weeks	Please describe current national policy to assist in identifying likely changes

PMTCT Section E2. Key Considerations for Implementing WHO Recommendations 4, 5 and 7:
Option B: Triple ARV prophylaxis for pregnant women ineligible for ART starting in ANC and continued during breastfeeding period and infant prophylaxis

Implementation of new recommendations may require:

MATERNAL ISSUES:

- MAJOR revisions to national policy guidelines including for adult first and second line drugs that complement the triple ARV prophylaxis regimen
- Consideration of SIGNIFICANT cost implications of providing triple ARV prophylaxis in both the antenatal and breastfeeding period with substantial increase in price of triple ARV regimens to be used
- Decentralization and strengthened linkages between multiple different entry points (e.g., to ensure delivery of ARV regimens in ANC, PNC, child health services, ART)
- Improved methods to handle increased complexity of assessing women who require ART for their own health
- Strengthened long-term follow-up mechanisms to tailor prescribing triple ARV prophylaxis according to length of breastfeeding
- Changes in national drug procurements, stocks, and management — phased transition period to implement new regimen and utilization of previous ARV prophylaxis stocks
- Increased health system capacity to implement new ARV regimens — additional training, HR, job aides, tools
- Changes to national monitoring systems (e.g., national indicators, databases, registers, etc.)

INFANT ISSUES — similar to prophylaxis for eligible women on ART

- Strengthened follow-up systems for mothers/infants
- Increased adherence support needs for mother/infant pairs

- Strengthened linkages between MCH and ART
- Strengthened monitoring of safety — possible clinical toxicity if infant and mother taking NVP-based regimen during breastfeeding
- Adaptations to national pediatric first-line ART protocols and infant feeding guidelines
- Consideration of the availability and cost implications for drugs to cover six-week period either NVP or AZT
- Changes in national drug procurements, stocks, and management — phased transition from AZT to NVP and utilization of existing AZT stocks
- Increased health system capacity to implement — HR, training, tools
- Changes to national monitoring systems (e.g., national indicators, databases, registers, etc.)

PMTCT Section E3. Estimating Resource Implications of Implementing WHO Recommendation 4, 5 and 7:
Option B: Triple ARV prophylaxis for pregnant women ineligible for ART starting in ANC and continued during breastfeeding period and infant prophylaxis

Program Area	Approximate Resources Required To Implement Policy	Approximate Resources Available	Are Existing Resources Sufficient to Implement Policy?	Additional Resources That Could Be Mobilized
Policy/Laws/Regulations				
Human Resources				
Protocols and Tools				
Infrastructure				
Commodities				
Laboratory Services				
Monitoring				
MCH/RH/HIV Linkages				
Local Leadership/Advocacy				
Community				

1.3 GUIDELINE IMPLEMENTATION PLANNING TOOL FOR INFANT AND YOUNG CHILD FEEDING IN THE CONTEXT OF HIV*

Recommended Approach to Using this Tool:

4. Review the key changes in the revised WHO recommendations for Infant and Young Child Feeding in the Context of HIV in Table 1

5. For each of the key changes, use Section A-E 1 (comparing key changes inherent in the revised WHO recommendation to revised national policies) to examine whether these changes differ from current implementation practice

6. For each of the key changes in the revised WHO recommendations that differ from current implementation practice:

    a. Use Section A-E 2 to list the country-specific issues for the program/district to consider in relation to implementation of each of the potential key changes in to national policy

    b. Use Section A-E 3 to analyze the resource implications of implementing each key change

*The Foundation greatly acknowledges the contributions of Rae Galloway, Kiersten Israel-Ballard, and Jennifer Marcy of PATH's PMTCT Team to this section (1.3) of the toolkit. These individuals made significant technical input, particularly through the creation of a table comparing the 2009 WHO recommendations on HIV and infant feeding with previous WHO recommendations, which informed the development of this tool.

IYCF in the context of HIV

IYCF Table 1: Key Changes in the Revised WHO Recommendations

Recommendation	Key Changes
Key Principles 3 and 4	National or sub-national health authorities should decide on the most appropriate infant feeding strategy for health services in context/ mothers living with HIV should be informed of the recommended infant feeding strategy and informed of alternatives.
WHO Recommendation 1	Mothers known to be HIV-positive should be provided with lifelong ART or ARV prophylaxis interventions to reduce HIV transmission through breastfeeding according to WHO recommendations.
WHO Recommendation 2	In settings where health services will principally support and promote breastfeeding mothers known to be HIV-infected (and whose infants are HIV un-infected or of unknown HIV status), mothers should exclusively breastfeed their infants for the first 6 months of life, introducing appropriate complementary foods thereafter, and continue breastfeeding for the first 12 months of life. Breastfeeding should then only stop once a nutritionally adequate and safe diet without breast milk can be provided.
WHO Recommendation 3	Mothers known to be HIV-infected who decide to stop breastfeeding at any time should stop gradually within one month. Mothers or infants who have been receiving ARV prophylaxis should continue prophylaxis for one week after breastfeeding is fully stopped.
WHO Recommendation 4	When mothers known to be HIV-infected decide to stop breastfeeding at any time, infants should be provided with safe and adequate replacement feeds to enable normal growth and development.
WHO Recommendation 5	Mothers known to be HIV-infected should only give commercial infant formula milk as a replacement feed to their HIV uninfected infants or infants who are of unknown HIV status, when specific conditions are met.
WHO Recommendation 6	Mothers known to be HIV-infected may consider expressing and heat-treating breast milk as an interim feeding strategy.
WHO Recommendation 7	If infants and young children are known to be HIV-infected, mothers are strongly encouraged to exclusively breastfeed for the first 6 months of life and continue breastfeeding as per the recommendations for the general population that is up to two years or beyond.

IYCF SECTION A: KEY PRINCIPALS 3 AND 4: NATIONAL OR SUB-NATIONAL HEALTH AUTHORITIES SHOULD DECIDE ON THE MOST APPROPRIATE INFANT FEEDING STRATEGY FOR HEALTH SERVICES IN CONTEXT/MOTHERS LIVING WITH HIV SHOULD BE INFORMED OF THE RECOMMENDED INFANT FEEDING STRATEGY AND INFORMED OF ALTERNATIVES		
IYCF Section A1. Describe Revised National Policy in the Context of the Revised WHO Guidelines		
WHO 2006	**WHO 2010**	**Current National Policy**
The most appropriate infant feeding option for an HIV-infected mother should continue to depend on her individual circumstances, including her health status and the local situation, but should take greater consideration of the health services available and the counseling and support she is likely to receive.	**Key principle 3:** National or sub-national health authorities should decide whether health services will principally counsel and support mothers known to be HIV-infected to either: breastfeed and receive ARV interventions or avoid all breastfeeding, as the strategy that will most likely give infants the greatest chance of HIV-free survival **Key principle 4:** Pregnant women and mothers known to be HIV-infected should be informed of the infant feeding strategy recommended by the national or sub-national authority to improve HIV-free survival of HIV-exposed infants and the health of HIV-infected mothers, and informed that there are alternatives that mothers might wish to implement.	Please describe current national policy to assist in identifying likely changes in implementation

IYCF Section A2. Key Considerations of Implementing WHO Recommendation 1

Comments/Interpretation:

- The 2010 guidelines take a stronger "public health approach" by advising that national or sub-national authorities make the determination about which infant feeding practices will achieve the greatest likelihood of HIV-free survival. In essence, the recommendation is asking the authorities (e.g. MOH) to set the standard of care that is tailored to their country context and is based on strong evidence.
- Key Principle 4 points out that taking a public health approach does not mean that individual women forfeit their right to refuse the recommended practice (per the national standard of care).

This decision should be based on International recommendations and consideration of the:

- Socio-economic and cultural contexts of the populations served by maternal, newborn and child health services,
- Availability and quality of health services
- Local epidemiology including HIV prevalence among pregnant women
- Main causes of maternal and child malnutrition
- Main causes of infant and child mortality
- Capacity for appropriate counseling services

Implementation issues to consider:

IYCF Section A3. Estimating Resource Implications Related to Implementation of Infant Feeding Strategy for Health Services in Context				
Program Area	**Approximate Resources Required to Implement Policy**	**Approximate Resources Available**	**Are Existing Resources Sufficient to Implement Policy?**	**Additional Resources That Could Be Mobilized**
Policy/Laws/Regulations				
Human Resources				
Protocols and Tools				
Infrastructure				
Commodities				
Laboratory Services				
Monitoring				
Maternal and Child Health (MCH)/Reproductive Health (RH)/HIV Linkages				
Local Leadership/Advocacy				
Community				

IYCF SECTION B: WHO RECOMMENDATION 1: MOTHERS KNOWN TO BE HIV-INFECTED SHOULD BE PROVIDED WITH LIFELONG ANTIRETROVIRAL THERAPY OR ANTIRETROVIRAL PROPHYLAXIS INTERVENTIONS TO REDUCE HIV TRANSMISSION THROUGH BREASTFEEDING ACCORDING TO WHO RECOMMENDATIONS.
Please Refer to the following sections in the corresponding tool for ARV drugs for the treatment of pregnant women living with HIV and prevention of HIV infection in infants: • PMTCT Section C: WHO Recommendations 3&4: Option A/ Triple ART regimen for treatment in eligible pregnant women (CD4 < 350 or clinical stage 3 & 4) and infant prophylaxis • PMTCT Section D: WHO Recommendations 5&6: Option B: Combination ARV prophylaxis for non- treatment eligible pregnant women (CD4>350 or clinical stage 1&2) or pregnant women with HIV for whom eligibility in unknown and infant prophylaxis • PMTCT Section E: WHO Recommendation 4, 5 & 7: Option B: Triple ARV prophylaxis for pregnant women ineligible for ART starting in ANC and continued during breastfeeding period and infant prophylaxis

IYCF SECTION C: WHO RECOMMENDATION 2: IN SETTINGS WHERE HEALTH SERVICES WILL PRINCIPALLY SUPPORT AND PROMOTE BREASTFEEDING MOTHERS KNOWN TO BE HIV-INFECTED (AND WHOSE INFANTS ARE HIV UNINFECTED OR OF UNKNOWN HIV STATUS) SHOULD EXCLUSIVELY BREASTFEED THEIR INFANTS FOR THE FIRST 6 MONTHS OF LIFE, INTRODUCING APPROPRIATE COMPLEMENTARY FOODS THEREAFTER, AND CONTINUE BREASTFEEDING FOR THE FIRST 12 MONTHS OF LIFE. BREASTFEEDING SHOULD THEN ONLY STOP ONCE A NUTRITIONALLY ADEQUATE AND SAFE DIET WITHOUT BREAST MILK CAN BE PROVIDED.		
IYCF Section C1. Describe Revised National Policy in the Context of the Revised WHO Guidelines		
WHO 2006	**WHO 2010**	**Current National Policy**
Exclusive breastfeeding is recommended for HIV-infected women for the first six months of life unless replacement feeding is acceptable, feasible, affordable, sustainable and safe (AFASS) for them and their infants before that time. At six months, if replacement feeding is still not acceptable, feasible, affordable, sustainable and safe, continuation of breastfeeding with additional complementary foods is recommended, while the mother and baby continue to be regularly assessed. All breastfeeding should stop once a nutritionally adequate and safe diet without breast milk can be provided.	**Recommendation 2:** *[In settings where health services will principally support and promote breastfeeding]* mothers known to be HIV-infected (and whose infants are HIV uninfected or of unknown HIV status) should exclusively breastfeed their infants for the first 6 months of life, introducing appropriate complementary foods thereafter, and continue breastfeeding for the first 12 months of life. Breastfeeding should then only stop once a nutritionally adequate and safe diet without breast milk can be provided.	Please describe current national policy to assist in identifying likely changes in implementation:

IYCF Section C2. Key Considerations for implementing exclusive breastfeeding as the infant feeding strategy

Comments/Interpretation:

- The 2006 and 2010 guidelines both recommend exclusive breastfeeding from birth to six months, but the 2010 guidelines extend the duration of breastfeeding to 12 months.
- Both sets of guidelines indicate that breastfeeding should only stop when a safe and nutritionally adequate diet can be provided without breast milk.

Implementation of new guidelines may require:

- Enhanced counseling on infant and young child feeding
- Exclusive breastfeeding for the first 6 months of life
- Introduction of appropriate complementary foods
- Continuing breastfeeding for the first 12 months of life
- Assessment to stop breastfeeding when a nutritionally adequate and safe diet can be provided without breast milk
- In order to implement these recommendations, some considerations are at specific levels:
- Policy level: need to implement the WHO recommendations and adapt national policy to reflect them, get buy-in at all levels, and change other policies that affect women's ability to successfully practice exclusive breastfeeding (e.g. workplace policies to allow women more maternity leave
- Facility level: provide enhanced counseling, trained providers are needed.
- Changing the perception
- training, re-training, supervision, materials/tools (training materials, supervision materials, IEC materials for clients, job aides for providers)
- System for monitoring the implementation of enhanced counseling and the impact/outcomes of the counseling
- Organization of health services at facilities needs to allow adequate time and space to conduct enhanced counseling for HIV-positive women

▪ Community education/sensitization to support women for good infant feeding practices ▪ At all levels, need to ensure that once policy makers recommend breastfeeding for mothers with HIV that it becomes the standard of care and the message is that breastfeeding for mothers with HIV is the best way to achieve HIV-free survival.
Implementation issues to consider:

IYCF Section C3. Estimating Resource Implications of Implementing Exclusive Breastfeeding as the Infant Feeding Strategy				
Program Area	**Approximate Resources Required to Implement Policy**	**Approximate Resources Available**	**Are Existing Resources Sufficient to Implement Policy?**	**Additional Resources That Could Be Mobilized**
Policy/Laws/Regulations				
Human Resources				
Protocols and Tools				
Infrastructure				
Commodities				
Laboratory Services				
Monitoring				
MCH/RH/HIV Linkages				
Local Leadership/Advocacy				
Community				

IYCF SECTION D: RECOMMENDATION 3: MOTHERS KNOWN TO BE HIV-INFECTED WHO DECIDE TO STOP BREASTFEEDING AT ANY TIME SHOULD STOP GRADUALLY WITHIN ONE MONTH. MOTHERS OR INFANTS WHO HAVE BEEN RECEIVING ARV PROPHYLAXIS SHOULD CONTINUE PROPHYLAXIS FOR ONE WEEK AFTER BREASTFEEDING IS FULLY STOPPED.		
IYCF Section D1. Describe Revised National Policy in the Context of the Revised WHO Guidelines		
WHO 2006	**WHO 2010**	**Current National Policy**
At six months, if replacement feeding is still not acceptable, feasible, affordable, sustainable and safe, continuation of breastfeeding with additional complementary foods is recommended, while the mother and baby continue to be regularly assessed. All breastfeeding should stop once a nutritionally adequate and safe diet without breast milk can be provided.	**Recommendation 3:** Mothers known to be HIV-infected who decide to stop breastfeeding at any time should stop gradually within one month. Mothers or infants who have been receiving ARV prophylaxis should continue prophylaxis for one week after breastfeeding is fully stopped. Stopping breastfeeding abruptly is not advisable.	Please describe current national policy to assist in identifying likely changes in implementation:

IYCF Section D2. Key Considerations of Implementing WHO Recommendation 3

Comments/Interpretation:

- The 2006 guidelines did not recommend abrupt or rapid weaning due to the associated increased risk of HIV transmission, but did not give a timeframe for cessation of breastfeeding. The 2010 guidelines explicitly state that the weaning process should be gradual and should take approximately one month.

Implementation of new recommendations may require:

- Enhanced and more frequent counseling to specifically assess when it is safe to stop breastfeeding and how to safely do so
- Incentives for women to continue accessing postnatal follow-up with a trained health-care worker (facility or home based) for counseling and support to determine when it is safe to stop BF and how to safely stop.
- Counseling should be coordinated with implementation of the ARV drug regimen (treatment/prophylaxis) that is implemented in that setting (i.e. to ensure that drugs are continued until 1 week after BF stops)
- Availability of foods etc. for children

Implementation issues to consider:

IYCF Section D3. Estimating Resource Implications of Implementing WHO Recommendation 3				
Program Area	**Approximate Resources Required To Implement Policy**	**Approximate Resources Available**	**Are Existing Resources Sufficient To Implement Policy?**	**Additional Resources That Could Be Mobilized**
Policy/Laws/Regulations				
Human Resources				
Protocols and Tools				
Infrastructure				
Commodities				
Laboratory Services				
Monitoring				
MCH/RH/HIV Linkages				
Local Leadership/Advocacy				
Community				

IYCF SECTION E: RECOMMENDATION 4: WHEN MOTHERS KNOWN TO BE HIV-INFECTED DECIDE TO STOP BREASTFEEDING AT ANY TIME, INFANTS SHOULD BE PROVIDED WITH SAFE AND ADEQUATE REPLACEMENT FEEDS TO ENABLE NORMAL GROWTH AND DEVELOPMENT.		
IYCF Section E1. Describe Revised National Policy in the Context of the Revised WHO Guidelines		
WHO 2006	**WHO 2010**	**Current National Policy**
At six months, if replacement feeding is still not acceptable, feasible, affordable, sustainable and safe, continuation of breastfeeding with additional complementary foods is recommended, while the mother and baby continue to be regularly assessed. All breastfeeding should stop once a nutritionally adequate and safe diet without breast milk can be provided.	**Recommendation 4:** When mothers known to be HIV-infected decide to stop breastfeeding at any time, infants should be provided with safe and adequate replacement feeds to enable normal growth and development. (See Table E1.1 below for appropriate alternatives to breast milk for different time periods)	Please describe current national policy to assist in identifying likely changes in implementation:

Table E1.1. Acceptable Alternatives to Breast Milk during Different Time Periods

Time period	Alternatives to breast milk
Birth to 6 months	Commercial powdered infant formula (only if conditions listed below are met), or Heat-treated expressed breast milk
After 6 months	Commercial powdered infant formula (only if conditions listed below are met), or Heat-treated expressed breast milk, or Modified animal milk (boiled for infants under 12 months of age)

IYCF Section E2. Key Considerations of Implementing WHO Recommendation 4

Comments/Interpretation:

- Both sets of recommendations advise against giving animal milk (modified or otherwise) to infants younger than 6 months, but in the 2006 recommendations, home-modified animal milk is given as an option for short periods when commercial formula is not available. The 2009 recommendations explicitly state that home-modified animal milk is not a recommended replacement feed for infants younger than 6 months; however, they indicate that infants over 6 months can receive animal milk (boiled for children younger than 12 months).

Implementation of new recommendations may require:

- Inclusion of nutritionists to help create or modify existing counseling materials to train health-care workers on how to assess what options might be available and appropriate to ensure safe and adequate replacement foods.
- Creation or adaption of materials to support heat treatment of breast milk. Some countries have already begun to promote this practice so some training tools are available to be adapted.

Considerations should be made for how to support women when complementary feeding (defined as breastfeeding and giving other foods after the child is 6 months of age) their child, particularly when the child is between 6 and 12 months of age.

Implementation issues to consider:

IYCF Section E3. Estimating Resource Implications of Implementing WHO Recommendation 4				
Program Area	**Approximate Resources Required to Implement Policy**	**Approximate Resources Available**	**Are Existing Resources Sufficient to Implement Policy?**	**Additional Resources That Could Be Mobilized**
Policy/Laws/Regulations				
Human Resources				
Protocols and Tools				
Infrastructure				
Commodities				
Laboratory Services				
Monitoring				
MCH/RH/HIV Linkages				
Local Leadership/Advocacy				
Community				

IYCF SECTION F: WHO RECOMMENDATION 5: MOTHERS KNOWN TO BE HIV-INFECTED SHOULD ONLY GIVE COMMERCIAL INFANT FORMULA MILK AS A REPLACEMENT FEED TO THEIR HIV-UNINFECTED INFANTS OR INFANTS WHO ARE OF UNKNOWN HIV STATUS, WHEN SPECIFIC CONDITIONS ARE MET.		
IYCF Section F1. Describe Revised National Policy in the Context of the Revised WHO Guidelines		
WHO 2006	**WHO 2010**	**Current National Policy**
When replacement feeding is acceptable, feasible, affordable, sustainable and safe, avoidance of all breastfeeding by HIV-infected women is recommended.	**Recommendation 5:** Mothers known to be HIV-infected should only give commercial infant formula milk as a replacement feed to their HIV uninfected infants or infants who are of unknown HIV status, when specific conditions are met: *[see list of six criteria on pg. 1 of this tool].*	Please describe current national policy to assist in identifying likely changes in implementation:

IYCF Section F2. Key Considerations for Implementing WHO Recommendation 5
Comments/Interpretation: • In the 2010 guidelines, WHO no longer recommends using the AFASS criteria for assessing whether replacement feeding is appropriate and safe. In the place of the AFASS criteria, WHO has introduced an expanded list of criteria that more accurately describe the conditions (in more familiar language).
Implementation of new recommendations may require: • Decide how to translate the concepts listed in the recommendation into action (note: this is a similar dilemma faced with the previous recommendations that also listed assessment criteria for safely formula feeding, also known as the AFASS criteria)
Implementation issues to consider:

IYCF Section F3. Estimating Resource Implications of Implementing WHO Recommendation 5				
Program Area	**Approximate Resources Required To Implement Policy**	**Approximate Resources Available**	**Are Existing Resources Sufficient To Implement Policy?**	**Additional Resources That Could Be Mobilized**
Policy/Laws/Regulations				
Human Resources				
Protocols and Tools				
Infrastructure				
Commodities				
Laboratory Services				
Monitoring				
MCH/RH/HIV Linkages				
Local Leadership/Advocacy				
Community				

IYCF SECTION G: WHO RECOMMENDATION 6: MOTHERS KNOWN TO BE HIV-INFECTED MAY CONSIDER EXPRESSING AND HEAT-TREATING BREAST MILK AS AN INTERIM FEEDING STRATEGY.		
IYCF Section G1. Describe Revised National Policy in the Context of the Revised WHO Guidelines		
WHO 2006	**WHO 2010**	**Current National Policy**
Previous recommendations offered heat-treatment of expressed breast milk as an option for HIV-positive mothers;	Recommendation 6: Mothers known to be HIV-infected may consider expressing and heat-treating breast milk as an interim feeding strategy. *[See pg. 1 of this tool for times when a mother may consider heat-treating her breast milk.]*	Please describe current national policy to assist in identifying likely changes in implementation:

IYCF Section G2. Key Considerations for Implementing WHO Recommendation 6
Comments/Interpretation: • Previous recommendations offered heat-treatment of expressed breast milk as an option for HIV-positive mothers; the 2009 recommendations advise that heat-treating breast milk only be utilized as an interim strategy during specific situations and acknowledge that additional research is needed to determine its feasibility as a longer-term feeding option.
Implementation of new recommendations may require: • Need to determine the feasibility of implementing and supporting heat treatment of breast milk nationally. • Need to produce or adapt counseling materials on the heat treatment of breast milk for training purposes. Materials need to be adapted to be appropriate to the context. • Strengthen training for health-care workers on how to counsel women with HIV on the heat treatment of breast milk.
Implementation issues to consider:

IYCF Section G3. Estimating Resource Implications of Implementing WHO Recommendation 6				
Program Area	**Approximate Resources Required to Implement Policy**	**Approximate Resources Available**	**Are Existing Resources Sufficient to Implement Policy?**	**Additional Resources that Could be Mobilized**
Policy/Laws/Regulations				
Human Resources				
Protocols and Tools				
Infrastructure				
Commodities				
Laboratory Services				
Monitoring				
MCH/RH/HIV Linkages				
Local Leadership/Advocacy				
Community				

IYCF SECTION H: WHO RECOMMENDATION 7: IF INFANTS AND YOUNG CHILDREN ARE KNOWN TO BE HIV-INFECTED, MOTHERS ARE STRONGLY ENCOURAGED TO EXCLUSIVELY BREASTFEED FOR THE FIRST 6 MONTHS OF LIFE AND CONTINUE BREASTFEEDING AS PER THE RECOMMENDATIONS FOR THE GENERAL POPULATION THAT IS UP TO TWO YEARS OR BEYOND.		
IYCF Section H1. Describe Revised National Policy in the Context of the Revised WHO Guidelines		
WHO 2006	**WHO 2010**	**Current National Policy**
Breastfeeding mothers of infants and young children who are known to be HIV-infected should be strongly encouraged to continue breastfeeding.	Recommendation 7: If infants and young children are known to be HIV-infected, mothers are strongly encouraged to exclusively breastfeed for the first 6 months of life and continue breastfeeding as per the recommendations for the general population that is up to two years or beyond.	Please describe current national policy to assist in identifying likely changes in implementation:

IYCF Section H2. Key Considerations for Implementing WHO Recommendation 7
Comments/Interpretation: • The 2010 guidelines place additional emphasis on the recommended duration of breastfeeding for HIV-positive infants and young children.
Implementation of new recommendations may require: • Determining how to communicate the advantages of breastfeeding once a child is identified as having HIV.
Implementation issues to consider:

IYCF Section H3. Estimating Resource Implications of implementing WHO Recommendation 7				
Program Area	**Approximate Resources Required To Implement Policy**	**Approximate Resources Available**	**Are Existing Resources Sufficient To Implement Policy?**	**Additional Resources That Could Be Mobilized**
Policy/Laws/Regulations				
Human Resources				
Protocols and Tools				
Infrastructure				
Commodities				
Laboratory Services				
Monitoring				
MCH/RH/HIV Linkages				
Local Leadership/Advocacy				
Community				

1.4 GUIDELINE IMPLEMENTATION PLANNING TOOL FOR TREATMENT OF INFANTS AND CHILDREN LIVING WITH HIV

Recommended Approach to Using this Tool:

1. Review the key changes in the revised WHO guidelines for ARV Drugs for Infants and Children Living with HIV in PEDS Table 1
2. For each of the key changes, use Section A-E 1 (comparing key changes inherent in the revised WHO recommendation to revised national policies) to examine whether these changes differ from current implementation practice.
3. For each of the key changes in the revised WHO recommendations that differ from current national policy:
    a. Use Section A-E 2 to list the country-specific issues for the program/district to consider in relation to adaptation of each of potential key changes in to National policy
    b. Use Section A-E 3 to analyze the resource implications of implementing each key change

Table 1: Key Changes in the Revised WHO Guidelines

- ART initiation in HIV-infected infants and children
- ARV Regimens for HIV-infected infants and children
- Specific regimens for certain conditions
- Switching regimens and Initiation of second-line regimens in infants and children

PEDS SECTION A: ART INITIATION IN HIV-INFECTED INFANTS AND CHILDREN

PEDS Section A1. Describe Revised National Policy in the Context of the Revised WHO Guidelines

WHO 2006	WHO 2010	Current National Policy
ART initiation if: <12 mo 12 -35 mo if CD4 <20% or <750 36 -59 mo if CD4< 20% or <350 ≥5 years if CD4 <15% or <200	All children >24 months irrespective of clinical or immunological stage All children <18 months fulfilling criteria for presumptive severe HIV All children of all ages with WHO stage 3 or 4 Children 24 to 59 months if CD4 <750 or <25% Children ≥5 years if CD4 <350	Please describe revised national policy to assist in identifying likely changes in implementation:

PEDS Section A2. Key Considerations of Implementing Revised ART Initiation in HIV-infected Infants and Children

Implementation of new recommendations may require:

- Additional resources to provide ARVs for treatment for all children <2 years living with HIV
- If not already in place, expansion of capacity to perform EID and CD4 testing for children older than 2 years, including commodities, logistics and training of lab personnel
- Training and re-training of staff on new guidelines, including presumptive diagnosis

- Training of health professionals on appropriate WHO clinical staging – need for resources including qualified trainers for various countries
- Decentralization of laboratory and ART services into primary health-care center — task sharing, monitoring and logistic implications
- Increased human resource capacity to initiate treatment — training, supervision, mentorship
- Increased funding to treat more patients with HIV
- Possible revision of national ARV guidelines and policies

Implementation issues to consider:

PEDS Section A3. Estimating Resource Implications Related to Implementing Revised ART Initiation in HIV-infected Infants and Children

Program Area	Approximate Resources Required to Implement Policy	Approximate Resources Available	Are Existing Resources Sufficient To Implement Policy?	Additional Resources That Could Be Mobilized
Policy/Laws/Regulations				
Human Resources				
Protocols and Tools				
Infrastructure				
Commodities				
Laboratory Services				
Monitoring				

Maternal and Child Health (MCH)/Reproductive Health (RH)/HIV Linkages				
Local Leadership/Advocacy				
Community				

PEDS SECTION B: REVISED ARV REGIMENS FOR HIV-POSITIVE INFANTS AND CHILDREN

PEDS Section B1. Describe Revised National Policy in the Context of the Revised WHO Guidelines

WHO 2006	WHO 2009	Current National Policy
AZT + 3TC + NVP/EFV D4T + 3TC + NVP/EFV ABC + 3TC + NVP/EFV	Preferred : AZT + 3TC + NVP If NNRTI exposed: AZT + 3TC + LPV/r Alternative: AZT+ 3TC + ABC	Please describe revised national policy to assist in identifying likely changes in implementation:

PEDS Section B2. Key Considerations of Implementing revised ARV Regimens for HIV-infected Infants and Children

Implementation of new recommendations may require:

- Revision of procurement of ARVs to accommodate new regimens, including child-friendly formulations
- Proper documentation of NVP exposure status to identify correct 1st line regimen

Implementation issues to consider:

PEDS Section B3. Estimating Resource Implications Related to Implementing Revised ARV Regimens for HIV-Infected Infants and Children				
Program Area	**Approximate Resources Required To Implement Policy**	**Approximate Resources Available**	**Are Existing Resources Sufficient to Implement Policy?**	**Additional Resources That Could Be Mobilized**
Policy/Laws/Regulations				
Human Resources				
Protocols and Tools				
Infrastructure				
Commodities				
Laboratory Services				
Monitoring				
MCH/RH/HIV Linkages				
Local Leadership/Advocacy				
Community				

PEDS SECTION C: SPECIFIC REGIMENS FOR CERTAIN CONDITIONS		
PEDS Section C1. Describe Revised National Policy in the Context of the Revised WHO Guidelines		
WHO 2006	**WHO 2010**	**Current National Policy**
For TB and anemia, same as 2009. For hepatitis B (HBV) or hepatitis C (HCV) there were no guidelines	*Child adolescent with severe anaemia or severe neutropenia:* ABC + 3TC + NVP *Child < 3 years on TB treatment* NVP + 2NRTI or 3NRTI (AZT+ 3TC + ABC) *Child > 3 years on TB treatment* EFV + 2NRTI or 3NRTI (AZT+ 3TC + ABC) *Adolescent with HCV* Tenofovir (TDF) + emtricitabine (FTC) + EFV *Adolescent with HBV* EFV + 2NRTI	Please describe revised national policy to assist in identifying likely changes in implementation:

PEDS Section C2. Key Considerations of Implementing Specific Regimens for Certain Conditions
Implementation of new recommendations may require:
Implementation issues to consider:

PEDS Section C3. Estimating Resource Implications Related to Implementing Specific Regimens for Certain Conditions				
Program Area	**Approximate Resources Required To Implement Policy**	**Approximate Resources Available**	**Are Existing Resources Sufficient To Implement Policy?**	**Additional Resources That Could Be Mobilized**
Policy/Laws/Regulations				
Human Resources				
Protocols and Tools				
Infrastructure				
Commodities				
Laboratory Services				
Monitoring				
MCH/RH/HIV Linkages				
Local Leadership/Advocacy				
Community				
PEDS SECTION D: SWITCHING REGIMENS AND INITIATION OF SECOND-LINE REGIMENS IN INFANTS AND CHILDREN				

PEDS Section D1. Describe Revised National Policy in the Context of the Revised WHO Guidelines			
WHO 2006	**WHO 2010**	**Current National Policy**	
Clinical New or recurrent stage 3 or 4 clinical event ***Immunological*** Drop in CD4 to values at or below age-related CD4 threshold ▪ Age 12-35 mos <15% ▪ Age 36-59 mos <10% ▪ >5yrs CD4 count <100 ***Viral*** No established threshold	▪ Clinical failure (CF) ▪ Growth failure ▪ New/recurrent stage 4 > one year on ART ▪ Immunological failure (IF) ▪ CD4 count <200 or <10% ▪ Virological failure ▪ Clinical failure and or Immunologic Failure and VL >5000 copies/mL	Please describe revised national policy to assist in identifying likely changes in implementation:	
Second-line ARV regimens			
2NRTI + 1NNRTI in 1st line go to ddI +ABC + boosted PI ABC containing in 1st go to ddI +AZT + boosted PI Triple NRTI in 1st line go to ddI + EFV or NVP + boosted PI	NNRTI in first line - Boosted PI LPV/ r- in first line triple NNRTI AZT or d4T+ 3TC go to ABC 3TC or ABC ddI ABC + 3TC go to AZT 3TC or ABC ddI		

PEDS Section D2. Key Considerations of Implementing Switching to Switching Regimens and Initiation of Second-line Regimens in Infants and Children
Implementation of new recommendations may require: • Clinician training to assess clinical, immunological, virological failure • Alteration in procurement scheme for ARVs • Where feasible, capacity for viral load monitoring, including machines, laboratory training, lab network, logistics, etc. VIRAL LOAD ISSUES: • Access is limited in many countries – need to build new infrastructure • Viral load monitoring requires substantial investments: resource mobilization including HR and funds • Capacity building for laboratory to be able to handle- trainings, job aides, mentorship, supervision DRUG ISSUES: • Capacity to diagnose treatment failure and understanding when to switch- training, coaching and mentoring • Decentralization of case management, but with clear national coordination of systems to avoid undue delay to switch or premature switches. • Increased capacity to monitor safety and effectiveness — as the number of patients moving to second-line and eventually third line increases. • Changes to national monitoring systems (e.g., national indicators, databases, registers, etc.) • Increase health system capacity to implement – HR, training, tools • Resource mobilization activities for third line drugs. Cost of new molecules for third line- resource mobilization in a proactive manner.
Implementation issues to consider:

PEDS Section D3. Estimating Resource Implications Related to Implementing Switching to Initiation of Second-line Regimens in Infants and Children				
Program Area	**Approximate Resources Required To Implement Policy**	**Approximate Resources Available**	**Are Existing Resources Sufficient To Implement Policy?**	**Additional Resources That Could Be Mobilized**
Policy/Laws/Regulations				
Human Resources				
Protocols and Tools				
Infrastructure				
Commodities				
Laboratory Services				
Monitoring				
MCH/RH/HIV Linkages				
Local Leadership/Advocacy				
Community				

1.5 GUIDELINE IMPLEMENTATION PLANNING TOOL FOR TREATMENT OF ADULTS AND ADOLESCENTS LIVING WITH HIV

Recommended Approach to Using this Tool:

1. Review the key changes in the revised WHO guidelines for ARV drugs for adults and adolescents living with HIV in ADULTS Table 1
2. For each of the key changes, use Section A-E 1 (comparing key changes inherent in the revised WHO recommendation to existing national policies) to examine whether these changes differ from current national policy.
3. For each of the key changes in the revised WHO recommendations that differ from current national policy:
    a. Use Section A-E 2 to list the country-specific issues for the national program to consider in relation to adaptation of each of potential key changes in to national policy
    b. Use Section A-E 3 to analyze the resource implications of implementing each key change
4. Finally, summarize decisions on revised national policies in ADULTS Table 2

Antiretroviral therapy for Adults and Adolescents Living with HIV

Adults Table 1: Key changes in the revised WHO Guidelines

Recommendation	Key Changes
WHO Recommendation 1	Wider access to CD4 count
WHO Recommendation 2	Treatment threshold for ART in adults and adolescents
WHO Recommendation 3, 4, 5	Initiation of first-line ART regimens for treatment eligible adults and adolescents
WHO Recommendations 6, 7	Second-line ART regimens for treatment eligible adults and adolescents

ADULTS SECTION A: WHO RECOMMENDATION 1: WIDER ACCESS TO CD4 COUNT

ADULTS Section A1. Describe Revised National Policy in the Context of the Revised WHO Guidelines Policy

WHO 2006	WHO 2010	Current National Policy
CD4 for all HIV-positive adolescents and adults	Same policy but aggressively implemented to increase coverage of CD4 testing for all HIV-positive patients	Please describe current national policy to assist in identifying likely changes in implementation:

Adults Section A2. Key Considerations of Implementing WHO Recommendation 1 : Wider access to CD4 count

Implementation of new recommendations may require:

- Additional resources to prioritize CD4 count for all HIV-positive adolescents and adults— for procurement of machines, additional reagents, and support to human resources
- Improved and expanded lab-based CD4 capacity — additional infrastructure and human resources likely to be required to overcome bottlenecks
- Expansion of point-of-care CD4 testing using new technologies— additional resources, HR capacity, infrastructure
- Fortified sample transport systems with feedback of results between central labs and/or ART sites
- Introduction of electronic transfer of results between central labs and ART sites to facilitate timely dissemination of CD4 test results

Implementation issues to consider:

ADULTS Section A3. Estimating Resource Implications Related to Implementing WHO Recommendation 1 :

Wider access to CD4 count				
Program Area	**Approximate Resources Required To Implement Policy**	**Approximate Resources Available**	**Are Existing Resources Sufficient To Implement Policy?**	**Additional Resources That Could Be Mobilized**
Policy/Laws/Regulations				
Human Resources				
Protocols and Tools				
Infrastructure				
Commodities				
Laboratory Services				
Monitoring				
Maternal and Child Health (MCH)/Reproductive Health (RH)/HIV Linkages				
Local Leadership/Advocacy				
Community				

ADULTS SECTION B: WHO RECOMMENDATION 2: TREATMENT THRESHOLD FOR ART IN ADULTS AND ADOLESCENTS		
ADULTS Section B1. Describe Revised National Policy in the Context of the Revised WHO Guidelines Policy		
WHO 2006	**WHO 2010**	**Current National Policy**
ART for all adolescents and adults with CD4 < 200 cells/mm3 and/or clinical stage 4, for CD4 ranging 200-350 and WHO clinical stage 3, Consider treatment and initiate before CD4 count drops below 200	Initiate ART in all patients with HIV who have CD4 count <350 and/or WHO clinical stage 3 or 4	Please describe current national policy to assist in identifying likely changes in implementation:

ADULTS Section B2. Key Considerations of Implementing WHO Recommendation 2: Treatment threshold for ART in adults and adolescents
Implementation of new recommendations may require: Review of the ability / feasibility to prioritize all adults and adolescent who require treatment. Training of health professionals on appropriate WHO clinical staging – need for resources including qualified trainers for various countries Decentralization of laboratory and ART services into primary health-care centre — task sharing, monitoring and logistic implications Increased human resource capacity to initiate treatment — training, supervision, mentorship Increased funding to treat more patients with HIV Possible revision of national ARV guidelines and policies Increased laboratory capacity to monitor treatment for toxicity
Implementation issues to consider:

ADULTS Section B3. Estimating Resource Implications Related to Implementing WHO Recommendation 2: Treatment threshold for ART in adults and adolescents				
Program Area	**Approximate Resources Required To Implement Policy**	**Approximate Resources Available**	**Are Existing Resources Sufficient To Implement Policy?**	**Additional Resources That Could Be Mobilized**
Policy/Laws/Regulations				
Human Resources				
Protocols and Tools				
Infrastructure				
Commodities				
Laboratory Services				
Monitoring				
MCH/RH/HIV Linkages				
Local Leadership/Advocacy				
Community				

ADULTS SECTION C: WHO RECOMMENDATIONS 3, 4, 5: INITIATION OF FIRST-LINE ART REGIMENS FOR TREATMENT-ELIGIBLE ADULTS AND ADOLESCENTS AND TB AND HEPATITIS B/HIV CO-INFECTION		
ADULTS Section C1. Describe Revised National Policy in the Context of the Revised WHO Guidelines Policy		
WHO 2006	**WHO 2010**	**Current National Policy**
ART for adolescents and adults: When selecting appropriate ARV regimens, the following factors at the program level should be taken into consideration: ▪ Suitability of the drug formulation, especially the availability of fixed-dose combinations ▪ Licensing approval by national drug regulatory authorities for the product and recommended dose; ▪ Toxicity profile; ▪ Laboratory monitoring requirements; ▪ Potential for maintenance of future treatment options (sequencing of ARVs);	**ART for adolescents and adults:** Start one of the following regimens in ART-naïve individuals eligible for treatment: ▪ AZT + 3TC + EFV ▪ AZT + 3TC + NVP ▪ TDF + 3TC or FTC + EFV ▪ TDF + 3TC or FTC + NVP High value placed on avoiding the disfiguring, unpleasant and potentially life-threatening toxicity of stavudine (d4T), the need to select regimens suitable for use in most patient groups, and the benefits of using fixed-dose combinations.	Please describe current national policy to assist in identifying likely changes in implementation:

▪ Promotion of adherence (ARVs with once-daily or twice-daily dosing); ▪ Prevalent coexistent conditions (TB and HBV); ▪ Special considerations for women of childbearing potential or who are pregnant; ▪ Availability from local and international manufacturers, including procurement and supply chain logistics; ▪ Price and cost-effectiveness; Specific ARV requirements for HIV-2 infections that are naturally resistant to NNRTIs.		
TB/HBV-HIV Co-infection For patients with active TB diagnosed with HIV infection and eligible for ART: The first priority is to initiate standard anti-TB treatment (in accordance with national TB policy and guidelines). The optimal time to initiate ART is not known. For patients with CD4 cell counts above 200, the commencement of ART may be delayed until after the initial intensive phase of TB treatment has been	**TB/HBV-HIV Co-infection** 5. Start ART in all HIV-infected individuals with active tuberculosis 6. (TB) irrespective of CD4 cell count. 7. Start TB treatment first, followed by ART as soon as possible after starting TB treatment. 8. Use EFV as the preferred non-nucleoside reverse NNRTI in patients starting ART while on	Please describe current national policy to assist in identifying likely changes in implementation:

completed. The reason for this is to simplify the management of TB treatment and to deal with the challenges mentioned above [A-III]. In patients with CD4 counts above 350, ART can be delayed until after the completion of short-course TB therapy, following a reassessment of the patients' eligibility for ART (CD4 count (if available) and WHO clinical staging) and evaluation of the response to TB therapy and of CD4 cell counts, if available. In situations where both HIV and HBV require treatment, the ART regimens must contain 3TC and/or TDF. It is preferable to use 3TC and TDF together as both drugs have anti-HIV and anti-HBV activity and the use of TDF or 3TC as the only anti-HBV drug can result in more rapid development of resistance.	TB treatment. 9. Start ART in all HIV/HBV co-infected individuals who require treatment for their HBV infection, irrespective of CD4 cell count or WHO clinical stage.	

ADULTS Section C2. Key Considerations of Implementing WHO Recommendation 3: Initiation of first-line ART regimens for treatment eligible adults and adolescents

Implementation of new recommendations may require:
• Phasing out d4T
• Consideration of cost implications of different ARV regimens; AZT and TDF are more costly than many existing regimens in widespread use
• Substantive changes in national drug procurements, stocks and management to ensure sufficient availability and a phased transition period while existing buffer stocks in use
• Increased health system capacity to initiate and maintain delivery of new regimens including human resources, additional training, etc.
• Increased capacity to monitor safety and effectiveness — limited data on TDF use
• Changes to national monitoring systems; e.g., national indicators, databases, registers etc.
• Closer monitoring of patient with anemia
• Possible revision of national ARV guidelines and policies
• Increased laboratory capacity to monitor treatment for toxicity
• ***For TB and HBV co-infections:***
  • Careful management of these co-infections because of drug interactions and overlapping toxicity-
  • Increased vigilance of patients in this group because of increased risk of IRIS
  • Substantive changes in national drug procurements, stocks and management to ensure sufficient availability — phased transition period while existing buffer stocks in use

• Decentralization of ART in MCH and strengthened linkages between ANC and MCH • Increased health system capacity to initiate and maintain delivery of new regimens including human resources, additional training, etc. • Increased capacity to monitor safety and effectiveness — limited data on TDF use. • Changes to national monitoring systems (e.g., national indicators, databases, registers, etc.) • Need to increase laboratory capacity to appropriately screen HIV-positive patients for HBV infection • Need to increase capacity in the management of HIV/HBV co-infection – Trainings, laboratory monitoring, etc.
Implementation issues to consider:

ADULTS Section C3. Estimating Resource Implications Related to Implementing WHO Recommendation 3: Initiation of first-line ART regimens for treatment-eligible adults and adolescents				
Program Area	**Approximate Resources Required To Implement Policy**	**Approximate Resources Available**	**Are Existing Resources Sufficient To Implement Policy?**	**Additional Resources That Could Be Mobilized**
Policy/Laws/Regulations				
Human Resources				
Protocols and Tools				
Infrastructure				
Commodities				
Laboratory Services				
Monitoring				
MCH/RH/HIV Linkages				
Local Leadership/Advocacy				
Community				

ADULTS SECTION D: WHO RECOMMENDATIONS 6 AND 7: SWITCHING TO SECOND-LINE ART REGIMENS FOR TREATMENT-ELIGIBLE ADULTS AND ADOLESCENTS		
ADULTS Section D1. Describe Revised National Policy in the Context of the Revised WHO Guidelines Policy		
WHO 2006	**WHO 2010**	**Current National Policy**
The time of switching from first line to second line ART is dictated by treatment failure, which can be measured in three ways: clinically, by disease progression and WHO staging; immunologically, using trends in CD4 counts over time, and virologically, by measuring HIV viral loads (plasma HIV-1 RNA levels). ddI + ABC ***or*** TDF + ABC ***or*** TDF + 3TC (± AZT) ***or*** ddI + 3TC (± AZT) any option plus PI (ATV/r, FPV/r, IDV/r, LPV/r and SQV/r)	High value placed on using simpler second-line regimens and the availability of heat-stable, fixed-dose combinations. ATV/r and LPV/r are the preferred boosted PI's for second-line ART. If d4T or AZT has been used in first-line, use TDF + 3TC or FTC as the NRTI backbone in second-line. If TDF has been used in first-line, use AZT + 3TC as the NRTI backbone in second line.	Please describe current national policy to assist in identifying likely changes in implementation:

ADULTS Section D2. Key Considerations of Implementing WHO Recommendation 4: Switching to second-line ART regimens for treatment eligible adults and adolescents

Implementation of new recommendations may require:

VIRAL LOAD ISSUES:

- Access is limited in many countries – need to build new infrastructure
- Viral load monitoring requires substantial investments: resource mobilization including HR and funds
- Capacity building for laboratory to be able to handle- trainings, job aides, mentorship, supervision

DRUG ISSUES:

- Capacity to diagnose treatment failure and understanding when to switch- training, coaching and mentoring
- Decentralization of case management, but with clear national coordination of systems to avoid undue delay to switch or premature switches.
- Increased capacity to monitor safety and effectiveness — as the number of patients moving to second-line and eventually third line increases.
- Changes to national monitoring systems; e.g., national indicators, databases, register etc.
- Increase health system capacity to implement – HR, training, tools
- Cost of new molecules for third line- resource mobilization in a proactive manner.

Implementation issues to consider:

ADULTS Section D3. Estimating Resource Implications Related to Implementing WHO Recommendation 4: Switching to second-line ART regimens for treatment eligible adults and adolescents				
Program Area	**Approximate Resources Required To Implement Policy**	**Approximate Resources Available**	**Are Existing Resources Sufficient To Implement Policy?**	**Additional Resources That Could Be Mobilized**
Policy/Laws/Regulations				
Human Resources				
Protocols and Tools				
Infrastructure				
Commodities				
Laboratory Services				
Monitoring				
MCH/RH/HIV Linkages				
Local Leadership/Advocacy				
Community				

1.6 INVENTORY OF CLINICAL TOOLS, JOB AIDS, AND IEC MATERIALS TO BE UPDATED

Purpose

The purpose of this tool is to help implementation planners think through key points to consider when revising and/or developing clinical tools, job aids, and IEC (information, education and communication) materials in accordance with the revised WHO guidelines, to identify the materials that need to be updated or created for each technical area, and to provide a suggested process for revision/development of materials.

Potential uses for this tool

Clinical tools and job aids will need to be developed on a country-by-country basis when national policies/guidelines are revised in each country. This tool can be used to think through the materials and processes associated with the revision and development of these materials.

Instructions

1. Review the key points to consider when planning for updating/developing materials
2. Make a list of the specific types of materials to be updated/developed for each technical area
3. Review the suggested steps by which materials can be updated/developed and create a context appropriate plan.

1.6 CHECKLIST FOR UPDATING/DEVELOPING TOOLS, JOB AIDS, & IEC MATERIALS

Part A.: Key points to consider when planning for updating/developing materials

- Key changes and content inherent in the revised guidelines for each technical area to be integrated into existing material or serve as the basis for development of new materials
- What is the timeline for revising/updating the clinical tools, job aids and IEC materials and rolling them out?
- What are the necessary in-country process for development of materials and approval processes associated with finalizing materials?
- Who will be responsible for revising/updating the clinical tools, job aids, and IEC materials?
- What is the timeline for revising/updating and rolling out trainings based on the new national policy?

PART B: Types of materials to be updated/ developed

Table 1.6.1 - PMTCT

Category of materials	Specific clinical tools, job aids and IEC materials to revise in this context
Clinical tools and job aids	
Clinical guidelines	
Dosing charts/cards	
Clinical staging/classification tools	
Laboratory assessment tools (for monitoring CD4, etc.)	
Counseling cards/flipcharts/checklists	
Wall charts, posters, etc.	
Algorithms and other decision-making tools	

Other:	
Community and IEC materials	
IEC materials for health facilities (posters, etc.)	
Take-home materials (pamphlets, etc.)	
Community IEC materials	
Tools for community/lay health workers	
Other:	

Table 1.6.2 – Infant and Young Child Feeding

Category of materials	Specific clinical tools, job aids and IEC materials to revise in this context
Clinical tools and job aids	
Clinical guidelines	
Dosing charts/cards	
Clinical staging/classification tools	
Laboratory assessment tools (for monitoring CD4, etc.)	
Counseling cards/flipcharts/checklists	
Wall charts, posters, etc.	
Algorithms and other decision-making tools	
Other:	

Community and IEC materials	
IEC materials for health facilities (posters, etc.)	
Take-home materials (pamphlets, etc.)	
Community IEC materials	
Tools for community/lay health workers	
Other:	

Table 1.6.3 – Pediatric HIV Care and Treatment

Category of materials	Specific clinical tools, job aids and IEC materials to revise in this context
Clinical tools and job aids	
Clinical guidelines	
Dosing charts/cards	
Clinical staging/classification tools	
Laboratory assessment tools (for monitoring CD4, etc.)	
Counseling cards/flipcharts/checklists	
Wall charts, posters, etc.	
Algorithms and other decision-making tools	
Other:	

Community and IEC materials	
IEC materials for health facilities (posters, etc.)	
Take-home materials (pamphlets, etc.)	
Community IEC materials	
Tools for community/lay health workers	
Other:	

Table 1.6.4 – Adult HIV Care and Treatment

Category of materials	Specific clinical tools, job aids and IEC materials to revise in this context
Clinical tools and job aids	
Clinical guidelines	
Dosing charts/cards	
Clinical staging/classification tools	
Laboratory assessment tools (for monitoring CD4, etc.)	
Counseling cards/flipcharts/checklists	
Wall charts, posters, etc.	
Algorithms and other decision-making tools	
Other:	

Community and IEC materials	
IEC materials for health facilities (posters, etc.)	
Take-home materials (pamphlets, etc.)	
Community IEC materials	
Tools for community/lay health workers	
Other:	

PART C: Suggested steps by which materials could be updated/developed

- Identify and gather exiting materials
- Assess existing materials to determine:
    - What parts will need to be revised/updated?
    - Do any new materials need to be developed? If so, what materials are needed?
- Engage with MOH, partners, and other relevant stakeholders to develop a work plan, timeline, and budget for the revision and/or development of materials
    - Hire consultant(s) if necessary (if so, develop scope of work)
- Revise and/or develop materials
- Pre-test materials
- Revise materials based on results of pre-testing
- Print and disseminate