3.1 SUPPORTING IMPLEMENTATION PLANNING

PART A: CHECKLIST FOR PLANNING

The following is a checklist to support the planning processes that could be used by technical working groups supporting the Ministry of Health. 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. Not all of the implementation areas will require significant changes, depending on the extent of the national HIV/MCH programs. This is not an exhaustive list, but many of the questions remain relevant to whichever guidelines are adopted and/or changed.

The tool should generate specific activities that can then be used to develop a national implementation plan, a template of which is outlined below (see Part B). These activities can then be given specific timeframes and budget lines with clear designated roles and responsibilities.

Note: As will be seen, broad consultation will be required with different departments within Ministries — e.g., logistics, M&E; provincial, district, and site level; communities; partners; donors — to develop such a comprehensive plan. This does not mean that certain activities should not be prioritized and implemented immediately, hence the need to link this with an overall implementation plan that should at least give the broader activities that may 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 ,HR, 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? ▪ Pre-position commodities to support rollout (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 are required for national scale-up? ▪ Cadre of healthcare worker(s) 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 you introduce POC machines? If so how, who, etc.?

	▪ What revisions to training needs 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 — e.g., 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 (see monitoring position paper) 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	▪ Approach for implementation — will this be phased or immediate? ▪ Which sites will be considered to introduce regimens first (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 rollout? ▪ 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, build 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 — promotion of couple 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; e.g., Baylor, CHAI, JSI, UCSF, ICAP, etc. ▪ Logistics: JSI, CHAI, etc. ▪ Implementation partners: INGOs — e.g., EGPAF, ICAP, PATH, MSF, CHAI, etc. — and national NGOs ▪ Community: E.g., local NGOs and CBOs for tracking ▪ What needs to be done to strengthen partnerships?

PART B: GENERIC TEMPLATE FOR NATIONAL ROLL-OUT PLAN

Insert MOH Logo

Plan for Roll-out of the 2009 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 *2009 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. The subject headings are suggested only. The categories in each row match with Job Aide 4 and Part A of this Job Aide.

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					

3.2 PLANNING TOOL FOR PREVENTION OF MOTHER-TO-CHILD TRANSMISSION

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 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 PMTCT Table

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. Compare Revised WHO Recommendations to Existing National Policy

WHO 2006	WHO 2009	Current National Policy	Differences between WHO 2009 and 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:	Yes No

PMTCT Section A2. Key Considerations of Adopting WHO Recommendation 1: Wider access to CD4 count

Adoption 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

Issues for the national program to consider:

PMTCT Section A3. Estimating Resource Implications of Adopting WHO Recommendation 1 : Wider access to CD4 count				
Program Area	**Approximate Resources Required to Adopt Policy**	**Approximate Resources Available**	**Are Existing Resources Sufficient to Adopt 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. Compare Revised WHO Recommendations to Existing National Policy

WHO 2006	WHO 2009	Current National Policy	Differences between WHO 2009 and 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	Yes No

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

Adoption 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
- Possible revision of national ARV guidelines and policies

PMTCT Section B3. Estimating Resource Implications of Adopting WHO Recommendation 2: Raising treatment threshold for ART in pregnant women with HIV to 350 cells/mm^3

Program Area	Approximate Resources Required to Adopt Policy	Approximate Resources Available	Are Existing Resources Sufficient to Adopt 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 STAGING 3&4) AND INFANT PROPHYLAXIS

PMTCT Section C1. Compare Revised WHO Recommendations to Existing National Policy

WHO 2006	WHO 2009	Current National Policy	Differences between WHO 2009 and 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:	Yes No
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:	Yes No

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

Adoption of new recommendations may require:

MATERNAL ISSUES:

- Adaptations to national ARV and PMTCT guidelines including revisions to overall guidelines for adult 1st and 2nd line drugs
- 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

▪ Adaptations to national pediatric first-line ART protocols and Infant feeding guidelines ▪ Consideration of the availability and cost implications of drugs needed 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.
Issues for the national program to consider:

PMTCT Section C3. Estimating Resource Implications of Adopting WHO Recommendations 3&4: Triple ART regimen for treatment in eligible pregnant women (CD4<350 or clinical staging 3&4) and infant prophylaxis				
Program Area	**Approximate Resources Required to Adopt Policy**	**Approximate Resources Available**	**Are Existing Resources Sufficient to Adopt 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 STAGE 1 AND 2) OR PREGNANT WOMEN WITH HIV WHOSE ELIGIBILITY IS UNKNOWN, AND INFANT PROPHYLAXIS

PMTCT Section D1. Compare Revised WHO Recommendations to Existing National Policy

WHO 2006	WHO 2009	Current National Policy	Differences between WHO 2009 and 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 isunknown	**Maternal Prophylaxis** Antenatal AZT (from 14 weeks gestation) sd-NVP at onset of labor AZT+3TC during labor and Delivery AZT+3TC for seven dayspostpartum	Please describe current national policy to assist in identifying likely changes:	Yes No
HIV-Exposed Infant Prophylaxis sd-NVP 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	Please describe current national policy to assist in identifying likely changes:	Yes No

	infants, daily AZT or NVP for four to six weeks		

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

Adoption of new recommendations may require:

MATERNAL ISSUES

- Revisions to national adult ART and PMTCT guidelines
- Transitioning of sites using sd-NVP 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

Issues for the national program to consider:

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

Program Area	Approximate Resources Required to Adopt Policy	Approximate Resources Available	Are Existing Resources Sufficient to Adopt 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. Compare Revised WHO Recommendations to Existing National Policy

WHO 2006	WHO 2009	Current National Policy	Differences between WHO 2009 and 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	Yes No
	Breastfeeding Infant: ▪ NVP for 6 weeks Non-breastfeeding: ▪ AZT or NVP for 4 to 6 weeks	Please describe current national policy to assist in identifying likely changes	Yes No

PMTCT Section E2. Key Considerations for Adopting 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

Adoption 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 Adopting 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 Adopt Policy	Approximate Resources Available	Are Existing Resources Sufficient to Adopt 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 Table 2: Finalizing Policy Decisions on Antiretroviral Drugs for the Treatment of Pregnant Women Living with HIV and Prevention of HIV Infection in Infants

Policy Area	Final National Policy 2010	New National Policy or Unchanged?
A. Access to CD4 count		
B. Treatment threshold for pregnant women living with HIV		
C. Triple ART regimen for treatment in eligible pregnant women		
D. ARV regimen for treatment ineligible pregnant women, or for whom eligibility is unknown		

3.3 PLANNING TOOL FOR INFANT AND YOUNG CHILD FEEDING IN THE CONTEXT OF HIV

RECOMMENDED APPOACH 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 IYCF 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

    c. Finally, summarize decisions on revised national policies in IYCF Table 2

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. Compare Revised WHO Recommendations to Existing National Policy			
WHO 2006	**WHO 2009**	**Current National Policy**	**Differences between WHO 2009 and 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 improveHIV-free survival of HIV-exposed infants and the health of HIV-infected mothers,and informed that there are alternatives that mothers might wish to adopt.	Please describe current national policy to assist in identifying likely changes	Yes No

IYCF Section A2. Key Considerations of Adopting WHO Recommendation 1

Comments/Interpretation:

- The 2009 recommendations 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

Issues for our national program to consider:

IYCF Section A3. Estimating Resource Implications Related to Decision on the Most Appropriate Infant Feeding Strategy for Health Services in Context				
Program Area	**Approximate Resources Required to Adopt Policy**	**Approximate Resources Available**	**Are Existing Resources Sufficient to Adopt 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. Compare Revised WHO Recommendations to Existing National Policy

WHO 2006	WHO 2009	Current National Policy	Differences between WHO 2009 and 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	Yes No

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

Comments/Interpretation:

- The 2006 and 2009 recommendations both recommend exclusive breastfeeding from birth to six months, but the 2009 recommendations extend the duration of breastfeeding to 12 months.
- Both sets of recommendations indicate that breastfeeding should only stop when a safe and nutritionally adequate diet can be provided without breast milk.

Adoption of new recommendations 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 adopt these recommendations, some considerations are at specific levels:
- Policy level: need to adopt 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.

Issues for our national program to consider:

IYCF Section C3. Estimating Resource Implications of Adopting Exclusive Breastfeeding as the Infant Feeding Strategy				
Program Area	**Approximate Resources Required to Adopt Policy**	**Approximate Resources Available**	**Are Existing Resources Sufficient to Adopt 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. Compare revised WHO recommendations to existing National Policy			
WHO 2006	**WHO 2009**	**Current National Policy**	**Differences between WHO 2009 and 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	Yes No

IYCF Section D2. Key Considerations of Adopting WHO Recommendation 3

Comments/Interpretation:

- The 2006 recommendations 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 2009 recommendations explicitly state that the weaning process should be gradual and should take approximately one month.

Adoption 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 adoption 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

Issues for our national program to consider:

IYCF Section D3. Estimating Resource Implications of Adopting WHO Recommendation 3				
Program Area	**Approximate Resources Required To Adopt Policy**	**Approximate Resources Available**	**Are Existing Resources Sufficient To Adopt 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. Compare Revised WHO Recommendations to Existing National Policy			
WHO 2006	**WHO 2009**	**Current National Policy**	**Differences between WHO 2009 and 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	Yes No

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 adopting 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).

Adoption 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.

Issues for our national program to consider:

IYCF Section E3. Estimating Resource Implications of Adopting WHO Recommendation 4				
Program Area	**Approximate Resources Required to Adopt Policy**	**Approximate Resources Available**	**Are Existing Resources Sufficient to Adopt 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. Compare Revised WHO Recommendations to Existing National Policy			
WHO 2006	**WHO 2009**	**Current National Policy**	**Differences between WHO 2009 and 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	Yes No

IYCF Section F2. Key Considerations for Adopting WHO Recommendation 5
Comments/Interpretation: ▪ In the 2009 recommendations, 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).
Adoption 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)
Issues for our national program to consider:

IYCF Section F3. Estimating Resource Implications of Adopting WHO Recommendation 5				
Program Area	**Approximate Resources Required To Adopt Policy**	**Approximate Resources Available**	**Are Existing Resources Sufficient To Adopt 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. Compare Revised WHO Recommendations to Existing National Policy			
WHO 2006	**WHO 2009**	**Current National Policy**	**Differences between WHO 2009 and 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	Yes No

IYCF Section G2. Key Considerations for Adopting 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.

Adoption 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.

Issues for our national program to consider:

IYCF Section G3. Estimating Resource Implications of Adopting WHO Recommendation 6				
Program Area	**Approximate Resources Required to Adopt Policy**	**Approximate Resources Available**	**Are Existing Resources Sufficient to Adopt 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. Compare Revised WHO Recommendations to Existing National Policy

WHO 2006	WHO 2009	Current National Policy	Differences between WHO 2009 and 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	Yes No

IYCF Section C2. Key Considerations for Adopting WHO Recommendation 7
Comments/Interpretation: ▪ The 2009 recommendations place additional emphasis on the recommended duration of breastfeeding for HIV-positive infants and young children.
Adoption of new recommendations may require: ▪ Determining how to communicate the advantages of breastfeeding once a child is identified as having HIV.
Issues for our national program to consider:

IYCF Section C3. Estimating Resource Implications of adopting WHO Recommendation 7				
Program Area	**Approximate Resources Required To Adopt Policy**	**Approximate Resources Available**	**Are Existing Resources Sufficient To Adopt 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 Table 2: Finalizing Policy Decisions on Infant and Young Child Feeding in the Context of HIV

Policy area	Final National Policy 2010	New National Policy or Unchanged?
A. Decision on the most appropriate infant feeding strategy for health services		
B. Provision of life-long ART for eligible pregnant women living with HIV or ARV prophylaxis to reduce HIV transmission through breastfeeding		
C. Policies in relation to exclusive breastfeeding		
D. Policies in relation to cessation of breastfeeding and ARV prophylaxis as appropriate		
E. Policies on provision of safe and adequate replacement feeds to enable normal growth and development for when mothers living with HIV decide to stop breastfeeding		
F. Policies related to provision of infant formula milk as a replacement feed to their HIV un-infected infants or infants who are of unknown HIV status, when specific conditions are met:		
G. Policies related to expression and heat-treating of breast milk as an interim feeding strategy		
H. Policy related to the recommended duration of exclusive breast feeding for children known to be HIV-infected.		

3.4 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 recommendations 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 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 PEDS Table 2

ANTIRETROVIRAL THERAPY FOR HIV INFECTION IN INFANTS AND CHILDREN

Adults Table 1: Key Changes in the Revised WHO Recommendations

- 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. Compare Revised WHO Recommendations to Existing National Policy

WHO 2006	WHO 2009	Current National Policy	Differences between WHO 2009 and 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 mo fulfilling criteria for presumptive severe HIV All children of all ages with WHO stage 3 or 4 Children 24 to 59mo if CD4 <750 or % <25 Children ≥5 years if CD4 < 350	Please describe current national policy to assist in identifying likely changes	Yes No

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

Adoption 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 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

Issues for our national program to consider:

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

Program Area	Approximate Resources Required to Adopt Policy	Approximate Resources Available	Are Existing Resources Sufficient To Adopt 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. Compare Revised WHO Recommendations to Existing National Policy			
WHO 2006	**WHO 2009**	**Current National Policy**	**Differences between WHO 2009 and 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 current national policy to assist in identifying likely changes	Yes No

PEDS Section B2. Key Considerations of Adopting revised ARV Regimens for HIV-infected Infants and Children
Adoption 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
Issues for our national program to consider:

PEDS Section B3. Estimating Resource Implications Related to Adopting Revised ARV Regimens for HIV-Infected Infants and Children

Program Area	Approximate Resources Required To Adopt Policy	Approximate Resources Available	Are Existing Resources Sufficient to Adopt 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. Compare Revised WHO Recommendations to Existing National Policy			
WHO 2006	**WHO 2009**	**Current National Policy**	**Differences between WHO 2009 and 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 current national policy to assist in identifying likely changes	Yes No

PEDS Section C2. Key Considerations of Adopting Specific Regimens for Certain Conditions
Adoption of new recommendations may require:
Issues for our national program to consider:

PEDS Section C3. Estimating Resource Implications Related to Adopting Specific Regimens for Certain Conditions				
Program Area	Approximate Resources Required To Adopt Policy	Approximate Resources Available	Are Existing Resources Sufficient To Adopt 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. Compare Revised WHO Recommendations to Existing National Policy			
WHO 2006	**WHO 2009**	**Current National Policy**	**Differences between WHO 2009 and 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 below 200 or <10% ▪ Virological failure ▪ Clinical failure and or Immunologic Failure<u>and</u> VL > 5000 copies/mL	Please describe current national policy to assist in identifying likely changes	Yes No
Second-line ARV regimens			
2NRTI+1NNRTI in 1st line go to ddi +ABC + boosted PI ABC containing in 1st go to ddi +AZT +	NNRTI in first line - Boosted PI LPV/ r- in first line triple NNRTI		

boosted PI Triple NRTI in 1st line go to ddi + EFV or NVP + boosted PI	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 Adopting Switching to Switching Regimens and Initiation of Second-line Regimens in Infants and Children

Adoption 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, register etc. ▪ Increase health system capacity to implement – HR, training, tools   ▪ Cost of new molecules for third line- resource mobilization in a proactive manner.
Issues for our national program to consider:

PEDS Section D3. Estimating Resource Implications Related to Adopting Switching to Initiation of Second-line Regimens in Infants and Children				
Program Area	**Approximate Resources Required To Adopt Policy**	**Approximate Resources Available**	**Are Existing Resources Sufficient To Adopt 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 Table 2: Finalizing Policy Decisions on Antiretroviral Therapy for Infants and Children Living with HIV

Policy area	Final National Policy 2010	New National Policy or Unchanged?
A. ART initiation in HIV-infected infants and children		
B. ARV regimens for HIV-infected infants and children		
C. Specific regimens for certain conditions		
D. Switching regimens and initiation of second-line regimens in infants and children		

3.5 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 recommendations 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 RECOMMENDATIONS

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. Compare Revised WHO Recommendations to Existing National Policy

WHO 2006	WHO 2009	Current National Policy	Differences between WHO 2009 and 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	Yes No

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

Adoption 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

Issues for our national program to consider:

ADULTS Section A3. Estimating Resource Implications Related to Adopting WHO Recommendation 1 : Wider access to CD4 count				
Program Area	**Approximate Resources Required To Adopt Policy**	**Approximate Resources Available**	**Are Existing Resources Sufficient To Adopt 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. Compare Revised WHO Recommendations to Existing National Policy			
WHO 2006	**WHO 2009**	**Current National Policy**	**Differences between WHO 2009 and 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 cells/mm3	Initiate ART in all patients with HIV who have CD4 count <350 cells/mm3 and/or WHO clinical stage 3 or 4	Please describe current national policy to assist in identifying likely changes	Yes No

ADULTS Section B2. Key Considerations of Adopting WHO Recommendation 2: Treatment threshold for ART in adults and adolescents
Adoption 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
Issues for our national program to consider:

ADULTS Section B3. Estimating Resource Implications Related to Adopting WHO Recommendation 2: Treatment threshold for ART in adults and adolescents

Program Area	Approximate Resources Required To Adopt Policy	Approximate Resources Available	Are Existing Resources Sufficient To Adopt 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. Compare Revised WHO Recommendations to Existing National Policy			
WHO 2006	**WHO 2009**	**Current National Policy**	**Differences between WHO 2009 and 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;	**ART for adolescents and adults:** Start one of the following regimens in ART-naïve individualseligible 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	Please describe current national policy to assist in identifying likely changes	Yes No

▪ Potential for maintenance of future treatment options (sequencing of ARVs); ▪ 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.	benefits of using fixed-dose combinations.		
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	**TB/HBV-HIV Co-infection** 1. Start ART in all HIV-infected individuals with active tuberculosis 2. (TB) irrespective of CD4 cell	Please describe current national policy to assist in identifying likely changes	Yes No

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 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.	count. 3. Start TB treatment first, followed by ART as soon as possibleafter starting TB treatment. 4. Use EFV as the preferred non-nucleoside reverseNNRTI in patients starting ART while on TB treatment. 5. 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 Adopting WHO Recommendation 3: Initiation of first-line ART regimens for treatment eligible adults and adolescents

Adoption 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, register 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.

Issues for our national program to consider:

ADULTS Section C3. Estimating Resource Implications Related to Adopting WHO Recommendation 3: Initiation of first-Line ART regimens for treatment eligible adults and adolescents

Program Area	Approximate Resources Required To Adopt Policy	Approximate Resources Available	Are Existing Resources Sufficient To Adopt 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. Compare Revised WHO Recommendations to Existing National Policy

WHO 2006	WHO 2009	Current National Policy	Differences between WHO 2009 and Current National Policy?
The time ofswitching from first line to second line ART is dictated by treatment failure, which can be measured in three ways: clinically, bydisease 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 availabilityof heat-stable, fixed-dose combinations. ATV/r and LPV/r are the preferred boosted PI's for second-lineART. If d4T or AZT has been used in first-line, use TDF + 3TCor FTC as the NRTI backbone in second-line. If TDF has been used in first-line, use AZT + 3TC as the NRTI backbonein second-line.	Please describe current national policy to assist in identifying likely changes	Yes No

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

Adoption 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.

Issues for our national program to consider:

ADULTS Section D3. Estimating Resource Implications Related to Adopting WHO Recommendation 4: Switching to second-line ART regimens for treatment eligible adults and adolescents

Program Area	Approximate Resources Required To Adopt Policy	Approximate Resources Available	Are Existing Resources Sufficient To Adopt 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 TABLE 2: FINALIZING POLICY DECISIONS ON ANTIRETROVIRAL DRUGS FOR ADULTS AND ADOLESCENTS LIVING WITH HIV

Policy area	Final National Policy 2010	New National Policy or Unchanged?
A. WHO Recommendation 1: Wider Access to CD4 Count		
B. WHO Recommendation 2: Treatment Threshold for ART in Adults and Adolescents		
C. WHO Recommendations 3, 4 and 5: Initiation of First-line ART Regimens for Treatment Eligible Adults and Adolescents		
D. WHO Recommendations 6 and 7: Second-line ART Regimens for Treatment Eligible Adults and Adolescents		

APPENDIX 3A: VISUAL AIDS

I.INFANT AND YOUNG CHILD FEEDING IN THE CONTEXT OF HIV

RECOMMENDED FEEDING PRACTICES

The following table summarizes the recommended feeding practices for infants born to mothers living with HIV. These recommendations apply only to infants who are HIV-negative or whose HIV status is unknown.

HIV-positive infants and young children should be exclusively breastfed from birth to six months, and should continue breastfeeding, together with appropriate complementary feeding, as per the recommendations for the general population (i.e. up to 24 months or beyond)

Time period	Recommended feeding practice during this time period:	Acceptable alternatives to breast milk during this time period:
Birth to 6 months	Exclusive breastfeeding	Commercial powdered infant formula (only if conditions listed below are met), or Heat-treated expressed breast milk
6 to 12 months	Continued breastfeeding, together with complementary foods	Commercial powdered infant formula (only if conditions listed below are met), or Heat-treated expressed breast milk, or Modified animal milk
After 12 months	Continued breastfeeding, together with complementary foods, until a safe and nutritionally adequate diet can be provided without breast milk	

CONDITIONS THAT MUST BE MET IN ORDER TO SAFELY REPLACEMENT FEED

- HIV-negative infants and infants whose HIV status is unknown should only receive replacement feeding if all of the following conditions are met:
  - Safe water and sanitation are assured at the household and community level
  - The mother or other caregiver can reliably provide sufficient formula milk to support normal growth and development of the infant
  - The mother or caregiver can prepare the formula milk cleanly and frequently enough so that it is safe and carries a low risk of diarrhoea and malnutrition

- The mother or caregiver can, in the first six months, feed the infant formula milk only and completely refrain from all breastfeeding
- The family is supportive of this practice
- The mother and/or caregiver can access health-care that offers comprehensive child health services

SAFE CESSATION OF BREASTFEEDING

Rapid or abrupt weaning is ***not advised***. When mothers living with HIV decide to stop breastfeeding:

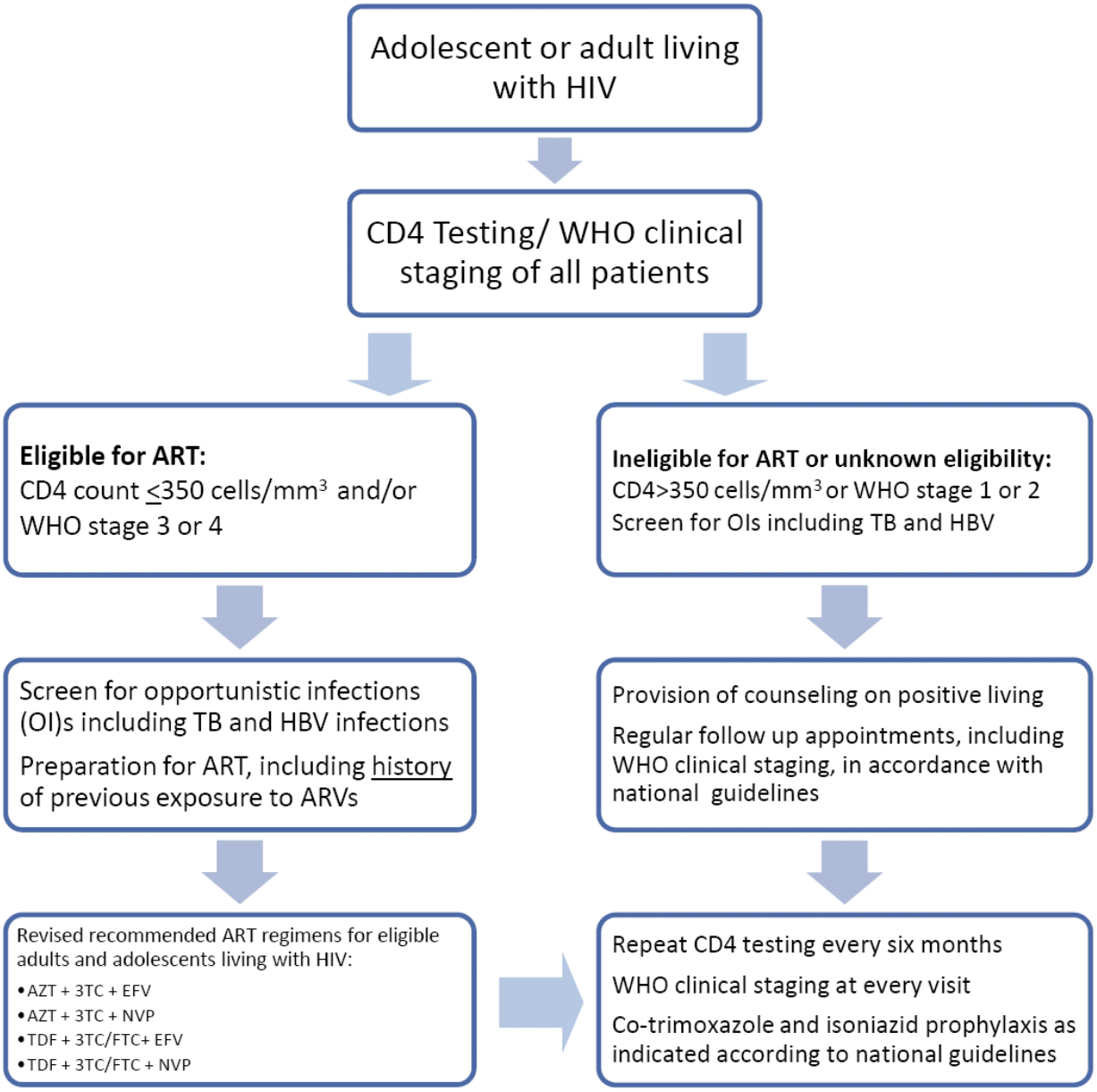
- Cessation of breastfeeding should be done gradually, over the period of about one month
- Infants should be provided with safe and adequate replacement feeds to enable normal growth and development

HEAT-TREATING BREAST MILK

- Heat-treating breast milk effectively kills HIV while preserving the milk's nutritional and immunological benefits. Mothers living with HIV may consider expressing and heat-treating their breast milk as an interim feeding strategy in the following situations:
  - If the infant is low birth weight or otherwise ill during the neonatal period and is unable to breastfeed;
  - If the mother is unwell and temporarily unable to breastfeed (e.g., if she is experiencing breast health problems);
  - During the transition period of stopping breastfeeding; or
  - If ARVs are temporarily unavailable.

II. ANTIRETROVIRAL THERAPY FOR ADULTS AND ADOLESCENTS LIVING WITH HIV

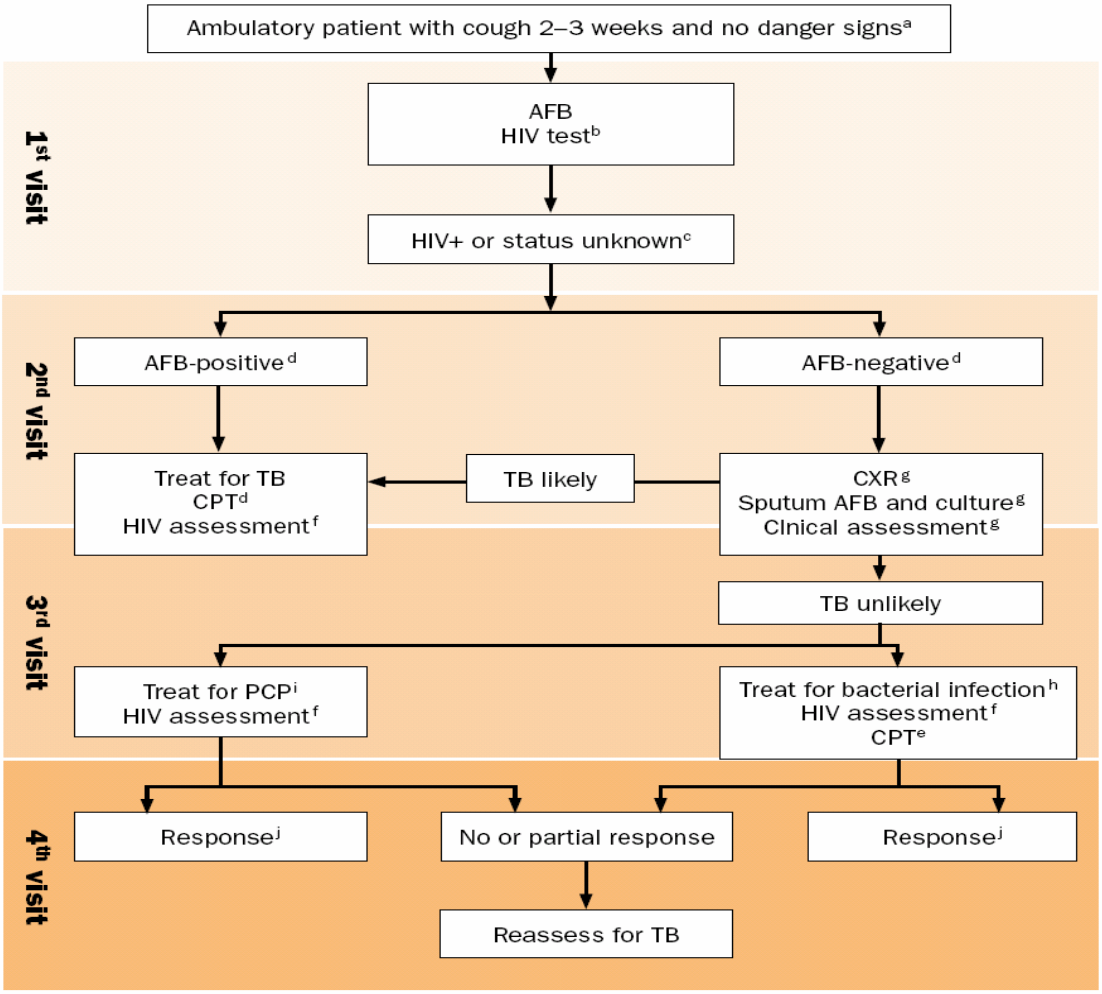
ALGORITHM FOR ENROLLMENT OF ADULTS AND ADOLESCENTS ON ART



III. EARLY DIAGNOSIS OF TB

FIGURE 1

Algorithm for the diagnosis of tuberculosis in ambulatory HIV-positive patient



[a] The danger signs include any one of: respiratory rate > 30/minute, fever > 39 °C, pulse rate > 120/min and unable to walk unaided.
[b] For countries with adult HIV prevalence rate ≥ 1% or prevalence rate of HIV among tuberculosis patients ≥ 5%.
[c] In the absence of HIV testing, classifying HIV status unknown ias HIV-positive depends on clinical assessment or national and/or local policy.
[d] AFB-positive is defined at least one positive and AFB-negative as two or more negative smears.
[e] CPT = Co-trimoxazole preventive therapy.
[f] HIV assessment includes HIV clinical staging, determination of CD_4 count if available and referral for HIV care.
[g] The investigations within the box should be done at the same time wherever possible in order to decrease the number of visits and speed up the diagnosis.
[h] Antibiotics (except fluoroquinolones) to cover both typical and atypical bacteria should be considered.
[i] PCP: *Pneumocystis carinii* pneumonia, also known as *Pneumocystis jirovecii* pneumonia.
[j] Advise to return for reassessment if symptoms recur.

Source: Improving the diagnosis and treatment of smear-negative pulmonary and extra pulmonary tuberculosis among adults and adolescents (WHO 2006)

IV. SUMMARY OF REVISED WHO GUIDELINES FOR ANTIRETROVIRAL THERAPY FORINFANTS AND CHILDREN LIVING WITH HIV

Immunological marker	**Clinical stage**		**Age-specific recommendation to initiate ART**		
	< 18 mo with presumptive severe HIV	***Children with WHO clinical stage 3 or 4***	***≤ 24 mo***	***24 -59 mo***	***≥5 years***
% CD4	All	All	All	<25%	
CD4 count	All	All		<750 cells/mm^3	<350 cells/mm^3

[1]WHO is developing additional guidance on what feeding practices to recommend if ARVs are not immediately available or if roll-out is delayed.

APPENDIX 3B. SAMPLE TERMS OF REFERENCE (TOR) FOR A NATIONAL TECHNICAL WORKING GROUP TO GUIDE REVISION AND ROLL-OUT OF NATIONAL PMTCT GUIDELINES

INTRODUCTION

The WHO revised its global guidance on HIV prevention, treatment and care with new recommendations released on November 30th, 2009 and revised set of guidelines were launched May 2010. The revised guidelines include four sets of linked guidelines: ARV drugs for treating pregnant women and preventing HIV in infants, infant and young child feeding in the context of HIV, pediatric HIV treatment, and adults and adolescent HIV treatment.

Please refer to the Summary of WHO Recommendations for an overview of key changes inherent in the revised recommendations. Full versions of the revised WHO guidelines on these topics are expected to be released in March 2010.

At the request of the MOH, a Technical Working Group (TWG) has convened to provide recommendations to the MOH regarding adoption of the revised WHO guidelines where this is appropriate, and to provide technical assistance in support of roll-out of guideline revisions in country programs.

OVERALL OBJECTIVES OF THE TECHNICAL WORKING GROUP

The TWG supports the MOH to:

- Objective 1: Recommend revisions to the current national guidelines on PMTCT/IYCF/PEDS/ADULT to reflect updated WHO recommendations.
- Objective 2: Provide technical assistance in the development of a national roll-out plan to support dissemination and implementation of the revised national PMTCT/IYCF/PEDS/ADULT guidelines.
- Objective 3: Monitor implementation of the revised national guideline roll-out plan.

PURPOSE

The purpose of this TWG is to bring together stakeholders to provide technical assistance in the revision and roll-out of revised national PMTCT/IYCF/PEDS/ADULT guidelines. The TWG has been led by the National HIV Coordinator (or other senior level MOH person) and will convene members from the following national government groups and implementing partners in support of revised national [PMTCT/IYCF/PEDS/ADULT]guidelines:

- PMTCT
- HIV/AIDS care and treatment (adult and pediatric)
- Reproductive health
- Maternal and child health
- Nutrition
- Logistics and supply chain management
- Health management information systems
- Information, education, and communication
- Laboratory
- Additional stakeholders such as: Ministry of Finance, Ministry of Works, civil society groups, donors

ROLES AND RESPONSIBILITIES

This TWG is chaired by the National HIV Coordinator from the MOH. The National HIV Coordinator convenes each meeting, leads meeting agendas, and assigns tasks to TWG members. He/she may also assign a designate to lead the work, in full collaboration with other critical stakeholders in the HIV response to facilitate the necessary integration between prevention and treatment.

At each meeting, a TWG member records meeting discussions and key decisions. TWG members attend all TWG meetings and carry out tasks as directed by the National PMTCT Coordinator.

APPROACH

The TWG meets once a month or more as needed and agreed by all TWG members.

MEETING ACTIVITIES

OBJECTIVE 1: RECOMMENDREVISIONS TO THE CURRENT NATIONAL GUIDELINES TO REFLECT UPDATED WHO RECOMMENDATIONS

- Reviews and discusses new WHO recommendations and existing national guidelines.
- Reviews existing national PMTCT/IYCF/PEDS/ADULT services and identifies which WHO recommendations can be adopted.
- Makes recommendations as to what revisions should be made to existing national PMTCT/IYCF/PEDS/ADULT guidelines

OBJECTIVE 2: PROVIDES TECHNICAL ASSISTANCE TO SUPPORT DEVELOPMENT OF A NATIONAL ROLL-OUT PLAN TO SUPPORT DISSEMINATION AND IMPLEMENTATION OF THE REVISED NATIONAL PMTCT/IYCF/PEDS/ADULT GUIDELINES (REFER TO PART 3.1 OF THIS TOOLKIT)

- Reviewsprogram areas where activities need to take place and identifiesexisting MOH and donor resources that can be utilized to support roll-out.
- Develops a national roll-out work-plan that reviews components of revised service implementation. At a minimum, this workplan includes:
  - Developing a plan to revise the national PMTCT/IYCF/PEDS/ADULT guidelines;
  - Identifying geographic or site-level priorities, including identification of the first learning sites to implement the revised guidelines;
  - Developing a training plan for all health care workers;
  - Developing a sensitization plan for all levels of service delivery;
  - Planning for revision of clinical support documentation and tools (SOPs, job aides, etc.);
  - Addressing revisions to the supply and distribution system; and,
  - Developing a plan to revise IEC materials.
  - Developing a national monitoring and evaluation plan for implementation including indicators to be adopted.

OBJECTIVE 3: MONITOR IMPLEMENTATION OF THE NATIONAL ROLL-OUT PLAN THROUGHOUT THE ROLL-OUT PERIOD (USE ROLL-OUT TEMPLATE IN SECTION 3.1 OF THIS TOOLKIT)

- Activity 1: Meet as a group on a routine basis (no less than once a month) and, using an agreed upon feedback format, present progress in roll-out implementation to key decision makers and stakeholders (e.g. Minister of Health).
- Activity 2: Rotate members of the TWG for note-taking responsibility of TWG meetings.
- Activity 3: begin considering longer term issues in monitoring impact of revised policies

EXPECTED OUTCOMES

1. Based on the WHO guideline revisions, recommended revisions to the national PMTCT/IYCF/PEDS/ADULT guidelines are presented to the MOH and recommendations are adopted.
2. A plan for revision of the national guidelines is developed
3. A fiscal implementation plan for roll-out of the revisions is developed.

DELIVERABLES

1. Terms of reference, membership roster, and meeting schedule for the TWG.
2. Develop and finalize a fiscal implementation plan to support roll-out of revised national PMTCT/IYCF/PEDS/ADULT guidelines. This plan should include a training plan and monitoring and evaluation plan to track progress of revised guideline roll-out