The New National Guidelines (2010) for PMTCT and Infant Feeding in the Context of HIV

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Presentation outline

- Evolution of the PMTCT guidelines in Uganda
- Rational for the new guidelines
- Highlights of the new Policy guidelines

Evolution of the PMTCT guidelines

- Guidance on PMTCT is provided regularly to countries by WHO
- Uganda launched the first PMTCT policy guidelines in 2002, following lessons learnt from the PMTCT pilot in 2000
  - Main drug was sd NVP tab for mother in labour and baby within 72 hours after delivery
  - AZT from 36 weeks of gestation, in labour and post partum in few sites
  - Recommending replacement feeding ideal for HIV positive pregnant women- infant formulae by UNICEF

Evolution of the PMTCT guidelines

- The Second set of guidance released in 2006,
  - Use of AZT from 28 weeks onwards as well as
  - Use of dual therapy (two drugs for PMTCT), 3TC +AZT from 32 weeks on wards
  - Boosted by Sd NVP in labour
  - Infant received sd NVP and AZT syrup for 7 days
  - EBF for at least 3 – 6 months to reduce HIV transmission while improving child survival
  - If mother has CD4 $\leq$ 350 or is stage III or IV, initiate on lifelong HAART
- Third set of Guidance from WHO in November 2009 (rapid advice) and detailed guidelines in July 2010 in Viena

Rationale of the new Guidelines

New Guidance is based on new evidence on:

- Benefits of earlier initiation of ARV prophylaxis during pregnancy in reducing mother-to-child transmission
- Effectiveness of ARV prophylaxis provided during breastfeeding in reducing mother-to-child-transmission
- Effectiveness of different ART regimens for children and adults
- Optimal timing and criteria for ART initiation in children & adults

In response to this evidence, the World Health Organization (WHO) released new guidance for PMTCT, EID, ART & Infant Feeding, *which the Ministry of Health has adapted to Uganda's setting*

Summary of new Changes

Prevention of Mother-to-Child Transmission (PMTCT):

1. ARV use for the HIV positive pregnant women

- Recommend initiation of ARVs earlier during pregnancy from 14 week of gestation

2. ARV use during Breast Feeding;

- Recommend ARV prophylaxis to either the baby or mother up to the end of all breastfeeding

3. Infant and Young Child Feeding (IYCF):

- Recommend HIV positive mothers to breastfeed for at least 12 months as long as the baby or mother is receiving ARV's

WHO recommended 2 equally-effective options for provision of PMTCT ARVs

Option A	Option B
Mother **If CD4 >350** • Antepartum AZT (from 14 weeks) • sdNVP + AZT/3TC at delivery • AZT/3TC for 7 days postpartum **If CD4 ≤350:** Lifelong ART	**Mother** **If CD4 >350** • HAART from 14 weeks of pregnancy until 1 week after breastfeeding has stopped **If CD4 ≤350:** Lifelong ART
Infant • If **breastfeeding**: daily NVP from birth until one wk after breastfeeding has stopped • If **not breastfeeding or mother on ART**: NVP for 6 wks	**Infant** • NVP for 6 weeks (regardless of whether mother is breastfeeding)

Uganda has adopted option B

But will initially transition sites to option A, and later from 2011 onwards to Option B in a phased manner as resources become available

In “Option A”, there are 2 PMTCT regimens depending on whether the woman needs treatment for her own health

1. Lifelong ART for HIV-infected pregnant women in need of treatment

- Triple-drug therapy (ART) is effective means of preventing MTCT

2. ARV Prophylaxis for HIV-infected pregnant women NOT requiring treatment

- Short-term provision of ARVs
- **Mother** receives ARVs during pregnancy, labour/delivery, and postpartum
- **Baby** receives ARVs during delivery and postpartum

In "Option A" Clinical staging and CD4 count are critical to determine whether the women receives prophylaxis or treatment

All HIV+ pregnant women must receive **CD4 test** or be **clinically staged** to determine eligibility for ART

	Clinical Stage	CD4 Count
Start ART	III or IV	≤ 350
Start ARV Prophylaxis	I or II	> 350

- **Don't wait for CD4 result to come back to start ARV's!**
- If CD4 testing is not readily available, use clinical staging alone to determine eligibility for ART
- Immediately start ARV Prophylaxis (stage I or II) or ART (stage III or IV)

1. PMTCT Regimens for pregnant women eligible for ART

If a pregnant women has CD4 ≤ 350, or is Stage III or IV, she should be initiated on lifelong ART as soon as possible

ART Regimens for Eligible Pregnant Women		
	1st Line	**2nd Line**
Preferred	AZT + 3TC + NVP (or EFV)	TDF + 3TC + LPV/r
Alternative	TDF + 3TC + NVP (or EFV)	AZT + 3TC + LPV/r

- **If anemic (Hb < 7.5 g/L), replace the AZT-containing regimen with TDF**
- **If 1st trimester, do not use EFV-containing regimen: Use NVP**

Baby receives daily NVP for <u>6 weeks after birth</u>
(breastfeeding or replacement feeding)

Note: *It is generally better to use NVP instead of EFV in pregnant women (unless there are toxicities). These women are on ART for life and most will become pregnant again---if on EFV in 1st trimester there is a risk of birth defects*

Why it is important to ensure that eligible pregnant women (≤350) are initiated on ART

In Uganda; Pregnant women with CD4 ≤ 350

account for:

- Approximately 40% of all HIV+ pregnant women
- Contribute to greater than 75% of overall transmission
- and greater than 80% of postpartum transmission
- 85% of maternal deaths within 2 years of delivery
  - Due the high viral loads

2. PMTCT Regimens for pregnant women receiving ARV prophylaxis (not eligible for ART)

1. Mother receives AZT starting at 14 weeks gestation, until delivery

- Combivir (AZT/3TC) is no longer given during pregnancy

2. Mother receives sdNVP + AZT/3TC at onset of labour delivery

3. Mother continues with AZT/3TC for 7 days postpartum

Breastfeeding	Replacement Feeding
Daily NVP prophylaxis until 1 week after cessation of breastfeeding	Daily NVP from birth until 6 weeks of age

- **Mothers recommended to breastfeed for 12 months while baby is on NVP**
- Mothers not encouraged to replacement feed, but they can if AFASS criteria is met

Anemic pregnant women with CD4 above 350 should be referred to an ART clinic and put on a 3-drug regimen if the anaemia cannot be corrected quickly

Pregnant women with severe anemia (Hb < 7.5 g/L or clinical diagnosis) cannot take AZT, but still need to receive ARV's for PMTCT!

- At the ART clinic, the pregnant women will be initiated on **"ART as prophylaxis"---** the ART will be stopped 1 week after the mother stops breastfeeding.
  - The baby will only receive NVP for 6 weeks
  - After stopping ART, the mother should remain in care at ART clinic

- The recommend ART regimen is **TDF + 3TC + EFV**

- The referring clinic must indicate on referral form that the mother is anemic

- The ART clinic must have TDF in stock, and know protocol to start mother on ART

Benefits of the New PMTCT policy guidelines

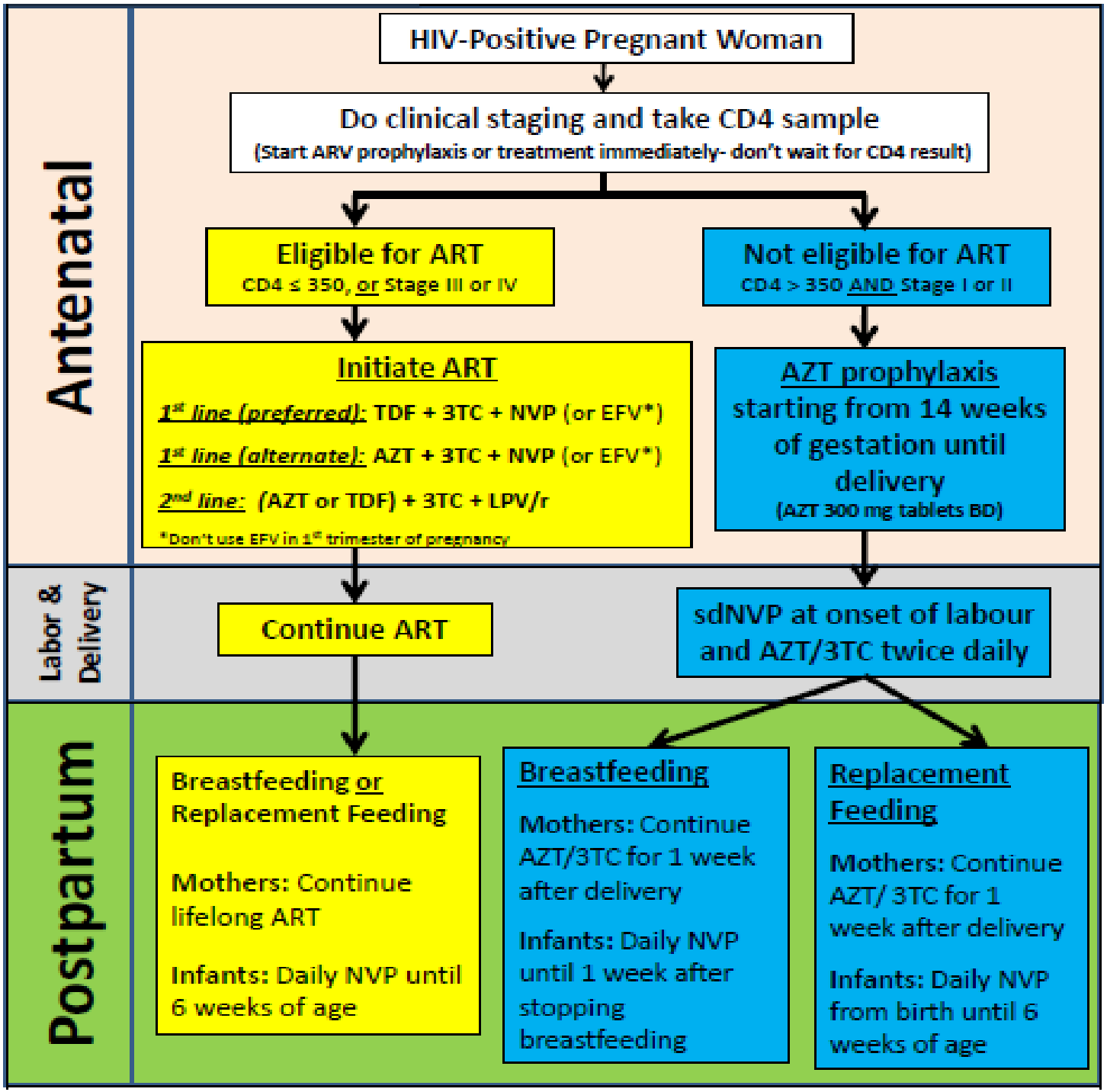
- AZT now started earlier in pregnancy—significantly reduces rates of intrauterine transmission
  - Women receive prophylaxis for more of the transmission period
- AZT can now be started at the woman's first visit
  - Currently many women come before 28 weeks but don't ever come back as a result they never receive ARVs for PMTCT
  - Other mothers currently come early but are initiated on AZT late because they return much later than 28 weeks
- Transmission through breastfeeding will decrease because the baby or mother will receiving ARV prophylaxis daily
- Mothers can breastfeed for a longer time because the baby is receiving NVP; hence contributing to "increased HIV free survival" through reduced HIV risk as well as morbidity and mortality from malnutrition

Dosing schedule for infant NVP prophylaxis

Infant Age		NVP Daily Dose (10 mg/ml formulation)
Birth to 6 weeks	Birth weight 2.0 to 2.5 kg	**1 ml once daily**
	Birth weight > 2.5 kg	**1.5 ml once daily**
>6 weeks to 6 months		**2 ml once daily**
>6 months to 9 months		**3 ml once daily**
>9 months to end of breastfeeding		**4 ml once daily**

Summary of 2010 National PMTCT Guidelines

Option A



"AFASS" criteria is used to determine whether a mother is able to replacement feed

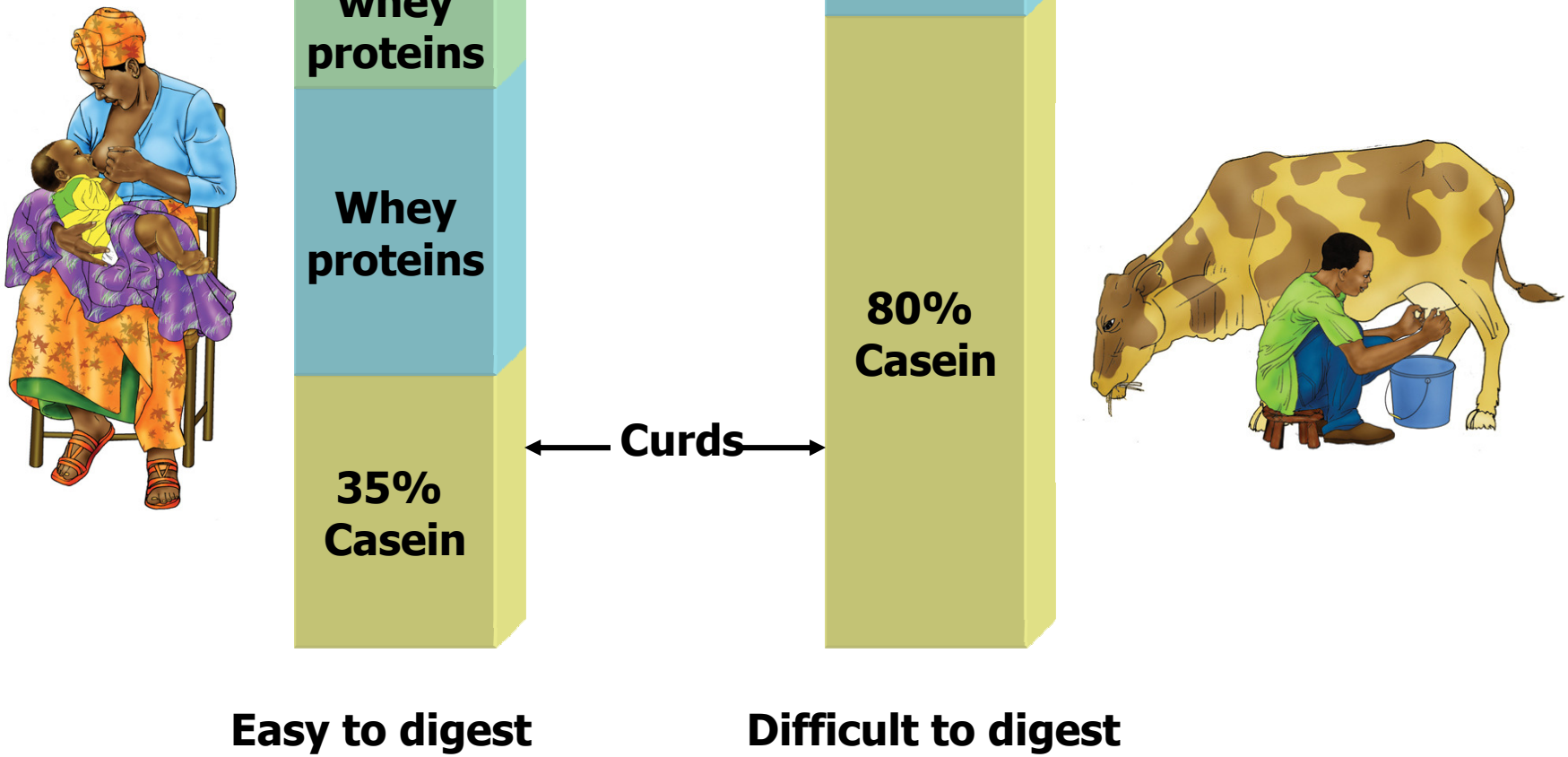
AFASS Criteria for Replacement Feeding

Acceptable	Mother perceives no significant cultural or social barriers to replacement feeding
Feasible	Mother has adequate *knowledge, skills, resources, and support* to correctly mix formula or milk, and feed the infant up to 12 times in 24 hours
Affordable	Mother and family can pay the costs of replacement feeding—fuel, clean water, and all ingredients— without compromising the health and nutrition of the family.
Sustainable	Mother has access to a continuous and uninterrupted supply of all ingredients needed for safe replacement feeding as long as the infant needs it
Safe	Replacement feeds are correctly and hygienically stored, prepared, and fed in nutritionally adequate amounts. Infant is fed by clean hands and preferably by cup

NOTE: Currently options for replacement feeding include commercial infant formula and modified animal milk

However, WHO recommended that animal milk should no longer be used for infants below 6 months. Uganda has not yet formally adopted this position

Differences in Quality of Proteins in Different Milks



In the current feeding guidelines, HIV-positive mothers stop breastfeeding exposed infants at 6 months

Current Feeding Guidelines (2006-2009)

- **Mothers encouraged to EXCLUSIVELY BREASTFEED until <u>6 months of age</u> if replacement feeding is not AFASS**
  - *Mothers should wean over the course of 2 weeks*
  - *If mothers cannot provide Sufficient animal milk at 6 months, they can continue to breastfeed while also introducing complementary feeds*
- **If mothers are able to meet the AFASS criteria at any time, encourage replacement feeding**
- **Infants confirmed HIV-positive should breastfeed exclusively for 6 months, & complementary feed until 24 months**

HIV+ mothers are **now** urged to breastfeed for 12 months while the exposed baby (unknown status) receives ARV prophylaxis

New Feeding Guidelines (2010)

- **Mothers strongly recommended to exclusively breastfeeding <u>until 6 months of age,</u> and continue breastfeeding while introducing complementary feeds <u>until 12 months of age</u>**
  - *If mothers cannot provide sufficient animal milk at 12 months, they can continue to breastfeed until able*
- **Exposed infants receive daily NVP prophylaxis until 1 week after cessation of breastfeeding**
- **Breastfeeding is the preferred feeding method. However, if mothers still desire to replacement feed, they can, if able to meet the AFASS criteria**
- **Infants confirmed HIV-positive should breastfeed exclusively for 6 months, & continue breastfeeding while adding in complementary feeds until 24 months**

Rationale for the new infant feeding guidelines

Challenges of the 2006-2009 Guidelines

When mothers breastfeed for 6 months, and without ARV prophylaxis:

- **Risk of HIV transmission is high**, especially since many mothers mixed feed.
- However, if mothers replacement feed it will lead to malnutrition since most cannot meet AFASS criteria

- **Risk of malnutrition after 6 months is high** because many mothers can't give their babies an adequate substitute
- However, if mother continue breastfeeding beyond 6 months, length of exposure to HIV is increased

Benefits of 2010 Guidelines

When mothers breastfeed for 12 months and with ARV PROPHYLAXIS:

- **Risk of HIV transmission is reduced** because ARV prophylaxis is provided throughout the breastfeeding period

- **Risk of malnutrition is greatly reduced** because babies are receiving breast milk for 12 months—by that age the baby has grown and the malnutrition risk is less

The counseling messages given to mothers during antenatal changes with the new guidelines

What we have been saying; In the current guidelines (2006-2009):

- Mothers are encouraged to breastfeed exclusively for 6 months and then stop; unless replacement feeding *if AFASS*

What to say; In the new guidelines (2010):

- HIV+ mothers are **strongly** encouraged to breastfeed their exposed infants for 12 months while on ARV's
  - Exclusive BF until 6 months, complementary from 6-12 months
- **Breastfeeding is no longer just "necessary" but "critical"** because of the nutritional need and because ARV prophylaxis now limits the risk of transmission
- However, if the mother still prefers to replacement feed after counseling, she can do so if AFASS criteria is met

Who and when to re-test for HIV:

	Who to Re-test	When to Re-Test
1	**Pregnant women who have tested HIV-negative in the 1st or 2nd trimester of pregnancy**	**Re-test in the 3rd trimester (preferably between 28-36 weeks)** *If woman does not return for testing in 3rd trimester, she should be re-tested during labour or just after delivery*
2	**Outpatients with a negative HIV test result, but with clinical conditions suggestive of HIV-infection**	**Re-test 4 weeks after HIV- negative test**
3	**Individuals with STIs who have an HIV-negative test result**	
4	**TB-infected individuals with an HIV-negative test result who have had a new potential HIV exposure**	

Who and when to re-test for HIV (continued):

	Who to Re-test	When to Re-Test
5	**HIV-negative persons with ongoing risk behaviors** (persons with known HIV-positive partner, partner of unknown status, sex workers, and injection drug users)	**Re-test at least annually**
6	**Persons with a specific incident of known HIV-exposure within the past 3 months, who test negative at the first testing encounter**	**Re-test 4 weeks after initial HIV- negative test**
7	**Persons with specific incidence of possible of HIV-exposure within the past 72 hours** (should receive Post-Exposure Prophylaxis and baseline HIV test)	**Re-test 4 weeks after exposure, and if negative re-test again at 12 weeks post-exposure**

Finally, Thank you for being A good Audience