

KITSO AIDS Training Program

**Summary of Major Changes
in the
2008 Guidelines**

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Summary (1): HIV Testing and Staging

- DNA PCR testing for all HIV-exposed babies at 6 weeks of age, with repeat confirmatory DNA PCR for positive results. *If first DNA PCR is positive, refer immediately for HAART, without waiting for repeat result.*
 - If patient presents 4-6 weeks of age, perform DNA PCR at that time, in case the patient does not return for testing at 6 weeks.
- For breastfeeding infants who initially test HIV-negative at 6 weeks, HIV testing 6 weeks after complete cessation of breast feeding
- A rapid test should be done at 18 months on all HIV-exposed, *non-breastfed* children who initially tested negative by DNA-PCR, to ensure that undisclosed breastfeeding has not resulted in HIV infection, and to detect rare instances of false-negative DNA PCR.
- WHO clinical staging is now the recommended standard for classifying the clinical status of HIV-infected patients.

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**Summary (2):
Screening and Monitoring Visits**

- CD4/clinical screening and monitoring visits must entail more than just obtaining a CD4 cell count:
 - WHO clinical staging by history and physical examination
 - Preventive education
 - General HIV education
 - Indicated prophylaxis
 - Discussion of family planning
 - Clinical screening for active TB infection
 - Adherence counseling
 - Emotional and supportive care
 - Evaluation for depression or other mental illness, with indicated treatment and referrals

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Summary (3): CTX Prophylaxis

- CTX prophylaxis should be given OD, not TIW, to ensure protection against diarrheal disease, malaria, TB, and respiratory infections other than PCP.
- Adults: give CTX if CD4 count < 200 cells/μL or active, current WHO stage 3 or 4 condition. If CD4 count is pending and the patient is WHO clinical stage 3 or 4, *do not wait for the CD4 count to return: start CTX.*
- Pregnancy is not a contraindication to CTX prophylaxis, if indicated as above, nor is breastfeeding.
- CTX must be given to all patients on ATT, regardless of CD4 count.

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**Summary (4):
Pediatric CTX Prophylaxis**

- HIV-exposed infants: give CTX from age 6 weeks to 12 months until tested HIV-negative *and not breastfeeding*. If breastfeeding, continue CTX until tested HIV-negative 6 weeks after complete cessation of breastfeeding.
- Children 1 to 5 years of age: CTX if CD4% < 25% (previously < 15%).
- Children > 5 years age: CTX if CD4% < 15% or total CD4 count < 200 cells/μL.
- Other pediatric indications for CTX: WHO stage 2, 3, or 4; virologic failure (until resuppressed); or children who are HAART-eligible but not on HAART for any reason (e.g., lack of care-giver, nonadherence).

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**Summary (5):
Adult HAART Eligibility**

- For adults and adolescents (pregnant and non-pregnant), eligibility for HAART is determined by having one of the following two criteria:
 - WHO clinical stage 3 or 4, or
 - CD4 cell count < 250 cells/μL (previously < 200 cells/μL)

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**Summary (6):
Adult HAART Eligibility (2)**

- If an HIV-infected patient of any age has an active WHO clinical stage 3 or 4 condition, the patient's clinical condition is poor, and the CD4 cell count or % is pending, *do not wait for the CD4 count or % to return: begin the patient on HAART* on the basis of the patient's having an active WHO clinical stage 3 or 4 condition and being in poor clinical condition. Likewise, *do not delay CTX prophylaxis*.
 - Before beginning HAART in an adult/adolescent patient without a CD4 count, as above, the possibility that the patient might have a high baseline CD4 count requires LPV/r-based or EFV-based HAART and not NVP, because of risk of NVP-induced hepatotoxicity with high baseline CD4 counts (see below).

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**Summary (7):
Pediatric HAART Eligibility**

- Eligibility for HAART for HIV-infected children:
 - Age <1 year, regardless of clinical or immunologic status
 - An HIV-exposed infant with a WHO clinical condition 2, 3, or 4, and for whom the DNA-PCR has not returned, must be followed monthly and discussed with an HIV Specialist for possible HAART initiation.
 - For age > 1 year:
 - WHO clinical stage 3 or 4, *or*
 - “Advanced” or “severe” immune suppression, according to WHO age-related CD4%/count criteria

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Summary (8): Non-Pregnant Adult HAART Regimens (No History of Maternal sd-NVP)

- First and second line ARV regimens for *new* adult patients (non-pregnant) have been changed:
 - First line: **TDF + FTC (or 3TC) + EFV/NVP**, according to the woman's reproductive potential
 - Second line: **AZT + 3TC + LPV/r**
 - Patients stable on the prior first line regimen of **AZT + 3TC + NVP/EFV** should continue this regimen, as long as there are no AZT side effects.
- Patients currently on d4T/3TC or d4T/ddI should be switched to TDF/FTC (or 3TC).

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Summary (9): Pediatric HAART Regimens (No History of Infant sd-NVP)

- First line ARV regimen for pediatric patients has remained the same (**AZT + 3TC + NVP/EFV**), but the second line regimen has been changed to **ABC + d4T + LPV/r**.
- Children already on prior second line regimen (**d4T + ddl + LPV/r**) may continue this regimen, as long as there are no ddl-related adherence problems. If adherence problems with ddl, switch to above new second line regimen, with follow-up priority viral load in 6 weeks to confirm continued virologic suppression.
- All pediatric patients with viral load not < 400 copies/mL by 6 months post-HAART initiation must be discussed with a pediatric HIV Specialist.

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**Summary (10):
sd-NVP in Women and Children**

- When initiating HAART in women and children, it is necessary to determine whether or not they received sd-NVP:
 - Women who received sd-NVP within the prior 6 months must be initiated on **TDF + FTC (or 3TC) + LPV/r**. Women initiated on HAART more than 6 months after sd-NVP may be initiated on standard first line HAART (**TDF + FTC + NVP**), but must be closely monitored for any evidence of treatment failure.
 - Infants who have received sd-NVP and who are initiated on HAART within the first 6 months of life must be discussed with a pediatric HIV Specialist. For infants initiating HAART after 6 months of age, **LPV/r-based HAART** should be used. A history of maternal participation in PMTCT is sufficient to assume that the infant received sd-NVP at birth.

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**Summary (11):
Key Points Before Beginning HAART:**

- Evaluate women and children for any past history of sd-NVP for PMTCT.
- Avoid NVP if baseline CD4 count > 250 cells/μL (women) or > 400 cells/μL (men). Alternative options are EFV or LPV/r.
- Use AZT-containing HAART for eligible pregnant women, if possible.
- Use WHO dosing guides for pediatric ARV dosing.

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Summary (12): Monitoring

- Recommendations for baseline and monitoring laboratory tests have been changed:
 - Baseline viral load must no longer be done either in adults or children. After full virologic suppression has been achieved 6 months post-HAART initiation in adults, viral load should be performed every 6 months.
 - Pediatric and adolescent patients require indefinite every-three-month viral loads.
 - After initial 3 and 6 month CD4 count/%, all age groups require only every 6 month CD4 count/%.

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Summary (13): Monitoring (2)

- Monitoring of FBC and AST/ALT for patients on HAART has been extensively streamlined, and in most cases must not be done on a routine, q3-month basis.
- Because of increased risk of treatment failure in pediatric and adolescent patients, viral loads on all patients less than 20 years of age should receive priority processing. The guidelines list other instances also requiring priority viral load or CD4 count.

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Summary (14): Monitoring (3)

- For adult patients who have remained stable on HAART for at least two years, clinical monitoring visits can be decreased to every six months.
- All ARV clinics must develop and implement an ongoing, timely procedure for reviewing laboratory tests for abnormal results promptly, including any detectable viral loads.
- PAP smear screening must be done annually on all HIV-infected women, with prompt follow-up of any abnormalities.

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**Summary (15):
Pregnancy, HAART, and PMTCT**

- In all cases, pregnant women who are eligible for HAART for their own HIV infection, must be started on HAART, without exception. If the woman's immune status is poor, HAART must not be deferred until the second trimester.
- If a pregnant woman is ineligible for HAART, give short-course AZT beginning at 28 weeks (or promptly if presentation > 28 weeks gestation).
 - Single-dose NVP should *not* be given at labor *if the woman has received at least 4 weeks of AZT*.
 - If she has received < 4 weeks of AZT, sd-NVP should be administered at onset of labor (do not repeat).
 - If history and clinic records are unclear about duration of AZT prophylaxis, then give sd-NVP (do not repeat).

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**Summary (16):
Pregnancy, HAART, and PMTCT (2)**

- Any pregnant woman presenting for care at 28 weeks gestation or more must immediately be started on AZT 300 mg BD, pending urgent screening for HAART eligibility. Once baseline evaluation has been completed, then AZT should be replaced with full HAART, if the woman is eligible for HAART for her own health.
- Even late in pregnancy, HAART should be started if the patient is eligible and is believed ready to start HAART. Unless active labor has started, it is never too late to begin HAART.

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**Summary (17):
Pregnancy, HAART, and PMTCT (3)**

- Anemia during pregnancy may complicate use of AZT for PMTCT, both with HAART and with short-course AZT prophylaxis. Such anemia can occur at baseline and/or after initiation of AZT.
 - Every effort should be made to use AZT, because of its demonstrated PMTCT efficacy. Both for the viability of the pregnancy and for allowing use of AZT for PMTCT, transfuse the patient as needed.
 - If transfusion is not possible, or if AZT-induced anemia is not manageable with transfusion, then switch to full d4T-containing HAART (both for women on short-course AZT prophylaxis and for women on AZT-containing HAART). Baseline CD4 cell count must determine whether the HAART is NVP- or LPV/r-based. If anemia improves on d4T-containing HAART, consider switching to AZT-based HAART, with close monitoring of HgB. If AZT cannot be used pre-partum, then still try to use it during delivery, with transfusion support as needed.
 - After delivery, women initially eligible for HAART should be switched to TDF-containing HAART. Consult an HIV Specialist as to whether or not HAART should be continued in those women who were initially ineligible for HAART.

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Summary (18): Infant Feeding

- Formula feeding must be acceptable, feasible, affordable, sustainable, and safe.
- Women deciding to use formula must be taught how to use it safely, and must not simply be given formula and told to use it.
- Clinics which dispense formula must not turn away a mother who requests additional formula for her baby, and must provide additional formula. However, follow-up home visits should be done to access proper formula use.

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Summary (19)

- Safe sex prevention messages must be targeted, and must not present all sexual activity as dangerous.
- Do NOT use systemic steroids to prevent or to treat benign NVP-associated rash.
- Patients on both rifampicin and EFV or NVP do not require an increase in the NNRTI dose.
- Quinolones (e.g., ciprofloxacin) and aminoglycoside antibiotics (e.g., amikacin) should be avoided as “empiric” antibiotic therapy, except for infections documented to be resistant to conventional therapy and sensitive to quinolones / aminoglycosides, because of potential compromise of second-line ATT drugs if the patient has undetected active TB instead of other bacterial infections.

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Summary (20)

- Patients on NVP who develop mild, non-toxic symptoms of early SJS or hepatitis without jaundice or fever may be able to stop NVP first, while continuing the two N[t]RTIs for 3-5 days before stopping them, to save EFV as an alternative ARV, once the early SJS/mild hepatitis has resolved.
- Decisions regarding PEP initiation must take into account the possibility that a source patient whose HIV test result is negative may be in the “window period” of HIV infection, and thus highly infectious for HIV.
- Pre-operative evaluation for surgical risk must not regard asymptomatic HIV infection as a reason to delay surgery.

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Summary (21)

- Pre- and post-exposure sexual prophylaxis is of unproven benefit, and must not be administered, except for cases of rape or defilement.
- Recurrent mono-dermatomal VZV, a single episode of multi-dermatomal VZV, and ophthalmic VZV are regarded in Botswana as WHO clinical stage 3 conditions.
- Prompt lumbar puncture for diagnosis of meningitis is an "opt out" procedure and does not require family consent.
- The 2008 treatment guidelines list a Protocol for Special Order ARVs and the names and contact details of HIV specialists who can be contacted any time for consultation about difficult cases.

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