Updates on Revised Antiretroviral Treatment Guidelines 2013

Overview

27 March 2013
Introduction of Fixed Dose combination (FDC)

FDCs will be available in facilities on 1 April 2013

The FDC ARV that will be rolled out in South Africa is **one ARV pill** which contains **three drugs**:

- tenofovir (TDF),
- emtricitabine (FTC) and
- efavirenz (EFV)

The implementation will be phased over a period of 1 year in order of priority
## Prioritisation for FDC implementation

<table>
<thead>
<tr>
<th>Priority</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>New patients (adults, adolescents and pregnant women) eligible to start ART</td>
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</table>
| 2        | 1. All pregnant women needing triple therapy  
          2. Breast feeding mothers currently stable on a FDC compatible regimen. |
| 3        | Virally suppressed patients currently on first line regimen, requiring a switch due to toxicity (e.g. stavudine) |
| 4        | Patients currently stable on a FDC compatible regimen, with TB comorbidity |
| 5        | Patients currently stable on a FDC compatible regimen with other comorbidities (e.g. hypertension, diabetes mellitus, etc.) |
| 6        | Patients currently stable on TDF-based regimen and who request a switch to a FDC |
| 7        | Patients currently stable on TDF-based regimen who, after counseling, agree to a switch to a FDC |
ART Treatment Guidelines Revised

- Drug regimens
- FDC (fixed dose combination)
- Laboratory tests
- M & E
- Integrated management (TB, Sexual Reproductive Health-Family Planning, Cervical screening, Nutrition)
Key Updates

- Timing of ART initiation in treatment-naive patients remains at cd4 ≤ 350
- Guidance on introduction of the fixed dose combination
- Considerations for patients with co morbidity
- Considerations for HIV-infected women of childbearing age
- Timing of ART initiation in patients with TB
- Guidance on management of patients requiring salvage therapy
- Guidance on management of stable patients and on new guidelines to improve adherence to treatment
Key changes in the 2013 treatment guidelines

- Phasing out separate Pre ART literacy sessions for ART eligible patients
- Introduction of concurrent adherence literacy to strengthen adherence support
- It is mandatory that patients are started on treatment within 7 days after being assessed as eligible for ART
- Introduced management of patients with co morbidity
- Early treatment offered to prevent transmission to uninfected patients
The FDCs will be phased in according to the following order of priority:

**Priority 1**

*New patients* *(adults, adolescents and pregnant women)* eligible to start ART.

**Priority 2**

*All pregnant women* needing *triple therapy and breast feeding mothers* currently stable on a FDC compatible regimen.
Revised PMTCT Antiretroviral Treatment Guidelines 2013
HIV Positive Test

- If positive and confirmed positive with 2\textsuperscript{nd} rapid test kit
  - Post-test counselling
  - Baseline bloods (CD4, Creatinine)
  - Initiate ART with the FDC on the same day \textit{regardless of CD4 cell count or gestational age}. \textit{Do not wait for blood results to initiate!}
  - Give client an appointment to return within 7 days for CD4 and Creatinine results
How to initiate ART

- All pregnant women, regardless of CD4 cell count, will be initiated on a fixed-dose-combination of FTC+TDF+EFV (one tablet) on the same day that they are diagnosed HIV positive (or within 7 days)
- FDC Tablet is taken once a day
  - In the evening
  - At the ‘same time’
- Routine antenatal booking bloods must be done (HB, RPR, Rh) at booking.
- Creatinine and CD4 are done on that same day and the patient asked to return for the results within 7 days.

IMPORTANT

ART is initiated on ALL HIV positive pregnant women immediately. There is no need to wait for the CD4 and Creatinine results before initiation.
ART Eligibility

- If CD4 ≤ 350 cells/mm³: lifelong ART

- WHO III/IV: lifelong ART, regardless of CD4

- If CD4 > 350 cells/mm³: continue ART for duration of pregnancy and FOR ONE WEEK AFTER cessation of breastfeeding
Updates

Revised PMTCT Indicators

NIDS 2013
<table>
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<tr>
<th>Antenatal 1st visit before 20 weeks</th>
<th>Antenatal client known HIV positive but NOT on ART at 1st visit</th>
<th>Antenatal client HIV 1st test positive</th>
<th>Antenatal client HIV re-test positive at 32 weeks or later</th>
<th>Antenatal client eligible for ART initiation</th>
<th>ART prophylaxis discontinued within 12 months after delivery</th>
<th>Infant 1st PCR test positive around 6 weeks</th>
<th>Infant initiated on CPT around 6 weeks</th>
<th>Infant rapid HIV test positive around 18 months</th>
<th>Infant given Nevirapine within 72 hours after birth</th>
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Live birth to HIV positive woman

Infant given Nevirapine within 72 hours after birth
**Criteria to Start ART**

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<th>Eligible to Start ART</th>
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<tr>
<td>▪ All children less than 5 years of age</td>
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<tr>
<td>▪ Children 5 years to 15 years with WHO clinical stage 3 or 4 or CD4 $&lt; 350$ cells/µl</td>
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## Criteria for Fast Tracking for ART

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<th>Require Fast-Track (i.e. start ART within 7 days of being eligible)</th>
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<tbody>
<tr>
<td>▪ Children less than 1 year of age</td>
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<tr>
<td>▪ WHO clinical Stage 4</td>
</tr>
<tr>
<td>▪ MDR or XDR-TB</td>
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<td>▪ CD4 Count &lt; 200 cells/ul or &lt; 15%</td>
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## What ART to start Children on?

<table>
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<th>First Line Regimen</th>
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<td>All infants and children under 3 years (or &lt; 10kg)</td>
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<tr>
<td>Children ≥ 3 years (and ≥ 10kg)</td>
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<tr>
<td>Currently on d4T-based regimen</td>
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$\infty$ Children ≥ 3 years and exposed to NVP for 6 weeks or longer (PMTCT) should be initiated on ABC + 3TC + LPV/r
Updates

Revised Adult and Adolescent Antiretroviral Treatment Guidelines 2013
Standardised ART eligibility criteria

Patients eligible to start lifelong ART

CD4 count $\leq$ 350 cells/mm³ irrespective of WHO clinical stage

- OR

Irrespective of CD4 count
  - All types of TB (in patients with TB drug resistant or sensitive, including extra pulmonary TB)

WHO stage 3 or 4 irrespective of CD4 count

Patients that require a fast-track

HIV positive women who are pregnant or breast feeding

- OR

Patients with low CD4 < 200

- OR

Patients with Stage 4, irrespective of CD4 count

- OR

Patients with TB/HIV co morbidity with CD4 count < 50

(Patients with Cryptococcus meningitis or TB meningitis (defer ART for 4-6 weeks))
Summary - Key changes in the 2013 treatment guidelines

- **There are no changes** in the preferred first line regimen
- **FDC introduced from 1 April 2013** for:
  - patients starting treatment for the first time;
  - HIV positive pregnant women; and
  - breastfeeding HIV positive women
- **There are no changes** on drugs for second line regime
- **A centralized procurement** of drugs to manage patients requiring salvage therapy will be established
- **Supplementary guidelines will be introduced** to manage stable patients and develop new protocols to improve adherence
Thank you