Updates on Revised Antiretroviral Treatment Guidelines 2013

Overview

27 March 2013

health
Department:
Health
REPUBLIC OF SOUTH AFRICA

Introduction of Fixed Dose combination (FDC)

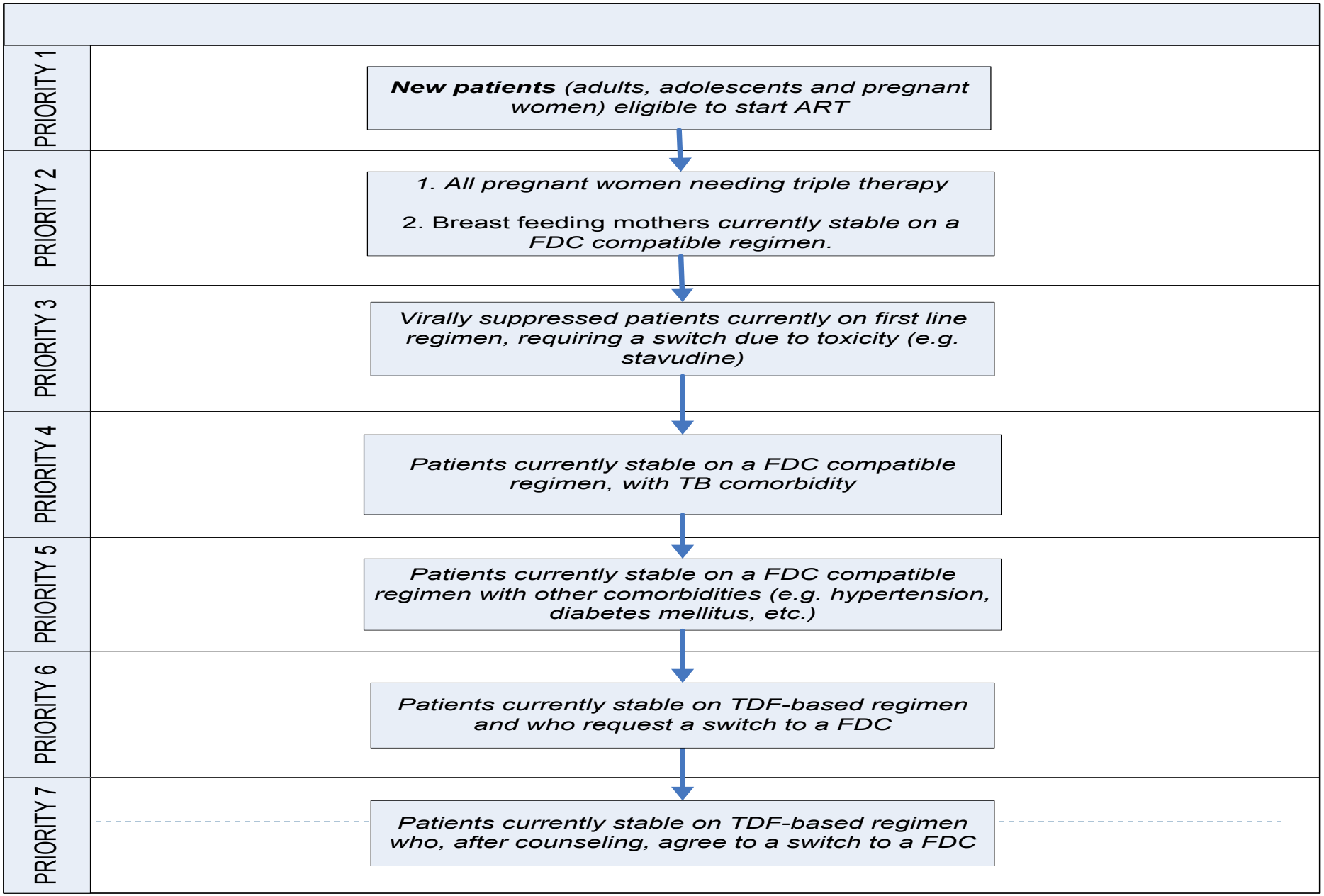
FDCs will be available in facilities on 1 April 2013

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



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

Implementation of fixed dose combination (FDC)1 April 2013

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.*

Updates

Revised PMTCT Antiretroviral Treatment Guidelines 2013

HIV Positive Test

- If positive and confirmed positive with 2nd rapid test kit
  - Post-test counselling
  - Baseline bloods (CD4, Creatinine)
  - Initiate ART with the FDC on the same day **regardless of CD4 cell count or gestational age.** 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

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

Tick register

		Live birth to HIV positive woman	Delivery register
		Infant given Nevirapine within 72 hours after birth	

Updates

Revised Infants and Children Antiretroviral Treatment Guidelines 2013

Criteria to Start ART

Eligible to Start ART

- All children less than 5 years of age
- Children 5 years to 15 years with WHO clinical stage 3 or 4 or CD4 $\leq$ 350 cells/µl

Criteria for Fast Tracking for ART

Require Fast-Track (i.e. start ART within 7 days of being eligible)
▪ Children less than 1 year of age ▪ WHO clinical Stage 4 ▪ MDR or XDR-TB ▪ CD4 Count < 200 cells/ul or < 15%

What ART to start Children on?

First Line Regimen	
All infants and children under 3 years (or < 10kg)	ABC + 3TC + LPV/r
Children ≥ 3 years (and ≥ 10kg)∞	ABC + 3TC + EFV
Currently on d4T-based regimen	Change d4T to ABC if Viral Load is undetectable If Viral load >1000 copies/ml manage as treatment failure If Viral load between 50 – 1000 copies/ml – consult with expert for advise

∞ 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 ≤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