Revised Anti-Retroviral Treatment Guideline

Update For Frontline Clinical Health Professionals

3/13/2013

health

Department:
Health
REPUBLIC OF SOUTH AFRICA

The following document highlights the changes National department of Health ARV treatment guidelines that will take effect on 2 April 2013

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Objectives

1. To update frontline clinical staff implementing PMTCT, paediatric and adult ARV treatment guidelines
2. Develop the capacity of frontline clinical staff to implement the revised ARV treatment guidelines
3. To update frontline clinical staff on the PMTCT national indicator data set (NIDS) 2013

Expected Results

1. Frontline clinical health professionals are fully informed about the revised PMTCT, pediatric and adult treatment guidelines and the use of fixed-dose combination (FDC) - what is different now.
2. Frontline clinical staff have the necessary knowledge and information to implement the revised treatment guidelines
3. Frontline clinical health professionals are fully briefed on the roll out of FDC and the eligibility criteria for each category of recipient
4. Frontline clinical staff are updated and informed on the workers the PMTCT national indicator data set (NIDS) 2013

Training Agenda

Time	Topic	Resource Material
9.00 – 9.15	Welcome and Introductions	
9.15 – 10:00	Rationale for revised Treatment Guidelines • Drug regimen • FDC • Laboratory • M & E • Integrated management (TB,FP, Cervical screening, Breast feeding)	Slides 1-8
10:00 – 10: 15	Refreshment break	
10:15 -13:00 **10.15 – 11.45** **11.45- 12.15** **12-15 – 12.45**	Revised ARV Treatment Guidelines – What are the changes? PMTCT (Including data collection, laboratory testing) Paediatrics Adult	 PMTCT Guidelines 2013 Combined ARV Treatment Guidelines 2013 Combined ARV Treatment Guidelines 2013
12:45 – 1:30	**Lunch**	
1:30 – 2:30	Group work and Case Studies	Pages 25-39
2:30 – 3:30	Group Work Presentations & Discussion	
3:30 -3: 45	Summary and Key take home messages for Frontline Health Workers on the revised Treatment Guidelines	Pages 40-41
3: 45 -3:50	Closure	

Rationale For The FDC Implementation

Current status in SA

- SA has highest HIV burden
- 2011 ANC Sero prevalence showing women still highly affected
- High mortality due to HIV and AIDS
- Largest HIV and AIDS program, but morbidity and mortality still high
- Strong political commitment to increase life expectancy of SA.

Rationale for revised Treatment Guidelines

- South Africa is committed to improving the health status of the citizens- NSDA
- Responded to the Global call to eliminate HIV and AIDS- May 2011
- SA to reduce morbidity & mortality due to HIV and AIDS
- Call to move to more efficacious regimens-IAS 2012

The Mandates

- NSP 2012/2016
- NSDA –the four outcomes
- Action Framework for elimination by 2015
    - Scale up coverage and improve quality of PMTCT to reduce MTCT to less than 5%
- MDGs 4,5 and 6
    - (4)Two thirds reduction in infant mortality
    - (5)Three quarters reduction in maternal deaths
    - (6)Combat HIV and AIDS

Important Areas For The Change

- Drug regimens
- FDC
- Laboratory
- M & E
- Integrated management (TB, SRH-FP, Cervical screening, Breast)

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 to 2013 ARV Treatment Guidelines

- Phasing out separate Pre ART literacy sessions for ART eligible patients and
- Introduction of concurrent adherence literacy to strengthen adherence support
- It is mandatory that patients are started on treatment within 14 days after being assessed as eligible for ART
- Introduced management of patients with co morbidity
- Early treatment offered to prevent transmission to uninfected patients

Fixed Dose combination

- The Minister announced that fixed dose combination (FDC) therapy will be introduced on the 1 April 2013 (see Figure 1)
- FDCs will be available in facilities on 1 April 2013
- The FDC will be introduce in phased manner over period of 1 year
- On the 1 April 2013 HIV positive pregnant women and those breast feeding and patients initiating ART for the first time will be prioritized
- Patients with co infections and co morbidities will be the next priority group
- Finally patients requiring switching and patients who are virally suppressed requiring switching from three drugs to FDC

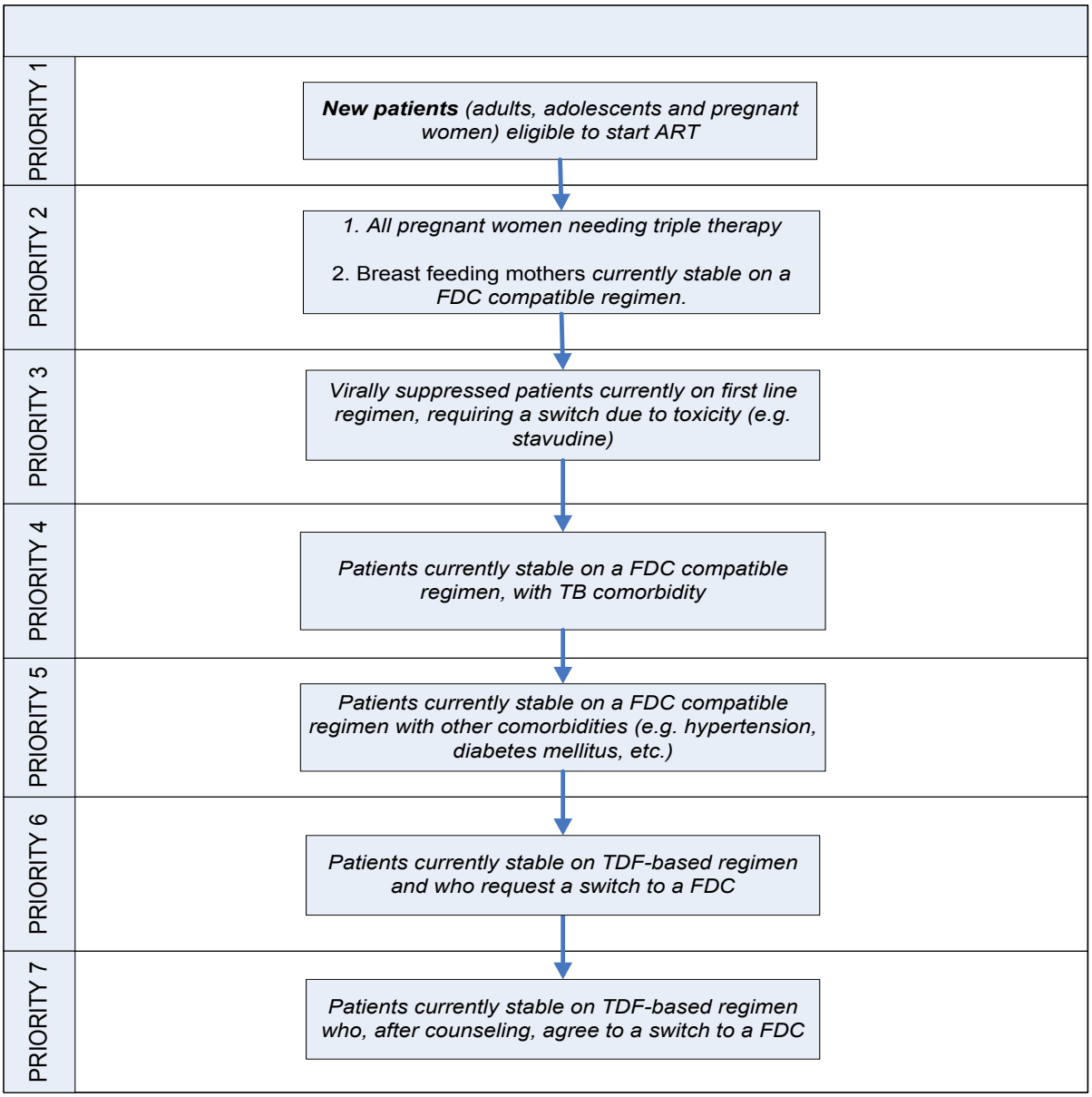

Figure 1 Roll Out Plan

Revised ARV Treatment Guideline

PMTCT Guideline

(Refer to Attached PMTCT Guidelines)

- Encourage all women to book as early as possible in pregnancy, preferably before 14 weeks gestation
- Do not turn women away when trying to book
- All women coming to the clinic for first antenatal booking must be seen on the same day

Baseline screening and ANC

- Group HIV pre-test counseling
- Opt-out approach
- **Booking bloods should include RPR, Rh, Hb check and HIV**
- **For HIV:** Individual testing with rapid test kit
- Individual post-test counseling
- **Tetanus**
- **Iron, folic acid, vit C, Calcium**

HIV Negative Test

- If negative, repeat 12 weeks after first test or at 32 weeks gestation or later
    - Counsel about condom use and partner testing
    - Consider re-testing at delivery, at 6/52 post natal EPI visit, 3 monthly while breastfeeding and then at least annually

HIV Positive Test

- If positive and confirmed positive with 2nd rapid test kit
    - Post-test counseling
    - 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!**
    - Bring client back within 7 days for CD4 and Creatinine results

Also Discuss:

- Partner testing/status/treatment
- Infant feeding
- Continue condom use and counsel about future contraception plan after delivery
- Cervical screening 6/52 postpartum
- On-going adherence

Screen for TB

- Active TB disease is common in women living with HIV. All pregnant women should be actively screened for TB symptoms.
- If an HIV positive patient has symptoms suggestive of TB, a sputum specimen must be collected for GeneXpert testing, and the TB Xpert diagnostic algorithm followed.
- Although it is important to investigate patients for TB before starting ART, in most pregnant patients, initiation of ART prophylaxis or lifelong treatment should not be delayed for TB investigations.
- The healthcare provider should suspect TB in a woman living with HIV if any of the following 4 symptoms are present:
    - Current cough of any duration.
    - Fever
    - Night sweats
    - Weight loss or poor weight gain
- Any woman living with HIV who has none of these symptoms can be considered for eligibility for isoniazid preventive therapy by performing a tuberculin skin test.

Screen For Neuropsychiatric Illness

- Use of efavirenz is contraindicated in individuals with active psychiatric illness.
- In practice, any woman with an active psychiatric illness should not receive an efavrienz-containing antiretroviral regimen without consultation.
- Mild depression is not a contraindication to efavirenz

Screen For Renal Disease

- Use of tenofovir is contraindicated in individuals with renal disease. Renal disease is uncommon in HIV-infected pregnant women.
- At the first antenatal visit, women at increased risk of renal disease may be identified through a pre-pregnancy history of:
    - diabetes or hypertension,
    - a previous kidney condition requiring hospitalization,
    - ≥2+ proteinuria on urine dipstix.
- A serum creatinine of >85 µmol/L is considered abnormal in pregnancy
- (other methods of estimating renal function, including estimated glomelurlar filatration rate from the Cockroft-Gault equation, are inaccurate in pregnancy).

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
- Tablet to be 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 must return for the results within 7 days**. ART is initiated on ALL HIV positive pregnant women immediately. There is no need to wait for the CD4 and Creatinine results before initiation.**

Counsel Women On FDC Use Itself

- Screen for contra-indications to FDC
    - Known renal disease
    - Previous or current history of psychiatric illness (psychosis)
    - Symptomatic for TB
- Explain what monitoring bloods will be required (CD4, VL, Creatinine – see later slide) and when they will be done
- Counsel that EFV is safe in pregnancy (many clients will read the package insert and panic)
- Common side effects: most self-limiting or develop **tolerance**
    - Somnolence/dizziness/strange dreams common, but usually improve
    - Shift workers need reassurance that symptoms of somnolence/dizziness usually improve
    - Client must be aware of potential renal toxicity but that this will be monitored
    - Explain that FDC unlikely to cause rash
    - Seek attention at clinic/hospital immediately if there is a problem, but emphasise **importance to continue treatment regardless**

NB!!!

- **DO NOT WAIT FOR CD4 AND CREATININE RESULTS BEFORE STARTING THE PATIENT ON TREATMENT**
- **If CD4≤350 cells/mm³: lifelong ART**
- **If CD4>350 cells/mm³: continue ART for duration of pregnancy and FOR ONE WEEK AFTER cessation of breastfeeding**

Already On ART And Pregnant

- Check when CD4, VL and monitoring bloods last done
- Check if virally suppressed
- Continue regimen if suppressed
- Assess adherence if not suppressed
    - Consider second-line ART
- If on EFV-containing regimen, **NO** need to switch
- If on 3 individual drugs (3TC+TDF+EFV) prioritise to FDC

Already on AZT

- Check CD4 cell count has been done. **If no count in past 6 months re-do CD4**
- Take blood for Creatinine
- Change to FDC

HIV Unknown Status In Labour Or Last Negative Test <32 Weeks Or >3 Months Ago

- Offer HIV counseling intrapartum for the benefit of mum and baby

Diagnosed HIV Positive Intrapartum

- Stat NVP and Truvada and 3 hourly AZT
- Start FDC as soon as possible if mom plans to breast feed
- CD4 and Creatinine tests
- To return to clinic/health facility within 7 days for results

Diagnosed HIV Positive Postpartum

- If breastfeeding, start FDC, take CD4 and Creatinine, come back for results within 7 days
- Counsel about EXCLUSIVE breastfeeding
- If seroconverts while breastfeeding
    - Start FDC immediately and do baseline bloods
    - Baby gets NVP for 6/52
    - PCR test for baby in case high degree of suspicion of infection (LBW, Sick baby)
    - If not breastfeeding **there is no need to start ART. Take CD4** and come back for results: if CD4<350 refer for lifelong ART:
    - **If infant<6 weeks old start NVP**

Infant Feeding

- HIV infected mothers (and whose infants are HIV uninfected or of unknown HIV status) should exclusively breastfeed their infants for the first 6 months of life while introducing appropriate complementary foods thereafter, and continue breastfeeding for the first 12 months of life.
- Breastfeeding should then only stop if a nutritionally adequate and safe diet without breast milk is possible
- 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: (referred to as AFASS - affordable, feasible, acceptable, sustainable and safe in the 2007 WHO recommendations **on HIV and Infant Feeding)**
    a) safe water and sanitation are assured at the household level and in the community, and,
    b) the mother, or other caregiver can reliably provide sufficient infant formula milk to support normal growth and development of the infant, and,
    c) the mother or caregiver can prepare it cleanly and frequently enough so that it is safe and carries a low risk of diarrhoea and malnutrition, and
    d) the mother or caregiver can, in the first six months, exclusively give infant formula milk, and,
    e) the family is supportive of this practice, and,
    f) the mother or caregiver can access health care that offers comprehensive child health services.

Infant Nevirapine

- All HIV exposed infants would take Nevirapine syrup for only 6 weeks irrespective of feeding choice
- Birth weight >2500g: 1,5ml daily at the same time **everyday**
- Birth weight<2500g: 1ml daily at the same time **everyday**

Infant Testing

- 6 week PCR teting for all HIV exposed infants
- If breastfed, repeat PCR 6 weeks after cessation of breastfeeding
- 18 month ELISA
- **Test at any age if symptomatic**
- **Please note: A negative PCR test any time before 6 weeks of age needs to be repeated at 6 weeks**

Monitoring Bloods

- Creatinine
    - If on TDF
    - Baseline, 3 months, 6 months, 12 months then annually
- CD4
    - Baseline and then annually
- VL
    - 6 months, 12 months and then annually
- **Remind mom to take ART to the hospital / clinic when in labour**
- **Remind mom to take ART** at usual time during labour and delivery or caesarean section
- Remind mom to have enough for the entire hospital stay
- Never to run out of medication
- Go to the clinic before the tablets run out, not after
- Have enough until the follow up visit post delivery
- Know where to follow up before discharge from hospital

Key Messages for PMTCT

Key Message – 1

- All ANC clients (newly diagnosed as HIV positive and those pregnant but not yet on HAART) to start FDC (single pill)/ART on the same day as 1st visit
- CD4 and creatinine test to be done and client asked to return within 7 days
- Further management based on CD4 counts, creatinine levels – see algorithms in the PMTCT guidelines

Key message -2

- All ANC clients that test HIV negative during pregnancy to repeat test every 12 weeks/3 months after 1 test, and/or at 32 weeks of gestation or later, at labour, during the postnatal period throughout period of breastfeeding
- Infant testing algorithm in the revised guidelines to be followed.

(Generated from DHIS on 2013/03/08)

IndicatorName	Numerator	Numerator Formula	Denominator	Denominator Formula	Definition	Use and Context	Type
Antenatal 1st visit before 20 weeks rate	Antenatal 1st visit before 20 weeks	SUM([Antenatal 1st visit before 20 weeks])	Antenatal 1st visit total	SUM([Antenatal 1st visit 20 weeks or later]) + SUM([Antenatal 1st visit before 20 weeks])	Women who have a booking visit (first visit) before they are 14 weeks into their pregnancy as proportion of all antenatal 1st visits	Monitors early utilisation of antenatal services	%
Antenatal 1st visit coverage (annualised)	Antenatal 1st visit total	SUM([Antenatal 1st visit 20 weeks or later]) + SUM([Antenatal 1st visit before 20 weeks])	Population estimated pregnant women (at ~10 weeks)	(SUM([Female under 1 year]) + SUM([Male under 1 year])) * 1.15	The proportion of potential antenatal clients coming for at least one (booking) antenatal visit. The census number of children under one year factorised by 1.15 is used as a proxy denominator - the extra 0.15 (15%) is a rough estimate to cater for late miscarriages (~10 to 26 w), still births (after 26 weeks gestation) and infant mortality. Pregnant women are regarded as potential antenatal clients from around 10 weeks gestation, i.e. spontaneous abortions before that as well as TOP cases are excluded	Monitors access to and utilisation of antenatal services	%
Antenatal client HIV 1st test positive rate	Antenatal client HIV 1st test positive	SUM([Antenatal client HIV 1st test positive])	Antenatal client HIV 1st test	SUM([Antenatal client HIV 1st test])	Antenatal clients tested HIV positive as proportion of antenatal clients HIV tested for the first time during current pregnancy	Monitors trends in HIV test positivity of antenatal clients and initiation of HIV positive antenatal clients on ART	%
Antenatal client HIV re-test at 32 weeks or later rate	Antenatal client HIV re-test at 32 weeks or later	SUM([Antenatal client HIV re-test at 32 weeks or later])	Antenatal client HIV 1st test negative	SUM([Antenatal client HIV 1st test]) - SUM([Antenatal client HIV 1st test positive])	Antenatal clients re-tested for HIV at 32 weeks gestation (or later) as proportion of antenatal clients tested negative for 1st HIV tests done during current pregnancy	Monitors implementation of PMTCT guidelines in terms of HIV re-testing at 32 weeks gestation. Used as a proxy indicator as it is not cost effective to monitor cohorts with paper-based systems	%
Antenatal client HIV re-test positive at 32 weeks or later rate	Antenatal client HIV re-test positive at 32 weeks or later	SUM([Antenatal client HIV re-test positive at 32 weeks or later])	Antenatal client HIV re-test at 32 weeks or later	SUM([Antenatal client HIV re-test at 32 weeks or later])	Antenatal clients re-tested positive for HIV at 32 weeks gestation (or later) as proportion of antenatal clients re-tested for HIV at 32 weeks (or later)	Monitors HIV infection during pregnancy	%
Antenatal client initiated on ART rate	Antenatal client initiated on ART	SUM([Antenatal client INITIATED on ART])	Antenatal client eligible for ART	SUM([Antenatal client HIV 1st test positive]) + SUM([Antenatal client HIV re-test positive at 32 weeks or later]) + SUM([Antenatal client known HIV positive but NOT on ART at 1st visit])	Antenatal clients on ART as a proportion of the total number of antenatal clients who are HIV positive and not previously on ART	Monitors implementation of PMTCT guidelines in terms of ART initiation of eligible HIV positive antenatal clients	%
Infant given NVP within 72 hours after birth uptake rate	Infant given NVP within 72 hours after birth	SUM([Infant given Nevirapine within 72 hours after birth])	Live birth to HIV positive woman	SUM([Live birth to HIV positive woman])	Infants given Nevirapine (NVP) within 72 hours of birth as proportion of live births to HIV positive women	Monitors implementation of the PMTCT guidelines in terms of NVP for HIV exposed infants	%
ART prophylaxis discontinued within 12 months after delivery rate	ART prophylaxis discontinued within 12 months after delivery	SUM([ART prophylaxis discontinued within 12 months after delivery])	Antenatal client initiated on ART	SUM([Antenatal client INITIATED on ART])	Antenatal clients on ART as a proportion of the total number of antenatal clients who are HIV positive and not previously on ART	Monitors implementation of PMTCT guidelines in terms of ART initiation of eligible HIV positive antenatal clients	%
Infant initiated on CPT around 6 weeks uptake rate	Infant initiated on CPT around 6 weeks uptake	SUM([Infant initiated on CPT around 6 weeks])	Live birth to HIV positive woman	SUM([Live birth to HIV positive woman])	Infants initiated on Co-Trimoxazole (CPT) around 6 weeks after birth (to prevent opportunistic infections) as proportion of live births to HIV positive women	Monitors implementation of the PMTCT guidelines in terms of Co-Trimoxazole prophylaxis (CPT) for HIV exposed Infants	%
Infant 1st PCR test around 6 weeks uptake rate	Infant 1st PCR test around 6 weeks uptake	SUM([Infant 1st PCR test around 6 weeks])	Live birth to HIV positive woman	SUM([Live birth to HIV positive woman])	Infants PCR tested for the first time around 6 weeks after birth as proportion of live births to HIV positive women	Monitors implementation of PMTCT guidelines in terms of PCR testing of HIV exposed Infants around 6 months. Infants PCR tested for the first time between 4 and 8 weeks must be included. Do NOT include repeat tests.	%
Infant 1st PCR test positive around 6 weeks rate	Infant 1st PCR test positive around 6 weeks	SUM([Infant 1st PCR test positive around 6 weeks])	Infant 1st PCR test around 6 weeks uptake rate	SUM([Infant 1st PCR test around 6 weeks])	Infants tested PCR positive for the first time around 6 weeks after birth as proportion of Infants PCR tested within 2 months	Monitors positivity in HIV exposed Infants around 6 weeks	%
Infant rapid HIV test around 18 months uptake rate	Infant rapid HIV test around 18 months	SUM([Infant rapid HIV test around 18 months])	Live birth to HIV positive woman	SUM([Live birth to HIV positive woman])	Infant rapid HIV test around 18 months after birth as the proportion of infants under 18 months. The denominator is collected 18 months before the numerator thus the indicator formula uses Live birth to HIV positive woman recorded 18 months ago in order to provide reliable output	Monitors the HIV sero-conversion of HIV exposed infants after 18 months	%
Infant rapid HIV test around 18 months positive rate	Infant rapid HIV test positive around 18 months	SUM([Infant rapid HIV test positive around 18 months])	Infant rapid HIV test around 18 months	SUM([Infant rapid HIV test around 18 months])	Infants tested positive for HIV antibodies around 18 months after birth as the proportion of Infants tested for HIV antibodies around 18 months.	Monitors the HIV sero-conversion of HIV exposed infants after 18 months	%

DataElementName	Definition	Definition_Extended	Use and Context	Inclusions	Exclusions	Calc	Collected By	Collection Points	Tools
Antenatal 1st visit before 20 weeks	A first visit by a pregnant woman to a health facility that occurs before 20 weeks after conception	The first visit by a pregnant woman within 20 weeks after conception to primarily receive antenatal care according to BANC. The first antenatal visit is often referred to as a 'booking visit'	The actual protocol followed during the visit might vary but it should include: Relevant screening procedures, laboratory tests (e.g. for syphilis), counselling and health promotion (often done in groups)		EXCLUDE a visit purely to take a pregnancy test	0	Clinician	PHC facility	Tick Register PHC
Antenatal 1st visit 20 weeks or later	A first visit by a pregnant woman to a health facility that occurs 20 weeks after conception or later	The first visit by a pregnant woman to a health facility 20 weeks or more after conception to primarily receive antenatal care according to BANC. The first antenatal visit is often referred to as a 'booking visit'	The actual protocol followed during the visit might vary but it should include: Relevant screening procedures, laboratory tests (e.g. for syphilis), counselling and health promotion (often done in groups)		EXCLUDE a visit purely to take a pregnancy test	0	Clinician	PHC facility	Tick Register PHC
Antenatal 1st visit total	First antenatal care visit to a health facility often referred to as a `booking visit` irrespective of the number of weeks pregnant		Auto-calculated by the DHIS: Antenatal 1st visit 20 weeks or later **PLUS** Antenatal 1st visit before 20 weeks			1	N/A	N/A	DHIS calculate
Antenatal client known HIV positive but NOT on ART at 1st visit	Antenatal clients with known HIV positive status but not on ART at their first antenatal visit. In the absence of documented proof, verbal confirmation of HIV status is acceptable and a CD4 count test must be done					0	Clinician	PHC facility	Tick Register PHC
Antenatal client HIV 1st test	Antenatal client who was tested for the first time during her current pregnancy	Antenatal clients should preferably be tested at first antenatal visits but may be tested for the first time at a subsequent follow-up visit	Each antenatal client who is not known HIV positive should be tested during her 1st antenatal visit			0	Clinician	Health facility	Tick Register PHC
Antenatal client HIV 1st test positive	Antenatal clients who tested positive for the first HIV test done during the current pregnancy	Count ONLY once on the day the HIV test was confirmed positive				0	Clinician	Health facility	Tick Register PHC
Antenatal client HIV re-test at 32 weeks or later	Antenatal clients who were re-tested for HIV at 32 weeks gestation or later after testing negative for HIV during an earlier antenatal visit	Each ANC client whose first HIV test was negative should be re-tested at 32 weeks or later to detect late sero-converters	The period between the first test and re-test should be at least 6 weeks			0	Clinician	Health facility	Tick Register PHC
Antenatal client HIV re-test positive at 32 weeks or later	Antenatal client who was tested positive for HIV at 32 weeks gestation or later after testing negative for HIV during an earlier antenatal visit	Count ONLY once on the day the HIV test was confirmed positive				0	Clinician	Health facility	Tick Register PHC
Antenatal client eligible for ART initiation	Antenatal clients who tested HIV positive during or before the pregnancy and are not on ART at 1st visit	Up until 2013/04/01 the criteria for ART initiation for antenatal women were: HIV positive antenatal client with a CD4 count under the specified threshold and/or a WHO staging of 4	Auto-calculated by the DHIS: Antenatal client known HIV positive but NOT on ART at 1st visit **PLUS** Antenatal client HIV 1st test positive **PLUS** Antenatal client HIV re-test positive at 32 weeks or later			1	Clinician	PHC facilities	DHIS calculate
Antenatal client INITIATED on ART	HIV positive antenatal clients who were initiated on ART during their current pregnancy	This may be viewed as an ART data element but is crucial for monitoring effective implementation of the PMTCT program. Collect ONLY at facility where ART is initiated				0	Clinician	ART Site	ART Register

									Antenatal 1st visit before 20 weeks	Tick register
									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	
									Live birth to HIV positive woman	Delivery register
									Infant given Nevirapine within 72 hours after birth	

Infants and Children Guidelines

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 < 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 (and < 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

Note: Children ≥ 3 years and exposed to NVP for 6 weeks or longer (PMTCT) should be initiated on ABC + 3TC + LPV/r

Second Line Regimen	
Failed First line Protease Inhibitor (PI) based regimen	
Failed First line PI Based regimen	***Recommended Second line regimen***
ABC + 3TC + LPV/r	**Consult with expert for advice***
D4T + 3TC + LPV/r	
Unboosted PI based regimen	
Failed First line NNRTI based regimen (discuss with expert before changing)	
Failed First line NNRTI Based regimen	***Recommended Second line regimen***
ABC + 3TC + EFV (or NVP)	AZT + 3TC + LPV/r
d4T + 3TC + EFV (or NVP)	AZT + ABC + LPV/r

Advice For The Expert

*Recommended Second Line regimen under expert advice	
ABC + 3TC + LPV/r	No previous daily NVP for PMTCT AZT + 3TC + EFV* + LPV/r * Use NVP if < 3 years or <10kg Previous Daily NVP for PMTCT Treat with Third line regimen
D4T + 3TC + LPV/r	No previous daily NVP for PMTCT AZT + ABC + EFV* + LPV/r * Use NVP if < 3 years or <10kg Previous Daily NVP for PMTCT Treat with Third line regimen
Previously on a regimen with unboosted PI (e.g. ritonavir alone), or with rifampicin while on LPV/r	Must be managed by an expert on basis of genotype resistance testing to confirm PI susceptibility.

Third line regimens	
Failing any 2nd line regimen	**Refer for specialist opinion – Regimen based on genotype resistance testing, expert opinion and supervised care.** **Access to third line ART will be managed centrally by the National Dept of Health.**

Investigations – At Diagnosis

At initial Diagnosis of HIV	Purpose
Verify HIV status	Ensure that national testing algorithm has been followed
Document weight, height, head circumference (<2yrs) and development	To monitor growth and development + identify eligibility for ART
Screen for TB symptoms	To identify TB/HIV co-infected
WHO Clinical Staging	To determine if patient is eligible for ART
Do the CD4 count	Children < 5 years – Baseline, DO NOT wait for CD4 count to start ART
	Children ≥ 5 years - To determine eligibility for ART and start cotrimoxazole prophylaxis as per national guideline
Hb or FBC if available	To detect anaemia or neutropenia

Investigations – Baseline

At Initiation of ART (Baseline)	Purpose
Hb or FBC	If less than 8 g/dl start ART and refer for specialist opinion
CD4 count (if not performed in last 6 months)	Baseline assessment
HIV Viral Load (VL)	Baseline assessment
Cholesterol + Triglyceride if on PI based regimen	Baseline assessment

Creatinine + urine dipstix if on TDF regimen	If abnormal refer for specialist opinion
ALT (if Jaundice or on TB treatment)	To assess for liver dysfunction

Monitoring – Treatment Response

On ART	Purpose
Height, weight, head circumference (<2yrs) and development	To monitor growth and development stages
Clinical assessment	To monitor response to ART and exclude adverse effects
CD4 at 1 year into ART, and then every 12 months	To monitor response to ART, stop cotrimoxazole prophylaxis as per national guideline
VL at month 6, 1 year into ART, then every 6 monthly in children < 5 years / 12 monthly in children 5 years to 15 years	To monitor viral suppression response to ART To identify treatment failure and to identify problems with adherence

Monitoring – Adverse Events

On ART	Purpose
Hb or FBC at month 1, 2, 3 and then annually if on AZT	To identify AZT-related anaemia
Cholesterol + Triglyceride at 1 year and then every 12 months if on PI based regimen	To monitor for PI-related metabolic side-effects
Clinical drug-related adverse events	To identify drug-related adverse events If develops jaundice or rash on EFV or NVP do Liver function test and refer to specialist

Adults and Adolescent Guidelines

Key Updates in 2013 Guidelines

- Timing of ART initiation in treatment-naive patients remains at cd4 count at 350
- Treatment as prevention based on early initiation and adherence support
- Guidance on introduction of the fixed dosed 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

Risks and Benefits of Earlier Initiation of ART

Delayed ART

- Drug toxicity
- Preservation of limited Rx options
- Risk of resistance (and transmission of resistant virus)

Early ART

- ↑ potency, durability, simplicity, safety of current regimens
- ↓ emergence of resistance
- ↓ toxicity with earlier therapy
- Risk of uncontrolled viremia
- Near normal survival if CD4+ count > 500
- ↓ transmission

Guidelines Moving Toward Early Treatment

- Early diagnosis, timely treatment can change the course of the epidemic

- Changes to guidelines reflect these goals
    - Evolution toward treatment of essentially all patients
    - Inclusion of treatment as prevention

Adults and Adolescent Eligibility to Start ART

Eligible to start ART
▪ CD4 count ≤350 cells/mm3 irrespective of WHO clinical stage **OR** ▪ Irrespective of CD4 count ○ All types of TB (In patients with TB/HIV drug resistant or sensitive TB, including extra pulmonary TB) ○ HIV positive women who are pregnant or breast feeding **OR** • Patients with Cryptococcus meningitis or TB meningitis (defer ART for 4-6 weeks) ▪ WHO stage 3 or 4 irrespective of CD4 count
Require fast track (i.e. ART initiation within 7 days of being eligible)
▪ 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 CD4 above 350, Not yet eligible for ART
▪ Transfer to a wellness programme for regular follow-up and repeat CD4 testing 6-monthly. ▪ Advise on how to avoid HIV transmission to sexual partners and children ▪ Initiate INH prophylaxis if asymptomatic for TB ▪ Provide counselling on nutrition and contraceptive and do annual pap smear

Standardised national ART regimens for adults and adolescents

1st Line		
All new patients needing treatment, including pregnant women	TDF + FTC (or 3TC) +EFV FDC preferred	Replace EFV with NVP in patients with significant psychiatric co-morbidity or intolerance to EFV and where the neuro-psychiatric toxicity of EFV may impair daily functioning, e.g. shift workers.
Contraindications to EFV	TDF + (FTC or 3TC) + NVP	Use NVP based regimen: In patients with significant psychiatric co morbidity or intolerance to EFV and where the neuro-psychiatric toxicity of EFV may impair daily functioning, e.g. shift workers.

1st Line		
Contraindication to TDF	AZT+ 3TC +EFV or (NVP)	Renal disease or the use of other nephrotoxic drugs e.g. aminoglycosides
Contraindication to TDF and AZT	d4T + 3TC+ EFV (or NVP)	Renal disease and anaemia or the use of other nephrotoxic drugs, aminoglycosides
Contraindication to TDF, AZT and d4T	ABC + 3TC + EFV (or NVP)	Renal disease, anaemia, peripheral neuropathy, the use of other nephrotoxic drugs
Currently on d4T-based regimen	TDF + FTC(or 3TC) + EFV FDC preferred	Mandatory if patients experience toxicity and patients who are at high risk of toxicity (high BMI or pregnant). Switch to TDF if virally suppressed and the patient has normal creatinine clearance, even if well tolerated.
2ndLine		
Management of virological failure		If plasma HIV RNA >1000 copies, Check for adherence, compliance, tolerability and drug- drug interaction and assess psychological issues. Repeat VL test 2 months later. If plasma VL confirmed >1000copies change regime to second line therapy
Failing on a TDF-based 1st line regimen	AZT+3TC+ LPV/r	Patients with anaemia and renal failure switch to ABC
Failing on a d4T-based 1st line regimen	TDF+3TC (or FTC) and LPV/r	
Dyslipidaemia or diarrhoea associated with LPV/r	Switch LPV/r to ATV/r	
Third line		
Failing any 2nd line regimen	Specialist referral	
Should be expert and genotype resistance testing based decision and supervised care Patients failing on second line therapy will be managed by an expert panel. The drugs for third line will be managed centrally. More discussion is required to deal with the modalities	Most likely regimen would be Raltegravir/Darunavir/ /Etravirine adjusted according to genotype Interpretation. Should be by expert and take into account prior exposure and predictable mutations	

Standardized National Monitoring for Adults and Adolescents with HIV

At initial Diagnosis of HIV	Purpose
Confirm HIV result with rapid antibody test	Ensure that national testing algorithm has been followed
Do CD4 count if HIV positive and WHO clinical staging	To assess eligibility for ART To assess eligibility for fast-tracking
Screen for pregnancy or ask if planning to conceive	To identify women who need ART for life or ARV prophylaxis for PMTCT (see section 6)
Screen for TB symptoms using the WHO questionnaire	To identify TB/HIV co-infected
Do the CD4 count on the same day	To identify eligibility for ART or ARVs for prophylaxis if pregnant
Do HB or FBC if requires AZT Creatinine if requires TDF For patients initiated on Nevirapine based regime do ALT	To detect anaemia or neutropenia, To detect renal insufficiency To exclude liver disease

On ART	Purpose
CD4 at 1 year on ART	To monitor immune response to ART
VL at month 6, 1 year on ART and then every 12 months	To identify treatment failures and problems with adherence
ALT only if on NVP and develops rash or symptoms of hepatitis	To identify NVP toxicity
FBC at month 3 and 6 if on AZT	To identify AZT toxicity
Creatinine at month 3 and 6, 1 year then every 12 months if on TDF	To identify TDF toxicity
Fasting cholesterol and triglycerides at month 3 if on LPV/r	To identify LPV/r toxicity

At Routine Follow-Up Visits for those not yet eligible for ART	Purpose
Repeat CD4 count at 6 months	To see if they have become eligible for ART
WHO clinical staging at every visit	To see if they have become eligible for ART
Screen for TB symptoms to identify TB suspects Offer IPT if no TB symptoms	To identify TB/HIV co-infection To prevent TB activation
Offer prevention for HIV positives	To prevent HIV transmission and re-infection To prevent STIs

Indications for urgent up-referral prior to initiation or when on therapy

- eGFR less than 60 ml/min
- Hb less than 8 g/dl
- BMI less than 18.5 kg/m2
- In a patient with TB, poor response to TB treatment

Case Studies

Group Work Instructions

1. Participants to form a team of 4-5 persons
2. Each team will receive a different case study to work on
3. The purpose of the case studies is to apply the technical information to real life settings
4. Each team will have 30 minutes to discuss the case study and answer the key questions.
    i. One group member should be selected to facilitate the group discussion;
    ii. one to take notes on a flip chart (if available) and
    iii. one to present to the plenary.
5. Each team will prepare a 10 minute presentation of their findings

For each case the team members must answer **4 questions :**

1. How would you treat the patient today? (give a detailed account of clinical practice)
2. What follow-up treatment is required?
3. What referrals would you make for the patient?
4. What is the data element you would need to capture/ note in each case?

These questions must be applied to the woman and if she has a new born baby the questions will also apply to the baby

Present Back to Plenary:

- Each group will have 10 minutes to present back to the plenary
- Discussion: the presentation will be followed by 5 minutes of discussion per case study including questions of clarification

PMTCT Cases

Case Study 1: Unbooked Pregnant Women

Lebo has not had any antenatal care. She is 38 weeks pregnant and is starting to have contractions. She asks her mother to take her to the nearest health facility.

1. How would you treat the patient today? (give a detailed account of clinical practice)
2. What follow-up treatment is required?
3. What referrals would you make for the patient
4. What is the data element you would need to capture/ note in each case?

Case Study 2: First ANC Visit

Thandi is 18 weeks pregnant. She goes to her clinic for her first antenatal care visit. At this visit she is offered an HIV test and the result is positive.

1. How would you treat the patient today? (give a detailed account of clinical practice)
2. What follow-up treatment is required?
3. What referrals would you make for the patient?
4. What is the data element you would need to capture/ note in each case?

Case Study 3: Return Visit

Thandi has had two previous antenatal care visits. The first visit was at approximately 20 weeks and another visit at 28 weeks. At her first ANC visit she had an HIV test. At that time, she tested negative. She is now 34 weeks pregnant. Her partner has been very sick for the past 4 weeks but refuses to go to the doctor.

1. How would you treat the patient today? (give a detailed account of clinical practice)
2. What follow-up treatment is required?
3. What referrals would you make for the patient
4. What is the data element you would need to capture/ note in each case?

Case Study 4: 6 days Postnatal Visit

Tsipwe's has been breastfeeding her baby since birth. She has brought her baby to the clinic for a checkup at 6 days. During pregnancy, Tsipwe was enrolled in the PMTCT programme

1. How would you treat the patient today? (give a detailed account of clinical practice)
2. What follow-up treatment is required?
3. What referrals would you make for the patient
4. What is the data element you would need to capture/ note in each case?

Case Study 5: TB and HIV

Lerato is pregnant with her first baby. She is approximately 16 weeks pregnant, but has not had any antenatal care yet. She has not been feeling very well, she thinks it may be because she is pregnant. Her symptoms include a cough, fever, night sweats and weight loss despite being pregnant. She comes to the health facility for antenatal care.

1. How would you treat the patient today? (give a detailed account of clinical practice)
2. What follow-up treatment is required?
3. What referrals would you make for the patient
4. What is the data element you would need to capture/ note in each case?

Case Study 6: Failure to Thrive Baby

Sesupo's baby is 8 weeks old. She has noticed that the baby is not gaining weight and appears to be sick. Sesupo was in the PMTCT programme during pregnancy, but because she has no help with the baby she has not taken the baby back to the facility for check-ups since birth. She takes her baby to the clinic.

1. How would you treat the patient today? (give a detailed account of clinical practice)
2. What follow-up treatment is required?
3. What referrals would you make for the patient
4. What is the data element you would need to capture/ note in each case?

Infant and Children Cases

Case Study 1: Eligibility For Art

Decide whether or not the following children are eligible to receive ART. Assume that age-appropriate HIV test has been done and HIV infection has been confirmed.

	AGE	STAGE	CD4 COUNT/PERCENTAGE	ANSWER
1.	4 years	1	900 cells/mm^3 or 40%	
2.	6 months	4	100 cells/mm^3 or 15%	
3.	9 months	1	950 cells/mm^3 or 45%	
4.	3 years	3	Not known	
5.	9 years	1	200 cells/mm^3	
6.	12 years	4	900 cells/mm^3	
7.	3 month	1	Not known	
8.	14 years	2	900 cells/mm^3	
9.	18 months	1	830 cells/mm^3 or 20%	
10.	6 month old	2	1500 cells/mm^3	

Case Study 2: Nancy: infant (<1yr)

Nancy is three months old and weighs 6 kg. Her mother was found to be HIV-infected during pregnancy. Nancy was tested for HIV at six weeks and PCR results are positive. A full blood count done at the same time, showed that her Hb is 11g/dL. She is breastfeeding and is generally well. Her length is 60 cm and her head circumference is 41 cm. Her temperature was recorded as 36.5^0C. She lifts her head when her mother carries her with support, responds to sounds and follows close objects with both eyes.

Her mother has not disclosed her own or Nancy's HIV status to anyone at home, but is a regular member of the clinic support group. She has been counselled regarding adherence, and is available and committed in ensuring that Nancy receives HIV care and Support.

a) Is Nancy eligible for ART? List the eligibility criteria that you have considered.

b) If you decide that she is eligible for ART, provide clinical management.

Case Study 3: Thabo: Child (1-5Yrs)

Thabo is a 4 year old boy. He has severe oral thrush. His temperature is 36.7 ^{0}C and his weight now is 12.3 kg. For the past 3 months his weight was 9.8 kg – he has not received any treatment for poor weight gain. A rapid test was done which shows that he is HIV positive. The diagnosis is confirmed with a second rapid test which is also positive and his blood was sent to the laboratory for a CD4 count and Viral Load today.

Thabo's mother has been on ART for the past 4 years. She has been taking her medication every day and is very motivated to take care of herself and of Thabo. She is supported by her mother who know that she is HIV-infected and on treatment. She now asks that Thabo should also receive ART. Thabo lives with his mother. She runs a spaza shop from home and looks after Thabo as well.

a) Is Thabo eligible for ART? List the eligibility criteria that you have considered.

b) If you decide that he is eligible for ART, how are going to manage Thabo

Case Study 4: Sara (Adolescent): case targeted at Drs

Sara is a **14 years** old girl in high school. She was born with HIV and has been on ARVs (ABC + 3TC+ EFV) for 7 years. Her mom who is also on ARVs reports that she (Sara) comes back home late this days-probably because she is at adolescent stage, she was no longer adhering to her treatment, and at times she missed clinic visits.

Three months ago her, VL was 1100 and today is 1 200, she looks sick and her mom is worried. Last month she has joined her mom in a support group and improvement on adherence has been noted.

Case Study 5: Providing ART follow-up care

Sipho is 23 months old boy, currently 18 months on ARVs (1st regimen), CD4 count, VL, Cholesterol + Triglycerides was done 12 months ago. He is responding well to treatment. No side effects ever reported by his mom. Today he came for his routine follow-up visit.

a) Provide routine follow-up care to him

Adult and Adolescent Cases

Case 1

A 47 year-old male presents at your clinic. He is HIV-infected. He weighs 62 kg, has CD4 count 170 cells/mm^3. He does not have active TB or any other opportunistic infections at present. He is taking cotrimoxazole prophylaxis without any notable side effects.

Is this patient eligible for ART? Why or why not?

If the patient is eligible for ART, what regimen should he start? What is the appropriate dose of each medication?

What lab tests should be obtained at baseline and when should they be repeated?

Case 2

A 26 year-old female presents at your clinic. She is HIV-infected. Her weight is 65 kg, who was treated for PCP 6 weeks ago. She is not currently pregnant and declines contraceptives. No active TB and no other opportunistic infections at present. She is taking cotrimoxazole prophylaxis without any apparent side effects.

Is this patient eligible for ART? Why or why not?

If the patient is eligible for ART, what regimen should they start? What is the appropriate dose of each medication?

What labs should be obtained at baseline and when should they be repeated?

Case 3

A 35 year-old male presents at your clinic. He is HIV-infected. He weighs 70 kg and has no history of recent weight loss. He has a current CD4 count of 400 cells/mm^3. He has a history of herpes zoster 2 years ago. No active TB at present or other opportunistic infections. He is taking cotrimoxazole with no apparent side effects.

Is this patient eligible for ART? Why or why not?

If the patient is eligible for ART, what regimen should they start? What is the appropriate dose of each medication?

What follow-up labs should be obtained?

Case 4

A 30 year-old female presents at your clinic. She is HIV-infected. She weighs 55kg, with a CD4 of 156 cells/ mm^3. She is on an injectable contraceptive. She was diagnosed with pulmonary TB and started on TB therapy a week ago. She does not appear to have any significant adverse events related to the medications.

1. Is this patient eligible for ART? Why or why not?

If the patient is eligible for ART, what regimen should they start? What is the appropriate dose of each medication?

What labs should be obtained at baseline and when should they be repeated?

Case 5

A 26 year-old male presents with a history of ART for one year and one month. Current regimen: stavudine, lamivudine and efavirenz. He has no symptoms today and reluctantly reports missing "several doses" over the past several months.

Vitals: Temp: 37C, Respiratory Rate: 16, Pulse: 67, Blood Pressure: 110/75

Exam: Within Normal Limits

Baseline CD4/VL: 130 cells/mm^3, 100,580 copies/mL

6 month CD4/VL: 250 cells/mm^3, < 400 copies/mL

1 year CD4/VL: 175 cells/mm^3, 10,890 copies /Ml

What do you suspect is occurring?

Is there an indication for switching or stopping a regimen? Why or why not?

If so, what should take place next and if the regimen needs to be changed, what part of the regimen should be switched/ stopped?

Overview on ART Treatment Regimen Changes

As of April 1st, 2013, changes to the ART treatment regimens will be implemented across the country. The target audience for this communication brief are all cadres of health care workers who interact with pregnant women, mothers and infants, and children.

Background:

On December 1, 2012, the Minister of Health announced the inclusion of fixed drug combinations (FDCs) for the national ART programme. This is a positive change for the programme and will benefit the patient and the health system, resulting in a more effective programme.

What are FDCs?

- FDC are combinations of two or more active drugs in a single dosage form

What are the programmatic benefits of FDCs?

For the patient:

- One Pill – convenient dosage regimen
- Easier to take
- Compliance
- Fewer side effects

For the health service:

- Easier storage
- Easier logistics

What do the guideline changes mean for women and children?

- All HIV positive pregnant women will start the triple drug prophylaxis from 14 weeks of pregnancy and continue throughout the breastfeeding period.
- Following the breast feeding period, women with CD4 counts less than 350 will continue on the triple drug prophylaxis.
- The fixed dose combination is more effective than dual therapy and has fewer side effects for the pregnant mother, in addition to its' convenient dosage regimen."

What are the changes in the new guidelines?

PMTCT Regimen

All pregnant women:

- Encourage all women to book early in pregnancy, preferably before 14 weeks gestation. All women coming to the clinic for first antenatal booking must be seen on the same day
- Booking bloods should include RPR, Rh, Hb check and HIV testing
- Tetanus; Iron, folic acid, vitamin C, Calcium should also be given at the first visit

For women who test negative at first ANC visit:

- Retest (12 weeks after the first HIV test) and/or at 32 weeks of gestation, in labour; 6 weeks postpartum; every 3 months while breastfeeding; and thereafter annually.

For women who test positive at first ANC visit:

- 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
- This tablet to be taken once a day, in the evening at the same time
- Creatinine and CD4 are done on that same day and the patient must return for the results within 7 days. ART is initiated on ALL HIV positive pregnant women immediately. There is no need to wait for the CD4 and Creatinine results before giving the FDC. This must take place on the same day.

Depending on CD4 test results, treatment options are:

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

For women who are on AZT at first ANC visit:

- Check CD4 cell count has been done. If not done in the past 6 months, repeat CD4 cell counts
- Take blood for Creatinine levels
- Change to FDC regimen on the same day as the ANC visit and ask women to return within 7 days for the blood results.

For women who are already on ART and pregnant

- Check when CD4, VL and monitoring bloods were last done
- Check if virally suppressed
    - Continue regimen if suppressed
    - Assess adherence if not suppressed
- If on 3 individual drugs (3TC+TDF+EFV) prioritise to FDC

For women who are diagnosed HIV positive during the intrapartum period

- Stat NVP and Truvada and 3 hourly AZT
- Start FDC as soon as possible if mom plans to breast feed
- CD4 and Creatinine tests
- To return to clinic within 7 days for results

All HIV Exposed Infants

- Nevirapine syrup for 6 weeks irrespective of feeding choice
    - Birth weight >2500g: 1,5ml daily at the same time everyday
    - Birth weight<2500g: 1ml daily at the same time everyday
- 6 week PCR tests for all HIV exposed infants
- In case a PCR test was done before 6 weeks due to any reason and was negative, repeat PCR test at 6 weeks for the infant
- If breastfed, repeat PCR tests 6 weeks after cessation of breastfeeding
- Exclusive breast feeding is the recommended feeding choice.
- 18 month rapid HIV tests done for all HIV exposed infants
- Test at any age if symptomatic (if < 18 months do a PCR test, and if >18 months do a HIV rapid test for diagnosis)