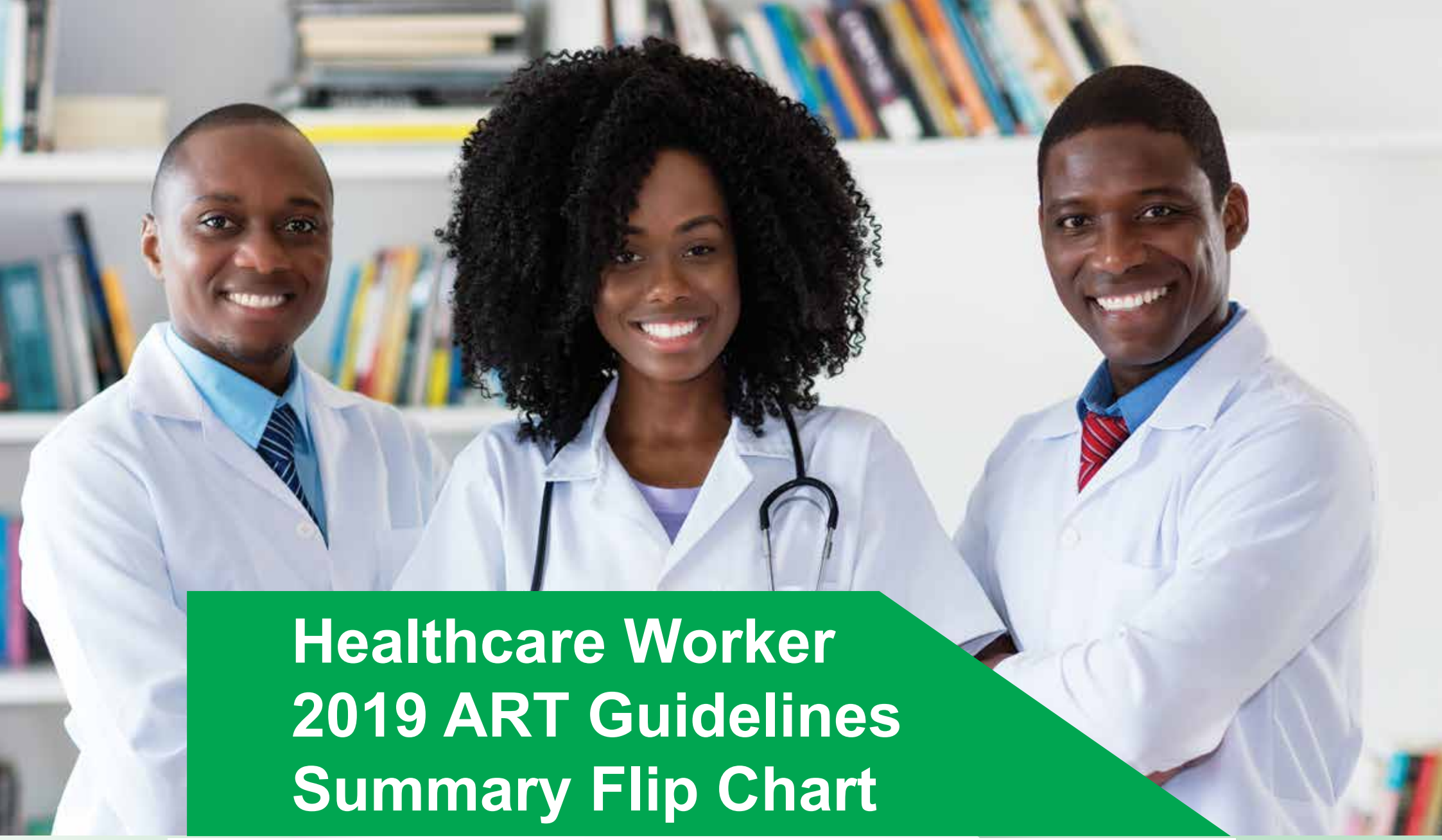


Healthcare Worker 2019 ART Guidelines Summary Flip Chart

health
Department:
Health
REPUBLIC OF SOUTH AFRICA

PEPFAR
U.S. President's Emergency Plan for AIDS Relief

2030 NDP

TABLE OF CONTENTS	PAGE

Guidance on this job aid

Why this job aid was developed

The purpose of this job aid is to enable quick reference to some important aspects of the 2019 guidelines.

The flip chart is to be used with reference to

The 2019 ART clinical Guidelines for the management of HIV in Adults, Pregnancy, Adolescents, Children, Infants, and Neonates.

The Standard operating procedures titled CCMDD-SOP16: Tenofovir & Lamivudine & Dolutegravir (TLD) - patient registration or transition.

Dolutegravir

NEW

An Integrase inhibitor – can be used in children from a weight of 20kg

TLD = TDF, 3TC, DTG: A fixed dose combination, to be used in persons ≥ 10 years and ≥ 35kg

PROPERTY OF DTG	DESCRIPTION
EFFICACY	Among the treatment naïve patients, DTG is **superior to both efavirenz (EFV) and ritonavir-boosted darunavir.**
TOLERANCE	**Better tolerated** and tends to be protective against treatment discontinuation due to fewer adverse events (AEs)
SAFETY	**Most adverse effects are mild and self limiting** (<5%) Pharmacovigilance is essential with new drug introduction
DRUG RESISTANCE	High barrier to resistance
METABOLISM	No need to adjust for renal dysfunction
COST	The prices of DTG formulations are 10–15% lower than current EFV based regimens

Benefits and risks of DTG vs EFV

Benefits of using DTG	Risks of using DTG
Provides rapid viral suppression	DTG may increase the risk of **neural tube defects (NTDs)** if used before or in the first six weeks of pregnancy
High genetic barrier to resistance	
No interaction with hormonal contraceptives	Drug interactions with rifampicin, metformin,anticonvulsants, and polyvalent cations (Mg2+, Fe2+, Ca2+, etc.)
Side effects are mild and uncommon	

Benefits of using EFV	Risks of using EFV
Safe in pregnancy	Low genetic barrier to resistance
No significant interaction with TB treatment	Drug interactions with contraceptives
	Neuropsychiatric side effects

Contraceptive options need to be available to women of reproductive potential on DTG

Women should be **provided a choice of contraceptives**, which includes condoms, oral contraceptives, implants, injectables, and intra-uterine contraceptive devices. Dual methods are recommended; a hormonal method or IUCD or Sterilization to prevent pregnancy, and a barrier method (male/female condoms) to prevent STI and HIV transmission.

Contraceptive choices need to **respect human rights** and enable the clients to make informed choices for themselves. Clients should be given comprehensive, scientifically accurate information in order to assist them to make an informed, voluntary choice of a contraceptive method.

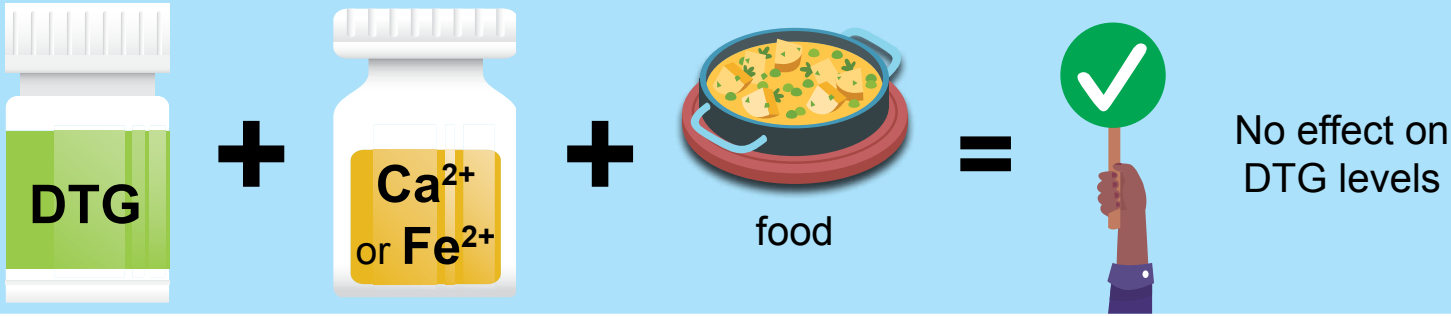
Drug interactions with Dolutegravir

Interacting Drug	Effect of Co-Administration	Recommendation
Rifampicin	↓ Dolutegravir	Double DTG dose to 50mg 12-hourly. If on TLD FDC, add DTG 50mg 12 hours after TLD dose
Anticonvulsants: • Carbamazepine • Phenobarbital • Phenytoin	↓ Dolutegravir	Avoid co-administration if possible **(sodium valproate,** lamotrigine, levetiracetam, and topiramate **do not interact with DTG, and can be used)**. Double DTG dose to 50mg 12-hourly for carbamazepine if alternative anticonvulsant cannot be used
Metformin	↑ Metformin	DTG increases metformin dose Maximum metformin dose should be 500mg 12-hourly
Polyvalent cations - significant interactions (Mg^{2+}, Fe^{2+}, Ca^{2+}, Al^{3+}, Zn^{2+}) e.g. antacids, sucralfate, multivitamin and nutritional supplements • Calcium supplements decrease DTG concentrations if taken together on an empty stomach. • Iron supplements decrease DTG concentrations if taken together on an empty stomach. • Magnesium/aluminium containing antacids decrease DTG concentrations regardless of food intake and should be taken a minimum of 2 hours after or 6 hours before DTG		

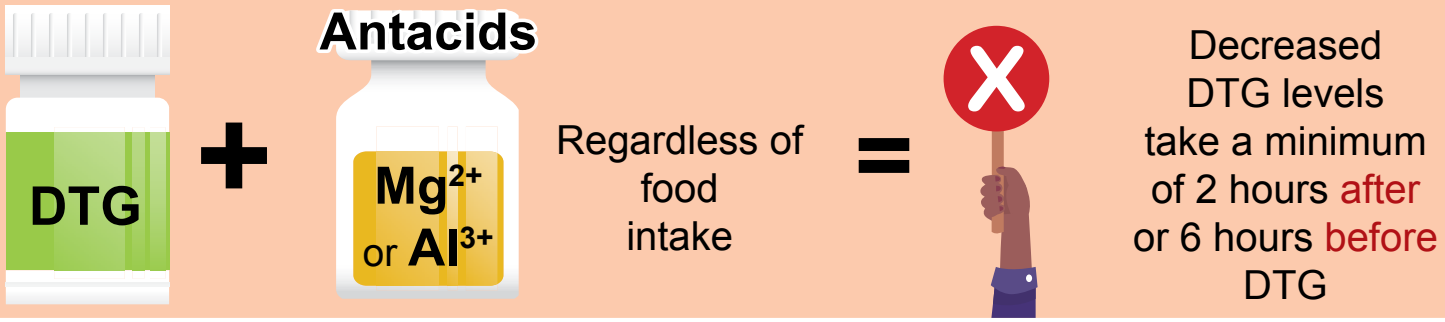
Drug interactions can result in suboptimal drug levels which can cause

1. **An elevated viral load**
2. **Drug resistance due to low drug pressure**

Drug interactions between DTG and the polyvalent cations
(calcium/iron supplements and antacids)



However, calcium (Ca^{2+}) and iron (Fe^{2+}) must be taken 4 hours apart



Suggested Dosing Schedule

DTG (TLD) can be taken in the morning or evening with calcium and with food. If insomnia is experienced, dose in the morning

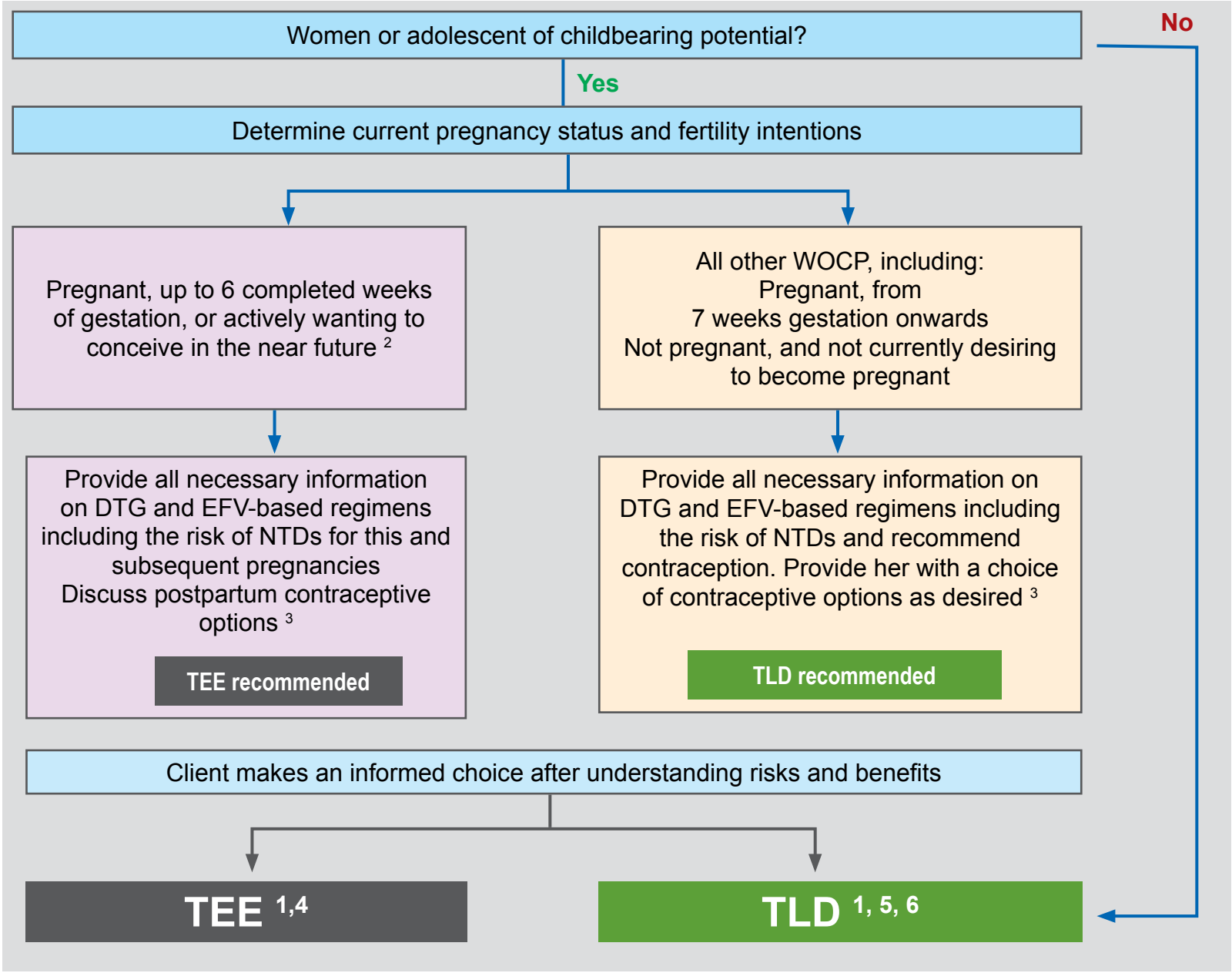
Option 1

- **DTG + Calcium 500mg + food in the morning**
- Ferrous sulphate 200mg at lunch with food (better tolerated)
- Calcium 500mg in the evening

Option 2

- Calcium 500mg + food in the morning
- Ferrous sulphate 200mg at lunch with food (better tolerated)
- **DTG + Calcium 500mg with food in the evening**

Adult women and adolescent girls at least 35kg and 10 years of age



Considerations for women of childbearing potential

1. Do not use tenofovir in adolescent girls weighing < 35kg. Use Abacavir
2. Start folate for women wanting to conceive but advise to defer conception until they are virally suppressed
3. Provide options form a comprehensive contraceptive commodity mix
4. IF TEE is used around conception, a switch to TLD can be offered if VL is suppressed.
5. Counsel the woman on use of DTG
6. A switch from TLD to TEE can be offered if a women wants to conceive and is concerned about NTDs

Enabling a Client to make an Informed Choice

The clinician should enable a client to make an informed choice by doing the following:

1

- Understand her current pregnancy status and fertility intentions:
  - Is she pregnant? If so, at what gestation?
  - If not, does she desire a pregnancy now?

2

Explain the risks and benefits of DTG vs EFV

0.3% risk for NTD on DTG
vs
0.1% risk of NTD on EFV

3

- Discuss and provide a choice of contraceptive options as desired
- Remember that dual methods are recommended

Summary of 1st Line Regimens

Integration of ART and Family Planning services essential!

Neonates, Infants & Children 0 to < 10 years of Age, Adolescents and Adults

2.5kg | Birth to < 4wks of age [3] | 3kg

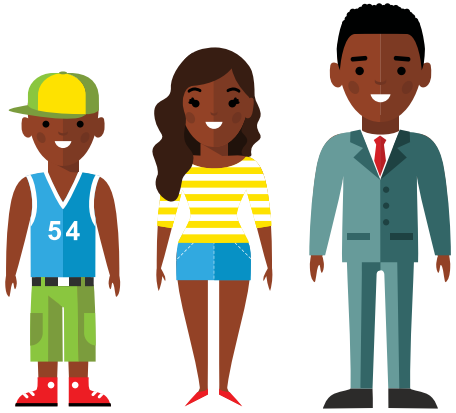
Neonates
AZT + 3TC + NVP

20kg | Or < 10 years of age | 35kg

Children
ABC + 3TC + DTG

3kg | ≥ 4 wks of age, and > 42 wks gestational age [4] | 20kg

Infants & Children
ABC + 3TC + LPV/r



35kg | and ≥ 10 years of age

Adolescents & Adults
TDF + 3TC + DTG/EFV

Important principles in VL Monitoring

Virological suppression is defined as VL of < 50 c/mL NEW

! **Any VL > 50 c/mL requires action**

VL 50-999 c/mL
Transient viral blip
Might be the start of virological failure

VL ≥ 1000 c/mL
Work-up for possible virological failure

If you Measure the VL → **You must Respond to the result!!**

A **thorough assessment** is essential for any patient with a viral load measuring ≥ 50c/mL

- Implement **interventions**
- **Repeat VL testing** to confirm VL re-suppression

Important principle when considering single drug substitutions

! Never change only one drug in a failing regimen!

Remember... The threshold for failure is 1000 c/mL

VL < 50 c/mL
Virological suppression

↓

Safe to switch one drug in the regimen?
Yes!!

VL 50 - 999 c/mL
Transient viral blip
Might be the start of virological failure

↓

Safe to switch one drug?
Unclear!
Do a thorough assessment and counselling, repeat VL in 3 months if still 50-999 c/mL, can switch

VL ≥ 1000 c/mL
Work-up for possible virological failure

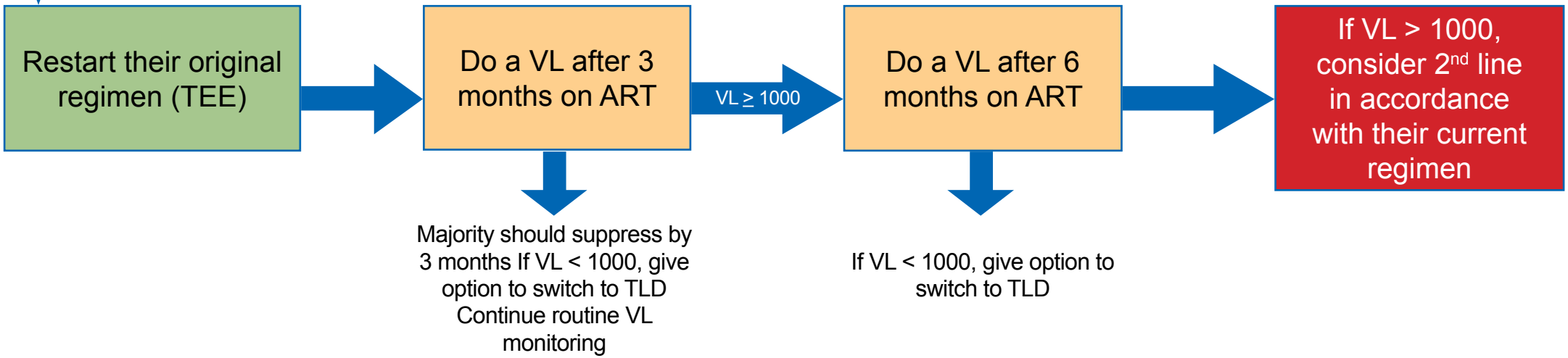
↓

Safe to switch one drug?
No!!
Work-up for possible failure
Switch to 2nd line

Re-initiating ART in Treatment Interrupters

Take a thorough history including:
- which drugs the client was taking, and for how long;
- the reasons for stopping ART;
- side-effects; and
- any information on VL measurements whilst on ART.

If the patient was
- clinically well on their first-line regimen,
- side-effects were not the reason for stopping ART, and
- their VL was suppressed (or no VL result is available)

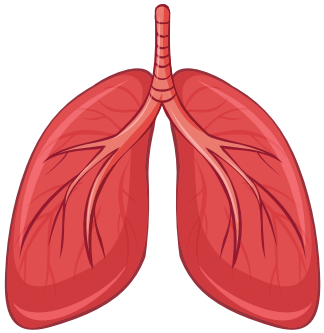


Dual Treatment of HIV and Active TB

Efavirenz
has no significant interaction with rifampicin

Dolutegravir
has significant interaction with rifampicin

Therefore, TB/HIV co-infection impacts on ART drug selection as follows:



TB Treatment started first
Clients who are **not yet on ART** when TB treatment is initiated

Initiate ART with an **EFV-containing regimen** — Once daily

ART started first
Clients who are **already on ART** when TB treatment is initiated

Adults who are **already on an EFV-containing regimen**
• **continue the EFV-containing** regimen

Clients who are **already on a DTG-containing regimen**
• remain on DTG and **boost DTG dose to 50 mg bd** — Twice daily

Summary of the changes in the new PMTCT Guideline (2019)

Central Theme: Maternal Viral Load Suppression

Other cross cutting themes

- Linking with HIV Prevention and Family Planning services
- Integrating services for the mother-infant-pair
- Promoting and protecting breastfeeding

Electronic gate keeping codes (to prevent VL rejection):

C#PMTCT
(during ANC & breastfeeding)

C#Delivery
(at delivery)

Specific Changes

Antenatal care

HIV-negative: HIV testing monthly at every full BANCPlus visit

Dolutegravir
- Potent VL suppressor
- Risk for NTDs
- Drug interactions

TB Screening and TPT
- Symptom screen and TB GeneXpert regardless of symptoms
- TPT during pregnancy if CD4 < 350

Labour and delivery

Delivery-VL for all HIV+ women

Stat NVP and TLD for women presenting in labour not on ART

Provide mother with 2 months ART supply at discharge

TLD= Tenofovir, lamivudine, dolutegravir

Postpartum Care and Breastfeeding

High risk infant prophylaxis (also given during BF if new diagnosis or high viral load):
- AZT for 6w
- NVP for minimum of 12w, until maternal VL suppressed

Breastfeeding for 24 months or longer in the context of viral suppression and enhanced infant prophylaxis

HIV-PCR at birth and 10 weeks remain
HIV-PCR at 6 months for all HIV-exposed
Maternal VL at 6 months and 6-monthly
18 month rapid/ELISA for all children
HIV confirmation with PCR until 24m

Algorithm for new enrolments into CCMDD for patients on TEE or TLD

New enrolments onto CCMDD for patients on TEE or TLD:
Patient can be enrolled onto CCMDD if patient is on ART and has a VL < 50 c/mL in the last 6 months.(If no VL in last 6 months, wait for next scheduled repeat VL as per the HIV guidelines)

VL <50 c/mL

Patient already clinically stable on a DTG containing regimen

Patient on EFV containing regimen

Check for Co-morbidities:
Does the medication taken for NCDs have known drug interactions with DTG?

Yes

Provide information on the risk and benefits of DTG and the use of contraception in WOCP. Explain to client that if they switch to TLD, they will not be immediately eligible for CCMDD, due to drug interactions that may affect the control of their chronic conditions.

Patient chooses to switch to TLD

Not immediately eligible for CCMDD. Chronic conditions must first be stabilised on adjusted chronic medication dosages

If patient is reassessed as
- clinically stable on adjusted chronic medication dosages, and
- VL < 50 c/mL in last 6 months

No

Provide information on the risk and benefits of DTG and the use of contraception in WOCP. Patient chooses to switch to TLD

No

Patient chooses to remain on current regimen

Yes

Switch to TLD

Yes

VL 50 - 999 c/mL

Do a thorough assessment of the cause of the elevated VL:
- **A.** Adherence Problems
- **B.** Bugs (Intercurrent Infections)
- **C.** In-Correct ART dosage
- **D.** Drug interactions
- **E.** Resistance

Implement interventions to re-suppress the VL, including advanced adherence support

Repeat VL in 3 months

VL 50 - 999 c/mL
Eligible for TLD switch. Do not enrol onto CCMDD until VL < 50 c/mL

VL ≥ 1000 c/mL

Ensure that the elevated VL is correctly managed according to the VL results management algorithm in the guidelines
Never do a single drug switch from EFV to DTG in a client who may be failing their first-line regimen.

Do not register on CCMDD.

Register on CCMDD

Algorithm for switching CCMDD patients to TLD

Switching of existing CCMDD patients from TEE to TLD:
Patients with a VL done in the last 6 months can be assessed for switching from TEE to TLD.
If no VL in last 6 months, wait for next scheduled repeat VL as per the HIV guidelines.

VL <50 c/mL

VL 50 - 999 c/mL

VL ≥ 1000 c/mL

Do a thorough assessment of the cause of the elevated VL:
- **A.** Adherence Problems
- **B.** Bugs (Intercurrent Infections)
- **C.** In-Correct ART dosage
- **D.** Drug interactions
- **E.** Resistance

Implement interventions to re-suppress the VL, including advanced adherence support
Repeat VL in 3 months

Ensure that the elevated VL is correctly managed according to the VL results management algorithm in the guidelines.
Never do a single drug switch from EFV to DTG in a client who may be failing their first-line regimen.

Deregister from CCMDD.

VL 50 - 999 c/mL
Eligible for TLD switch.

Check for Co-morbidities: Does the medication taken for NCDs have known drug interactions with DTG?

Yes

Provide information on the risk and benefits of DTG and the use of contraception in WOCP. Explain to client that if they switch to TLD, they will be deactivated from CCMDD, due to drug interactions that may affect the control of their chronic conditions. Patient chooses to switch to TLD.

Yes

Switch to TLD and deactivate patient from CCMDD

No

Provide information on the risk and benefits of DTG and the use of contraception in WOCP.
Patient chooses to switch to TLD.

Yes

No

No

Switch to TLD

Remain on TEE

If patient is reassessed as
- clinically stable on adjusted chronic medication dosages, and
- VL < 50 c/mL in last 6 months

Reregister on CCMDD

Patient remains on CCMDD

Repeat Prescription Collection Strategies (RPCs)
Differentiated Model of Care (DMoC)

Facility Pick-up Point: FAC-PUP (SOP 4)

Adherence clubs: AC (SOP 5)

External Pick-up Point: EX-PUP (SOP 6)

- Decanting of stable patients at 6 months (New criteria)
- Eligibility criteria for all RPCs revised (Refer to AGL SOP)
- CCMDD now recognised as supply system for ALL Repeat Prescription Collection strategy (RPCs).
- FAC - PuP and Adherence Clubs can also be pre-packed by facility/central dispensing unit (CDU).
- SOP 6 now called External Pick-up Point (EX-PUP)
- RPCs benefit from multi-month supply with annual visit schedule includes 2 and 3-month treatment supply annual schedules
- Same criteria for return to regular care across all RPCs

Eligibility Criteria	
Adults • Above 18 years • On treatment for at least 6 months • Most recent viral load (VL) taken in past 6 months < 50 copies/ml for HIV • Most recent HbA1c taken in past 6 months < 7% for Diabetes • 2 consecutive BP < 140/90 for Hypertension	**Children and Adolescents** • 5 - 18 years • On ART for at least 6 months with no regimen or dosage change in the last 3 months • Most recent VL taken in past 6 months < 50 copies/ml • Care givers counselled on disclosure process • Patient (>12 years/caregiver if patient<12 years) voluntarily opts for the RPCs option

We would like to acknowledge the involvement of the following organisations with the development of this flip chart:

Disclaimer: The printing of this material was supported by the Grant or Cooperative Agreement Number, GH001932-04, funded by the Centers for Disease Control and Prevention. Its contents are solely the responsibility of the authors and do not necessarily represent the official views of the Centers for Disease Control and Prevention or the Department of Health and Human Services.