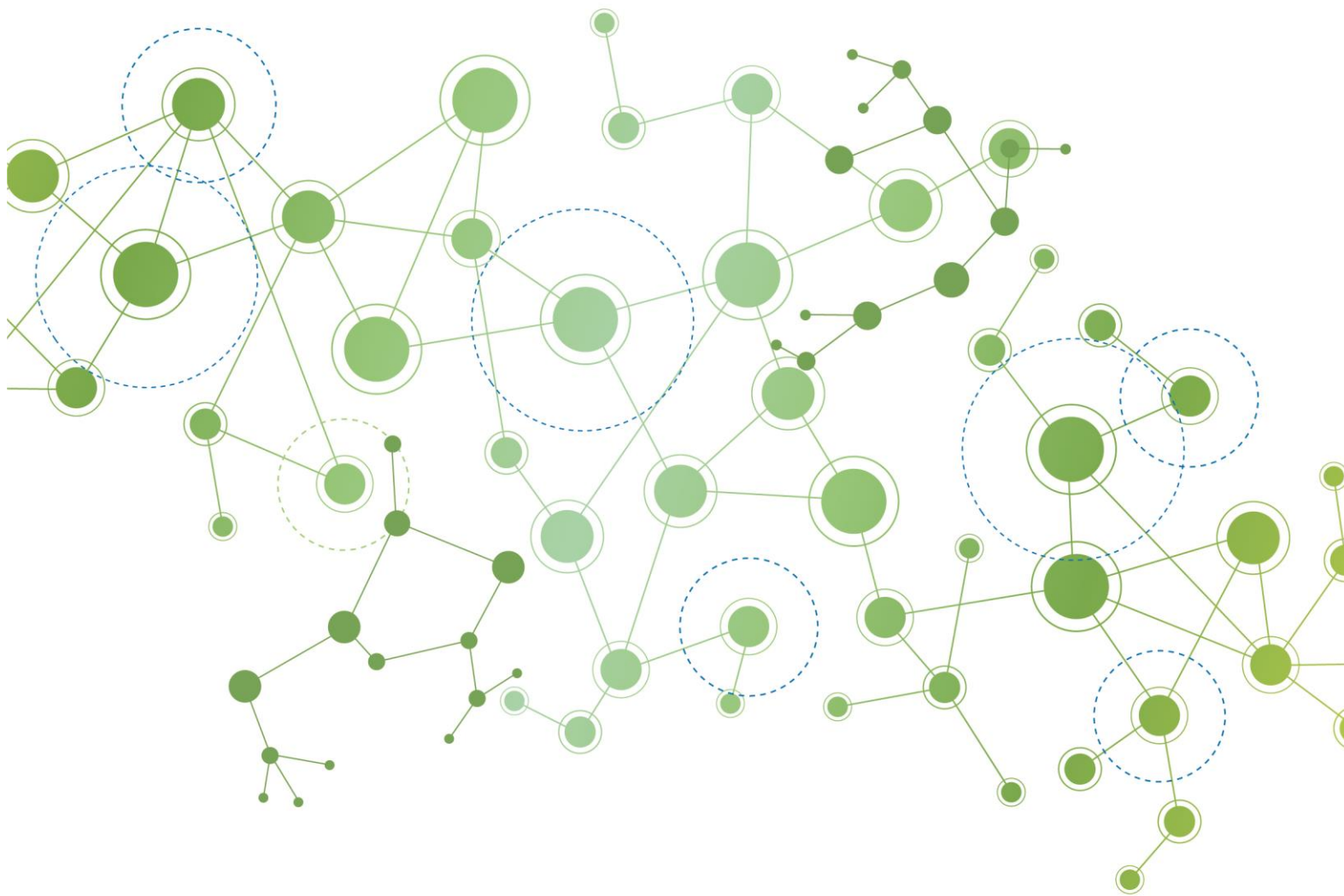


Capturing new fixed dose combination TLD (Tenofovir, Lamivudine and Dolutegravir) into the TB/HIV information system guidance



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Document control

Document name:	GUIDANCE ON CAPTURING NEW FIXED DOSE COMBINATION TLD (TENOFVIR, LAMIVUDINE AND DOLUTEGRAVIR) INTO THE TB/HIV INFORMATION SYSTEM
Compiled by:	TB/HIV information System Implementation Team (NIT)
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Version control

Date updated	Version	Updated by	Comment on changes
February 2020	1.0	NIT	New document

Approvals

Date approved	Version	Approved by	
February 2020	1.0	Dr. Gail Andrews	

Background

On 01 December 2020, the Minister of Health launched a new first line fixed drug combination therapy to be used by the South African HIV programme to treat HIV. The 3 in 1 pill, referred to as TLD, is a combination of 3 drugs, including Tenofovir (TDF), Lamivudine (3TC), and Dolutegravir (DTG).

DTG is associated with a more rapid viral suppression and higher genetic resistance barrier (WHO, 2018) and although there are increased outcome benefits, there is a reported risk of neural tube defects in women of childbearing potential, increased weight gain and the requirement of a booster dose of DTG for TB patients. It is therefore critical to ensure that this information is accurately documented and accounted for in the clinical stationery. However, not all information is required for capturing into the TB/HIV information system.

Monitoring patients initiated onto or switched to TLD is a critical component of HIV and TB programme management. This document provides guidance on how to account the initiation and/or switching of patients onto TLD.

Guiding principles:

TLD implementation can be monitored by applying the same principles used in the rollout of the previous Fixed Dose Combination (FDC) regimen, TFE (Tenofovir, Emtricitabine, Efavirenz). Acknowledging the need to monitor the implementation of TFE, the National Department of Health developed guidance for clinicians on how to document changes from existing drug regimens to the FDC, using existing HIV clinical stationery and subsequent capture in TIER.Net

It is important to note, that whilst the introduction of FDC did not require the modification or introduction of new clinical stationery, clinical instruction and guidance was required. The same approach that was taken for the rollout of TFE should be applied to the rollout of TLD.

Clinical Documentation

Recording a patient initiated onto TLD

In the HIV clinical stationery, the clinician is to complete/record the following:

- Verification of sex/age of HIV+ patient
- Patient's current pregnancy and contraception status
- Explanation of the potential risk of Neural Tube Defects associated with DTG in woman of childbearing potential
- Acknowledgement by the patient of her awareness and understanding of associated risks
- Patient acceptance/refusal of contraception, if pregnancy or current contraception status, is null
- Confirmation by patient of decision to commence TLD treatment if contraception is declined
- Prescription for TLD - Fixed Dose Combination Regimen
- Type of regimen
- Date of initiation
- FDC combination (to be documented on one line)
- Record 3 letter abbreviation for the drugs and the dosages

Patient details

To verify if an HIV + patient is female and of childbearing potential, the clinician is to document the sex and age of the patient in the corresponding fields below.

The image shows a complex form titled '1. PATIENT DETAIL Adult Patient Summary'. A red box highlights the 'LONG-TERM RECORD' section. Two blue arrows point upwards from the 'DOB' and 'Sex' fields in the summary table to the corresponding fields in the 'LONG-TERM RECORD' section.

1. PATIENT DETAILS		Adult Patient Summary	
First name	Mary Jane		
Surname	Smith		
DOB	12 / 10 / 1985	Sex:	M <input type="radio"/> F <input checked="" type="radio"/>
ID Number	XXXXXXXXXXXXXXXXXXXX		

DOB and Sex indicates if patient is of childbearing potential

Notes section

The notes section to document the following:

- Clinical assessment of patient’s current pregnancy and contraception status
- Explanation by clinician of potential risk of Neural Tube Defects associated with DTG
- Acknowledgement by the patient the awareness and understanding of associated risks

#	Date: / /
Weight / Height / BMI	kg / cm
Obs. (BP, Pulse, Temp, RR)	
Months on ART regimen	
Months on TB treatment	
Notes	Pt request switch to TLD, Pt of childbearing potential, NTD risks discussed, Pt ready to switch to TLD
STI symptoms/Condoms given	Yes No Yes No
Gene Xpert (Pos / Neg)	
TB M / C / S	
CD4 (CD4%)	
Viral Load	
Creatinine clearance	
HB / WCC / PLT	
ALT	
Other investigation results (incl. XR)	
DC to initial once captured	CD4 Viral load TB M C S Other
Assessment	
Adverse event / grade	
WHO stage	
Adherence	
ART regimen line	First line Second line Third line
Medication: ARV, prophylaxis	ARV1 ARV2 ARV3 ARV4 or other ARV5 or other ARV6 or other Cotrimoxazole IPT Fluconazole
Diets	Counselling (date/s) Referral (where/date) Next clinical appt date Signed (initialed)



Notes	Pt requests switch to TLD, Pt of childbearing potential, NTD risks discussed, Pt aware of risks and ready to switch to TLD LWP: 1/1/19, no current sexual partner
STI symptoms/Condoms given	Yes No // Yes No
FP (Method/follow-up date)	

Family Planning section

The clinician to indicate in this section that family planning (contraception) has been discussed, offered and accepted/declined by patient.

Notes	
STI symptoms/Condoms given	Yes No // Yes No
FP (Method/follow-up date)	

FP (Method/follow-up date)	No current FP; declined FP
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Assessment section

The current adherence section can be used to indicate that the patient consented to switching/being initiated on TLD despite being aware of the potential Neural Tube Defect risks associated with DTG

Assessment	HIV conditions / OIs, TB & other conditions	1	
		2	
		3	
		4	
	Adverse event / grade		
WHO stage			
Adherence	<i>pt aware of DTG risk, consented to TLD switch</i>		

Medication section

This section should be used to indicate initiation or switching from their current regimen to Fixed Dose Combination, TLD.

Switching to TLD:

The clinician to record the following:

- The name of drugs to be 'Stopped' in ARV line 1
- START and the date the patient was started on the regimen
- Type of regimen – first line, second line or third line.
- The FDC combination by providing 3 letter abbreviation for the drug and the dosage.

FIGURE 1. DOCUMENTING THE SWITCH IN REGIMENS IN THE CLINICAL STATIONERY

ART regimen line (please circle)	First line	Second line	Third line	IN ▼	OUT ▼	PH
	<i>START (mm/dd/yy)</i>	ARV1	<i>STOP current regimen (mm/dd/yy)</i>			
	ARV2	<i>TDF 300mg/3TC xxxmg/ DTG xxxmg</i>				
	ARV3					
	ARV4 or other					
	ARV5 or other	Amphotericin lozenges 10mg qid 10d				
	ARV6 or other					

Recording the initiation of a patient onto TLD:

- START and the date the patient was started on the regimen
- Type of regimen – first line, second line or third line.
- The FDC combination by providing 3 letter abbreviation for the drug and the dosage.

Initiation: ARVs, prophylaxis	ART regimen line (please circle)	First line	Second line	Third line	IN ▼	OUT ▼	PH	
	START (mm/dd/yy)	ARV1	TDF 300mg/3TC xxxmg/ DTG xxxmg					
		ARV2						
		ARV3						
		ARV4 or other						
		ARV5 or other	Amphotericin lozenges 10mg qid 10d					
		ARV6 or other						

Capturing a new patient initiated on TLD into the TB/HIV information system

NB: To identify the name of the drug, when capturing, place the mouse over the box containing the name of the drug, information regarding the generic and trade drug name will appear.

- The drug code for the TLD fixed dose combination will appear in TIER.Net as:
 - Regimen 1 – Tenofovir (TDF); Lamivudine (3TC); Dolutegravir (DTG)
- To capture select the corresponding drug from the clinical stationery
 - For TLD, select the following:
 - Select First line Regimen
 - Select: TDF – Tenofovir
 - Select 3TC – Lamivudine
 - Select DTG – Dolutegravir

FIGURE 2. CAPTURING NEW DRUG REGIMEN FOR DOLUTEGRAVIR BASED FDC

Details | Audit History

Visit Details
 Visit Date: 01 Dec 2019 | Health Provider: Nurse | Adherence club: [Clear]
 Pregnant: [] | TB Screening: No Symptoms | On IPT?: No

ARV's Prescribed

First Line Regimen	NRTI 1: TDF	NRTI 2: 3TC	NNRTI/PI/INSTI: EFV	DRV	Other: DTG
Second Line Regimen	d4T	FTC	NVP	RAL	Additional Drug
Salvage / 3rd Line	AZT	ddl	LPV/r	ETR	Old Coding
Stopped	ABC		RTV		1T30
			ATV		

Months ART prescribed: 1 Month
 Restarted ART this month (>3 month interruption)

Test Results
 New Edit Delete

Result Type	Result	Result Value	Result Percentage
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Other
 Next Clinical Appointment Date: 01 Jan 2020 | [Clear]
 Next Visit At: Facility Adherence club | Script Number

*NB: Although the abbreviation for the new Fixed Dose Combination is TLD, in TIER.Net, the drugs combination will appear as - **1T30**. The reason for this is that the letters “L” and “D” are already in use in TIER.Net. L references Lopinovir and D references Didanosine.*

Switching from current FDC – TFE to TLD

In most instances, a change of 2 or more drugs in a patients ART regimen constitutes a switch from first line to second line treatment therapy (in addition to other clinical determinations, including but not limited to 2 consecutive unsuppressed Viral Loads).

NB: Unless clearly documented as a switch by the clinician, the switch from Fixed Dose Combination TFE (Tenofovir, Emtricitabine, Efavirenz) to TLD does not require a switch in regimen.

- Open TIER.Net
- Select the patient
- Open a new visit, the previous drug regimen will appear greyed out
- Change the existing drugs to reflect the new fixed dose combination – TLD
 - Change FTC to 3TC
 - Change EFV to DTG

FIGURE 3. PREVIOUS DRUG REGIMEN

Visit Details
 Visit Date: [dropdown] Did Not Attend Health Provider: [dropdown] Adherence club: [dropdown] [Clear](#)

Pregnant: [dropdown] TB Screening: [dropdown] On IPT?: Yes [dropdown]

ARV's Prescribed

First Line Regimen	NRTI 1: TDF	NRTI 2: 3TC	NNRTI/PI/INSTI: EFV	DRV	Other:
Second Line Regimen	d4T	FTC	NVP	RAL	Additional Drug: [dropdown]
Salvage / 3rd Line	AZT	ddl	LPV/r	ETR	Old Coding: [dropdown]
Stopped	ABC		RTV	DTG	
			ATV		

Months ART prescribed: 1 Month
 Restarted ART this month (>3 month interruption)

Test Results
 New Edit Delete

Result Type	Result	Result Value	Result Percentage
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1TFE

FIGURE 4. REVISED DRUG REGIMEN REFLECTING TLD

Details Audit History

Visit Details
 Visit Date: 01 Dec 2019 Did Not Attend Health Provider: Nurse Adherence club: [dropdown] [Clear](#)

Pregnant: [dropdown] TB Screening: No Symptoms [dropdown] On IPT?: No [dropdown]

ARV's Prescribed

First Line Regimen	NRTI 1: TDF	NRTI 2: 3TC	NNRTI/PI/INSTI: EFV	DRV	Other:
Second Line Regimen	d4T	FTC	NVP	RAL	Additional Drug: [dropdown]
Salvage / 3rd Line	AZT	ddl	LPV/r	ETR	Old Coding: [dropdown]
Stopped	ABC		RTV	DTG	
			ATV		

Months ART prescribed: 1 Month
 Restarted ART this month (>3 month interruption)

Test Results
 New Edit Delete

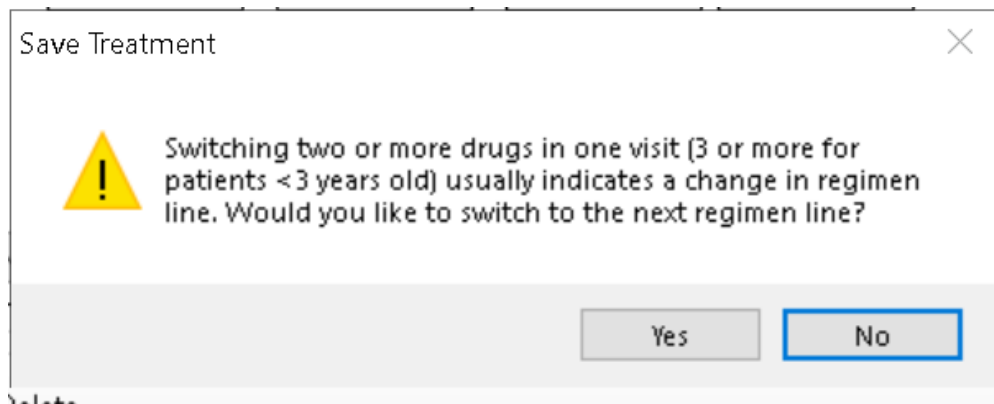
Result Type	Result	Result Value	Result Percentage
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Other
 Next Clinical Appointment Date: 01 Jan 2020 [Clear](#)

Next Visit At: Facility Adherence club Script Number: [input]

1T30

- When accounting for the switch in TIER.Net – a pop-up verification notice will appear with the following message;



- Unless the clinician has clearly documented a switch from Regimen 1 to Regimen 2, with either the Adverse Events or proof of 2 consecutive unsuppressed Viral Loads, **select NO**

Accounting for extra dose of DTG with TB patients

The 1.12 version of TIER.Net does not enable the capture of duplicates of drugs. Therefore, accounting for the additional dose of DTG cannot be done at this time. The ability to capture a 4th drug has been logged for correction in the next version release of the software. However, patients who are on an extra dose of DTG can be identified via indication of an active TB episode.

Accounting for women of childbearing potential

The clinical stationery will account for whether a woman of childbearing potential has been informed about the risk associated with DTG and whether the woman is on birth control. Importantly, the stationery will indicate if the woman has agreed to either initiating or switching of medication.