



## Trainings to support the National Integrated TB/HIV Information System Implementation

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## TLD 1/TLD 2 & VL Capturing in TIER.Net Clinical Guideline Changes 2023

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Date: 20 September 2023  
Venue: Knowledge Hub (Virtual)

# Objectives



## Update on ART Clinical Guidelines VTP Guidelines

- To provide guidance on Implementing optimized regimens and Viral load monitoring

## Capturing of TLD/ALD 1 & TLD/ALD 2 onto TIER.Net

- To demonstrate TIER.Net >10 years Capturing
- To demonstrate TIER.Net <10 years Capturing
- To provide guidance on Data Reporting

## Management of Viral Loads Results

- To discuss Caveats to the Viral Load results management rules in TIER.Net

## Management of Viral Load in TIER.Net

- To discuss the Viral Load journey
- To provide guidance on Viral Load capturing on TIER.Net from Clinical source
- To provide guidance on Data Quality – Viral Load
- To view Reports on program quality – Viral Load

# Agenda



Time	Topic	Speaker
13:00 – 13:10	Welcome	Mrs Thabile Msila
13:10 – 13:15	Introduction of panelist and speakers	Dr Tshepo Molapo
13:15 – 13:20	Objectives of the session	Dr Tshepo Molapo
13:20 – 13:30	Background into the revised ART guidelines regarding TLD 1 and TLD 2 and ALD	Dr Zamazamela Shelembe
13:30 – 14:00	TLD 2 and ALD capturing	Mr Matthew Chetty
14:00 – 14:10	Background into the revised ART guidelines regarding VLD monitoring revisions	Dr Zamazamela Shelembe
14:10 – 14:40	VLD capturing in various cohorts	Mr Matthew Chetty
14:40 – 14:55	Questions and Answer Session	All
14:55 – 15:00	Summary and take-home messages	Dr T Molapo & Mrs Thabile Msila



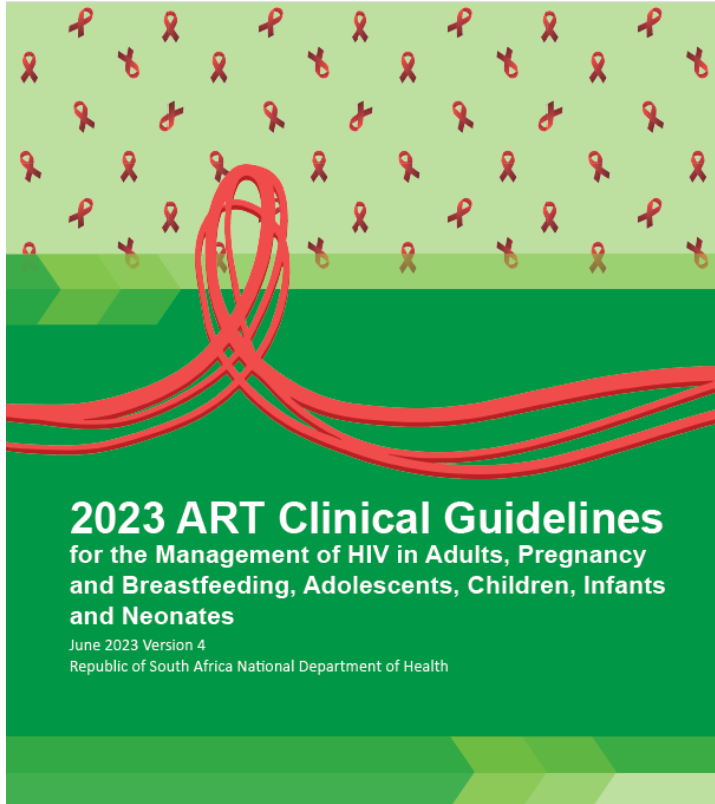
## Background into the revised ART guidelines regarding TLD 1 and TLD 2 and ALD

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Dr. Zamazamela Shelembe

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# 2023 ART Clinical Guidelines



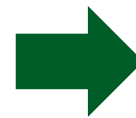
## South African HIV program big challenges including:

- Sub-optimal retention in the **first 12 months**. This also applies to first 12 months for a returning client.
- Sub-optimal **VL suppression** ( $< 50$  copies/mL)

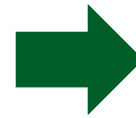
### Massive health system burden

High number of people living with HIV and people at risk of acquiring HIV requiring ongoing **HIV treatment and prevention services**

! Critical consideration for this update:



Reducing disengagement in the first 12 months on treatment (including after re-engagement)



Improving long-term viral load suppression (VLS)



# Implementing optimised regimens



## Definition

An optimised ART regimen means we provide PLHIV with the best-available ART in the most efficient and cost-effective manner possible

### An optimized regimen using DTG:

- simplifies regimens with reduced pill burden and dosing frequency
- enhances tolerability
- reduces toxicity
- reduces potential drug-drug interactions
- maintains viral suppression without jeopardizing future treatment options through the development of drug resistance

# Poll Question 1 (Single Selection)



**TDF + 3TC + DTG (TLD) is the preferred regimen for Pregnant Women  $\geq 30$  kg and  $\geq 10$  years of age**

**a) True**

**b) False**

**c) Not Sure**

# First-line ART regimens



**Dolutegravir (DTG) is the recommended drug in all clients  $\geq 4$  weeks of age and weigh  $\geq 3$ kg**

## Benefits of Dolutegravir:

- ✓ Provides rapid viral suppression.
- ✓ High genetic barrier to resistance.
- ✓ Minimal side effects and drug interactions.
- ✓ Well tolerated thus promotes adherence and retention on ART.

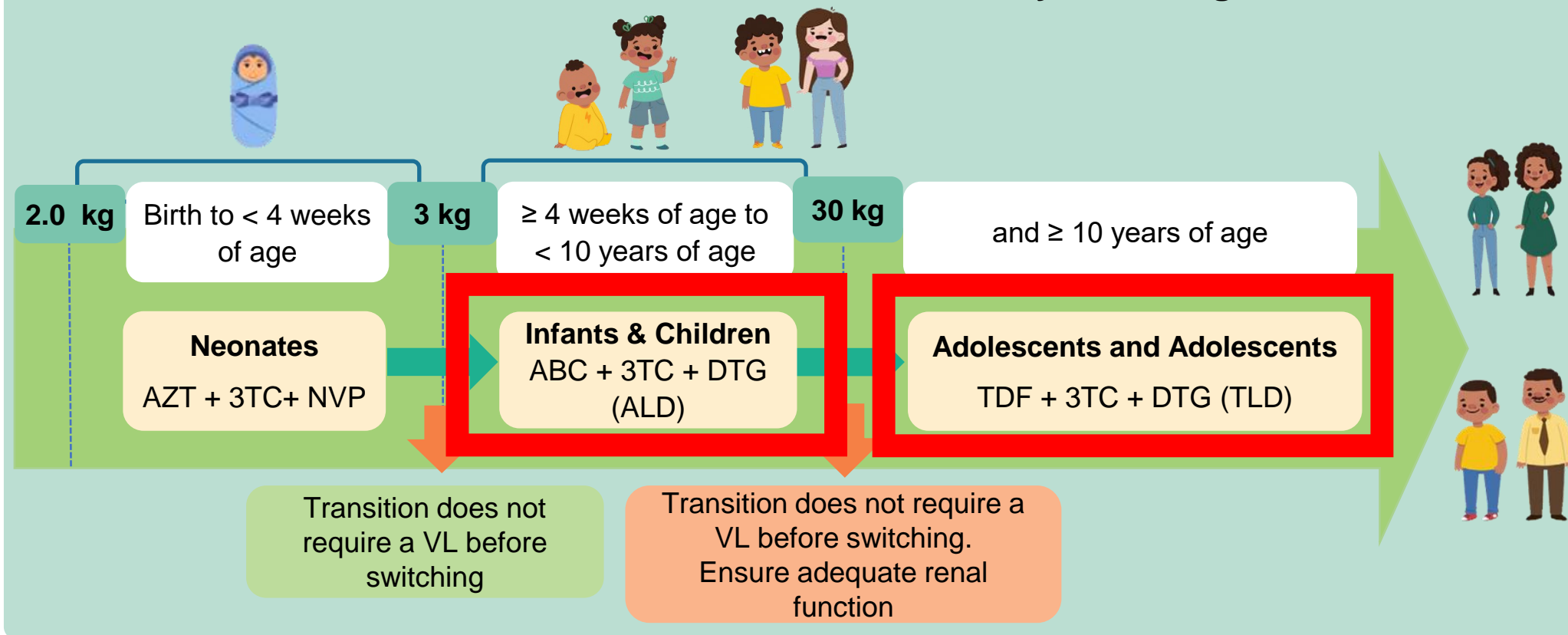


**Adult and Adolescent Males and Females, including Pregnant Women  $\geq 30$  kg and  $\geq 10$  years of age**

**TDF + 3TC + DTG (TLD)**



## Neonates, Infants and Children 0 to $< 10$ years of Age





# Recycling of TDF in second-line regimens



- Nucleosides And Darunavir/Dolutegravir in Africa (NADIA)
- This trial evaluated **options for second-line antiretroviral therapy** in patients failing on a non-nucleoside reverse transcriptase inhibitor (NNRTI) and tenofovir (TDF)-based first-line regimen. The trial aimed to answer the following:
  1. Is a **DTG**-containing regimen as effective as a darunavir-containing (**DRV/r**) regimen in 2nd-line?
  2. Is continuing **TDF and 3TC** in your second-line regimen as effective as using **AZT and 3TC**.

## Conclusion:

**DTG in combination with NRTIs was as effective as DRV/r including in those with extensive NRTI resistance in whom no NRTIs were predicted to have activity.  
TDF was superior to AZT as second-line therapy.**

# TLD will be used as:



A  
First-line  
regimen

A  
Second-line  
regimen

Part of  
Third-line  
regimens



If TLD is the most optimised regimen we have, and it can be used in 1<sup>st</sup>, 2<sup>nd</sup>, and 3<sup>rd</sup>-line regimens, that means that:

All new clients  
should be  
initiated  
on TLD, or...

Clients already on  
ART should be on  
TLD, or...

...be IN THE  
PROCESS of  
switching to TLD

# Switching clients already on ART



- Non VL-dependent switches will be conducted for clients regardless of VL result:

Non VL-dependent regimen switches	
Current Regimen	Regimen if change indicated
TEE (TDF/3TC/EFV)	<b>TDF/3TC/DTG (TLD):</b> a. Age $\geq$ 10 years AND b. Weight $\geq$ 30 kg AND c. No renal dysfunction <b>OR</b> <b>ABC/3TC/DTG (ALD)</b> a. Age < 10 years OR b. weight < 30 kg OR c. Abnormal renal dysfunction
AZT or ABC/3TC/ EFV (or NVP)	
AZT/3TC/DTG	
Any LPV/r/ or ATV/r regimen <b>less than 2 years</b>	

**Clients already on ART will also be switched onto optimised regimens containing DTG**

- VL-dependent switches will be conducted for clients according to their VL result:

**VL-dependent regimen switches**

All clients on LPV/r or ATV/r regimen for **more than 2 years** may also be switched after careful evaluation

• 2023 ART Clinical Guidelines for the Management of HIV in Adults, Pregnancy and Breastfeeding, Adolescents, Children, Infants and Neonates, page 14.

# A paradigm shift



In the new ART era of dolutegravir, TLD (or ALD) will be used as a

First-line regimen

Second-line regimen

Part of  
Third-line regimens

→ need to rethink our terminology related to “1<sup>st</sup> and 2<sup>nd</sup>-line”

TLD 1  
(or ALD 1)

Clients on a DTG-containing regimen, who **have never failed** a previous regimen  
(old “1<sup>st</sup> -line” terminology)

TLD 2  
(or ALD 2)

Clients on a DTG-containing regimen, who **have failed** a previous regimen  
(old “2<sup>nd</sup> -line” terminology)

• 2023 ART Clinical Guidelines for the Management of HIV in Adults, Pregnancy and Breastfeeding, Adolescents, Children, Infants and Neonates, page 2.

# Clinical Stationery

# Clinical stationary part 1: TLD 1



- Visit summary data must be captured from the clinical stationary as recorded by the clinician
- Example below is for the capturing of TLD 1

You will need to capture ART regimen from clinical stationary as noted below:

- Drug names will be written out under ARV1/2 and 3
- Regimen number in brackets

Adherence & Counselling		OUT	IN
ARV1	TDF 300 mg	TLD (1)	
ARV2	3TC 300 mg		
ARV3	DTG 50mg		
ARV4 or other			
ARV5 or other			
ARV6 or other			
Cotrimoxazole			
IPT			
Fluconazole			

Patient Treatment Detail - Month 0 (Aug 2023)

Details Audit History

Visit Details  
 Visit Date: 08 Aug 2023  
 Health Provider: Nurse  
 DMO:

Pregnant:  TB Screening: Asymptomatic  
 On TPT?: No

ARV's Prescribed

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

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

Test Results

Result Type	Result	Result Value	Result Percentage

Other  
 Next Clinical Appointment Date: 05 Sep 2023  
 Next Visit At:  Facility  Adherence club

Save Delete All Close

# Clinical stationary part 2: ALD 1



- Visit summary data must be captured from the clinical stationary as recorded by the clinician
- Example below is for the capturing of ALD 1

You will need to capture ART regimen from clinical stationary as noted below:

- Drug names will be written out under ARV1/2 and 3
- Regimen number in brackets

Adherence & Counselling		OUT	IN
ARV1	ABC 600 mg		
ARV2	3TC 300 mg		ALD (1)
ARV3	DTG 50mg		
ARV4 or other			
ARV5 or other			
ARV6 or other			
Cotrimoxazole			
IPT			
Fluconazole			

Patient Treatment Detail - Month 11 (Mar 2023)

Details Audit History

Visit Details  
 Visit Date: 07 Mar 2023  
 Health Provider: Nurse  
 DMOC:

Pregnant:  TB Screening: Asymptomatic  
 On TPT?: No

ARV's Prescribed

First Line Regimen	NRTI 1: TDF	NRTI 2: 3TC	NNRTI/PI/INSTI: EFV	DRV	Other: Additional Drug
Second Line Regimen	d4T	FTC	NVP	RAL	Old Coding
Salvage / 3rd Line	AZT	ddl	LPV/r	ETR	1A30
Stopped	ABC		RTV	DTG	
			ATV		

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

Test Results

Result Type	Result	Result Value	Result Percentage

Other  
 Next Clinical Appointment Date: 07 Apr 2023  
 Next Visit At:  Facility  Adherence club

Save Delete All Close

# Clinical stationary part 3: Additional DTG



Additional DTG is added for clients on:

- TB treatment
- Anticonvulsants: Carbamazepine, Phenobarbital and Phenytoin

You will need to capture ART regimen from clinical stationary as noted below:

- Drug names will be written out under ARV1/2 and 3
- Drug 4 as the additional drug
- Regimen number in brackets

History and examination	Date: / /	N / D /	
	Weight		
	Temp / Height		
	Months on HAART		
Investigations	Notes		
	STI screen FP / Condoms		
	Months on TB Rx (or TB symptoms if not on treatment)		
	TB M / C / S	Result 1	Result 2
Assessment	CD4 (CD4%)		
	Viral Load		
	ALT		
	HB / WCC / PLT		
Plan and treatment	Creatinine clearance		
	Other investigation results (incl. XR)		
	Adverse event / grade		
	WHO stage		
Medication, incl. ARVs prophylaxis	Notes		
	ARV1	TDF 300 mg	TLD (1)
	ARV2	3TC 300 mg	
	ARV3	DTG 50mg	
	ARV4 or other	DTG 50mg	
	ARV5 or other		
	ARV6 or other		
	Cotrimoxazole		
	IPT		
	Fluconazole		
Referral			
Date of next visit	/ /	Cons	
Signed (initialed)		Date/Signature	

Patient Treatment Detail - Month 6 (Jul 2023)

Details Audit History

Visit Details  
 Visit Date: 03 Jul 2023  
 Health Provider: Nurse  
 DMOC:

Pregnant:  TB Screening: Asymptomatic  
 On TPT?: No

ARV's Prescribed

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

Additional Drug: DTG  
 Old Coding:   
 1T300

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

Test Results

Result Type	Result	Result Value	Result Percentage

Other  
 Next Clinical Appointment Date: 31 Jul 2023  
 Next Visit At:  Facility  Adherence club

Save Delete All Close





# TLD 2 and ALD Capturing

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Mr Matthew Chetty

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# TLD 1/TLD 2 Capturing TIER.Net

- How to Capture new Clients
- How to Capture Clients that have transitioned to TLD 1/TLD 2

# How to capture a new Client on TLD 1 regimen for Adults and Adolescent



## Step 1 Patient Look-Up

- Click New – Enter Folder Number and search
- This is to prevent duplication

TIER.Net - [HIV Patient List]

File Setup Analysis Tools View Window Help

Country Details

HIV Registrations On Record Showing 1 – 38956 of 38956

New Edit Delete Search Filter Setup Columns Sort By:

SOUTH AFRICA

- ec Eastern Cape Province
- fs Free State Province
- gp Gauteng Province
- kz KwaZulu-Natal Province
- lp Limpopo Province
- mp Mpumalanga Province
- nc Northern Cape Province
- nw North West Province
- wc Western Cape Province

	Last HTS HIV Test Result	Last HTS HIV Test Date	Gender	Current Age
110			Female	26
111	Negative (Non-reactive)	19 Aug 2020	Male	26
112	Negative (Non-reactive)	02 Oct 2018	Male	37
113	Negative (Non-reactive)	06 Mar 2021	Female	26
114	Negative (Non-reactive)	17 Oct 2022	Male	34
115	Positive (Reactive)	09 Jan 2023	Female	32
▶116	Positive (Reactive)	10 Nov 2015	Male	36
117	Negative (Non-reactive)	08 Aug 2020	Male	33
118	Negative (Non-reactive)	04 Oct 2019	Male	44

Patient Lookup

You are first required to perform a search << Previous Page | Next Page >>

Select this patient Add New Sort By: Folder number Asc

Folder Number

PRN

Name

Surname

ID Number

Alternate ID Number

Date of Birth

Gender  Male  Female

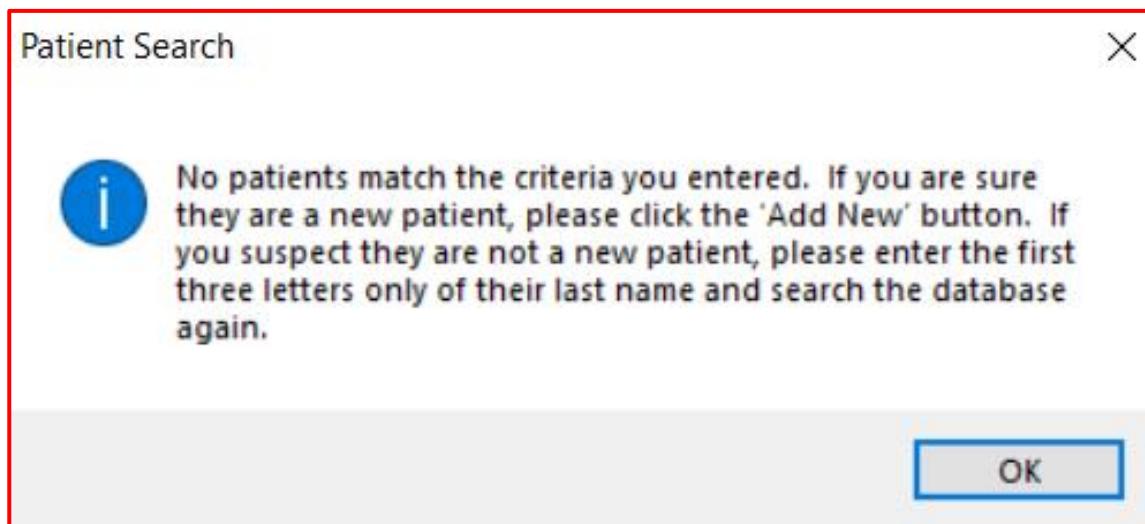
Folder number	PRN	First name	Surname	Date of birth	ID Number
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Close

# How to capture a new Client on TLD 1 regimen for Adults and Adolescent



- Step 2 Adding a New Patient
- Once Search yields “No Match” – Proceed to Add New
- Enter Client Information as per clinical chart and Click Save



**Patient Lookup** No records showing << Previous Page | Next Page >>

Select this patient Add New Sort By: Folder number Asc

Folder Number ACE1002  
 PRN  
 Name  
Surname  
 ID Number  
 Alternate ID Number  
 Date of Birth  
 Gender  Male

**Patient Details**

Personal Details Folder Number History

Patient Details

Folder Number ACE100230789  
PRN  
Name ACE  
Surname CHEN  
Date of Birth 13 May 1986 Clear  
ID Number  
Alternate ID Number  
Gender  Male  Female  
Contact Number 08423232323  
Street Address 21 HEIGHTS  
Suburb  
City  
Province  
Postal Code

Clear Save Close

# How to capture a new Client on TLD 1 regimen for Adults and Adolescent



## Step 3 Adding regimen

- Enter Clinical Information
- ARV's Prescribed = TDF + 3TC + DTG
- Clients ( $\geq 10$  years and  $\geq 30$ kg) that start treatment and given TLD1 (never failed a regimen)
- Code Combination = 1T30

Save Close HTS Pre-ART ART View History Generate Patient Summary

**Patient Details**  
 Folder Number: ACE100230789  
 PRN: [ ]  
 Patient: ACE.CHEN  
 ID Number: [ ]  
 Alternate ID Number: [ ]  
 Date of Birth: 13 May 1986  
 Gender: MALE  
 Treatment Supporter: [ ]  
 Contact Number: 08423232323  
 Address: 21 HEIGHTS  
 Service Point: [ ]

**ART Baseline**  
 ART Start Date: 01 Aug 2023  
 Prior ART: None (naïve)  
 Method into ART: New  
 Transferred In Date: [ ]  
 From Location: [ ]  
 Pregnant at ART Start: [ ]  
 Stage at ART Start: 1  
 On TB RX at ART Start: No  
 On TPT at ART Start: No  
 On CPT at ART Start: No  
 Outcome: [ ]

**Treatment Visits**

0 (Aug 23)						VL	CD4
1 (Sep 23)	2 (Oct 23)	3 (Nov 23)	4 (Dec 23)	5 (Jan 24)	6 (Feb 24)	VL	CD4
7 (Mar 24)	8 (Apr 24)	9 (May 24)	10 (Jun 24)	11 (Jul 24)	12 (Aug 24)	VL	CD4

Patient Treatment Detail - Month 0 (Aug 2023)

**Details** Audit History

**Visit Details**  
 Visit Date: 08 Aug 2023  
 Health Provider: Nurse  
 DMOCC: [ ]  
 Pregnant: [ ]  
 TB Screening: Asymptomatic  
 On TPT?: No

**ARV's Prescribed**

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

**Other**  
 Next Clinical Appointment Date: 05 Sep 2023  
 Next Visit At:  Facility  Adherence club

Save Delete All Close





# Existing Clients switching to TLD 1: Adults and Adolescent

- Step 1 Patient Look-Up
- Step 2 Select Correct Client
- Step 3 Go into patient record
- Step 4 Select Visit Date
- Step 5 Capture transition has advised and captured on a clinical chart by a clinician (ARV's Prescribed = TDF + 3TC + DTG)
- **Code Combination = 1T30**

Save Treatment



Switching two or more drugs in one visit (3 or more for patients < 3 years old) usually indicates a change in regimen line. Would you like to switch to the next regimen line?

Yes No

Patient Treatment Detail - Month 11 (Mar 2023)

Details Audit History

Visit Date: 07 Mar 2023 Health Provider: Nurse DMOC

Pregnant: Asymptomatic TB Screening: On TPT?: No

ARV's Prescribed

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

Months ART prescribed: 1 Month

Test Results

Result Type	Result	Result Value	Result Percentage
VL			CD4
			<b>91</b>
VL			CD4
VL			CD4
VL			CD4

Next Clinical Appointment Date: 07 Apr 2023

Next Visit At: Facility Adherence club

Save Delete All Close

Treatment Visits

Visit	Date	Regimen	CD4	VL
0	Apr 22			
1	May 22			
2	Jun 22			
3	Jul 22			
4	Aug 22			
5	Sep 22			
6	Oct 22			
7	Nov 22			
8	Dec 22			
9	Jan 23			
10	Feb 23			
11	Mar 23			
12	Apr 23			
13	May 23	1TFE		
14	Jun 23	1TFE		
15	Jul 23	1TFE		
16	Aug 23	1TFE		
17	Sep 23	1T30		
18	Oct 23			







# Switching to ALD 2: Paeds (<10 years or < 30kg)



Clients on a DTG-containing regimen, who **have failed** an earlier regimen (previous “second-line” terminology)

- Step 1 Patient Look-Up
- Step 2 Select Correct Client
- Step 3 Go into patient record
- Step 4 Select Visit Date
- Step 5 Capture transition has advised and captured on a clinical chart by a clinician (ARV’s Prescribed = ABC + 3TC + DTG)
- **Code Combination = 2A30**

Patient Treatment Detail - Month 13 (May 2023)

Details Audit History

Visit Details  
 Visit Date: 05 May 2023 Health Provider: Nurse DMOCC  
 Pregnant: No TB Screening: Asymptomatic On TPT?: No

ARV's Prescribed

First Line Regimen	NRTI 1: TDF	NRTI 2: 3TC	NNRTI/PI/INSTI: EFV	Other: DRV
Second Line Regimen	d4T	FTC	NVP	RAL
Salvage / 3rd Line	AZT	ddI	LPV/r	ETR
Stopped	ABC		RTV	DTG
			ATV	2A30

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

Test Results

Result Type	Result	Result Value	Result Percentage

Other  
 Next Clinical Appointment Date: 02 Jun 2023  
 Next Visit At:  Facility  Adherence club

Save Delete All Close

Treatment Visits

1 (May 22)	2 (Jun 22)	3 (Jul 22)	4 (Aug 22)	5 (Sep 22)	6 (Oct 22)	7 (Nov 22)	8 (Dec 22)	9 (Jan 23)	10 (Feb 23)	11 (Mar 23)	12 (Apr 23)	13 (May 23)	14 (Jun 23)	15 (Jul 23)	16 (Aug 23)	17 (Sep 23)	18 (Oct 23)
					0 (Apr)												
						1TFE	1TFE	1TFE	1TFE	1A30	1A30	2A30					

VL	91	CD4
VL		CD4
43012		
VL		CD4

# Data for Reporting

- Clients transition to TLD
- TROA on TLD

# NEW HIV+ ON TLD



- Filter from the front end of TIER.Net, Select ART Start date for the week/period in question
- Filter Last ART Visit Code and select 1T30, (Filter 1TFO, 2TFO and 2T30 then pull files with these regimens and review with clinicians, as possible 1T30)

HIV Registrations On Record Showing 1 – 4 of 4

New Edit Delete Search Filter Setup Columns Sort By: Last HTS HIV Test Result Desc

	ART start date	Last HTS HIV Test Date	Last ART Visit Code	Last HTS HIV Test Result	Current Age	Gender	Outcome	PrEP Status
	2022/06/06 - 2022/06/10		1T30					
Apply Filter Reset Help								
▶ 1	06 Jun 2022	06 Jun 2022	1T30	Positive (Reactive)	31	Male	None	
2	07 Jun 2022	07 Jun 2022	1T30	Positive (Reactive)	31	Male	None	
3	06 Jun 2022	06 Jun 2022	1T30	Positive (Reactive)	35	Female	None	
4	08 Jun 2022		1T30		26	Male	None	

# TROA on TLD



- Filter from the front end of TIER. Net
- Select ART LAST VISIT CODE 1T30/2T30
- Sort Outcome Column ASC-This will allow records with No outcomes to be displayed first
- Count the total records (Excluding an HIV Outcome)

HIV Registrations On Record Showing 1 - 20 of 20

New Edit Delete Search Filter Setup Columns Sort By: Outcome Asc

	ART start date	Last HTS HIV Test Date	Last ART Visit Code	Last HTS HIV Test Result	Current Age	Gender	PrEP Status	Outcome
	2022/05/01 - 2022/06/10		1T30					
Apply Filter Reset Help								
▶ 1	17 May 2022	17 May 2022	1T30	Positive (Reactive)	50	Male	None	
2	01 Jun 2022	01 Jun 2022	1T30	Positive (Reactive)	17	Female	None	
3	04 May 2022	04 May 2022	1T30	Positive (Reactive)	20	Female	None	
4	03 May 2022	03 May 2022	1T30	Positive (Reactive)	22	Male	None	
5	17 May 2022	17 May 2022	1T30	Positive (Reactive)	27	Female	None	
6	18 May 2022	18 May 2022	1T30	Positive (Reactive)	37	Female	None	
7	03 Jun 2022	03 Jun 2022	1T30	Positive (Reactive)	27	Female	None	
8	30 May 2022	30 May 2022	1T30	Positive (Reactive)	35	Female	None	
9	06 Jun 2022	06 Jun 2022	1T30	Positive (Reactive)	31	Male	None	
10	04 May 2022	04 May 2022	1T30	Positive (Reactive)	19	Female	None	
11	23 May 2022	23 May 2022	1T30	Positive (Reactive)	19	Male	None	
12	10 May 2022	10 May 2022	1T30	Positive (Reactive)	22	Female	None	
13	07 Jun 2022	07 Jun 2022	1T30	Positive (Reactive)	31	Male	None	
14	08 Jun 2022		1T30		26	Male	None	
15	12 May 2022	12 May 2022	1T30	Positive (Reactive)	28	Female	None	
16	25 May 2022	23 May 2022	1T30	Positive (Reactive)	45	Male	None	
17	17 May 2022	17 May 2022	1T30	Positive (Reactive)	29	Female	None	
18	30 May 2022	30 May 2022	1T30	Positive (Reactive)	16	Female	None	
19	06 Jun 2022	06 Jun 2022	1T30	Positive (Reactive)	35	Female	None	
20	11 May 2022	11 May 2022	1T30	Positive (Reactive)	30	Female	None	TFO



## Background into the revised ART guidelines regarding VLD monitoring revisions

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Dr. Zamazamela Shelembe

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# Poll Question 2 (Single Selection)



After ART initiation the 1<sup>st</sup> VL test will be done after 6 months on ART?

a) True

b) **False**

c) Not Sure

# Routine VL monitoring schedule on ART



## Dispensing cycle (DC)

- Number of days for which a client would have treatment if a single standard “monthly” quantity of tablets were dispensed.
- The term DC is preferred to the previously used term ‘month’ due to the potential discrepancy that may arise between the days of treatment dispensed (if 28-day pack sizes are used) and the days in a month (on average, 30 days).

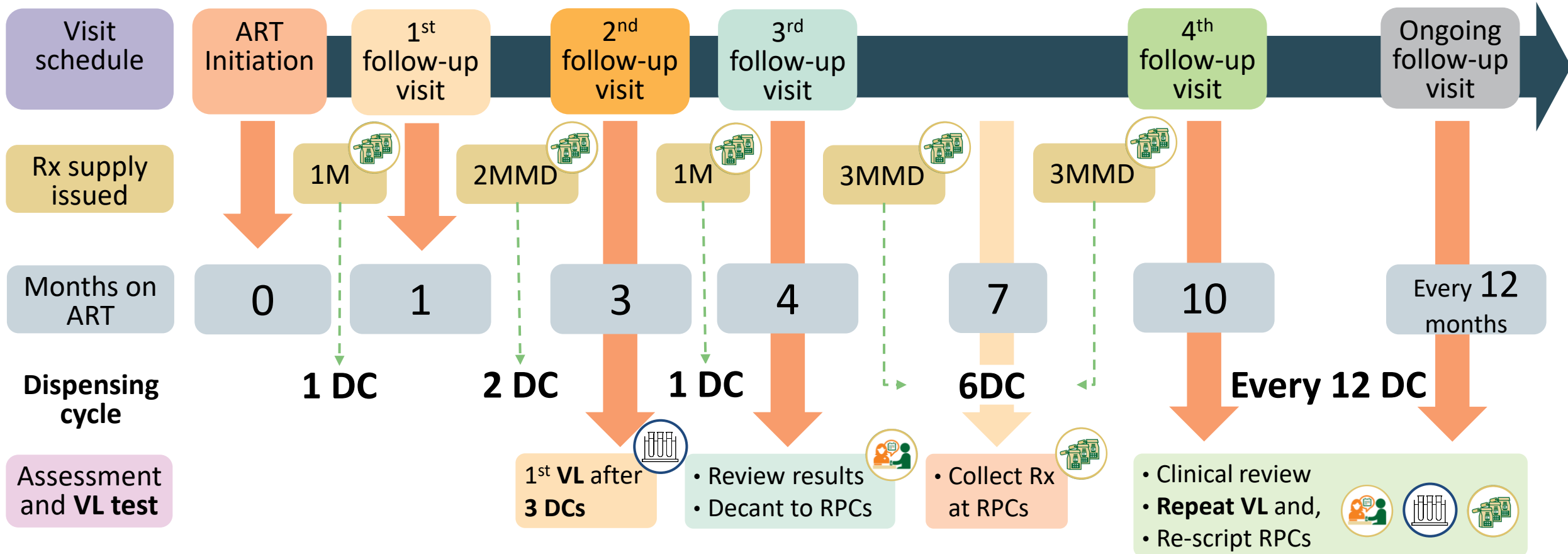
Tablet pack size	DC
28 tablet or 30 tablet packs	1 DC
90 tablets	3 DC

VL monitoring schedule		Intervention	TIER.net Cohort
1 <sup>st</sup> VL		<b>After</b> 3 DCs	6-month VL completion cohort
Clients who remain virally suppressed	2 <sup>nd</sup> routine VL	<b>From</b> 10 DCs aligned with clients scripting cycle	12-month VL completion cohort
	3 <sup>rd</sup> routine VL	<b>From</b> 22 DCs aligned with clients scripting cycle	24-month VL completion cohort
	4 <sup>th</sup> and subsequent VLs	VLs will be taken at intervals of 12 DCs intervals	36-month VL completion and ongoing

• 2023 ART Clinical Guidelines for the Management of HIV in Adults, Pregnancy and Breastfeeding, Adolescents, Children, Infants and Neonates, page 20.



# Timing of DCs and VL monitoring



- Rx = Treatment
- M = Month
- MMD = Multi-Month Dispensed
- DC = Dispensing cycle

**TIER.Net "Grace" period**  
 VL done from 60 up to 270 days on ART will be included in the 6-month cohort

**TIER.Net "Grace" period**  
 VL done from 271 up to 540 days on ART will be included in the 12-month cohort



# VLD capturing in various cohorts

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Mr Matthew Chetty

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# Management of Viral Loads Results

- TIER.Net and allocation of results in ART cohort report TIER.Net
- Caveats to the Viral Load results management rules in TIER.Net

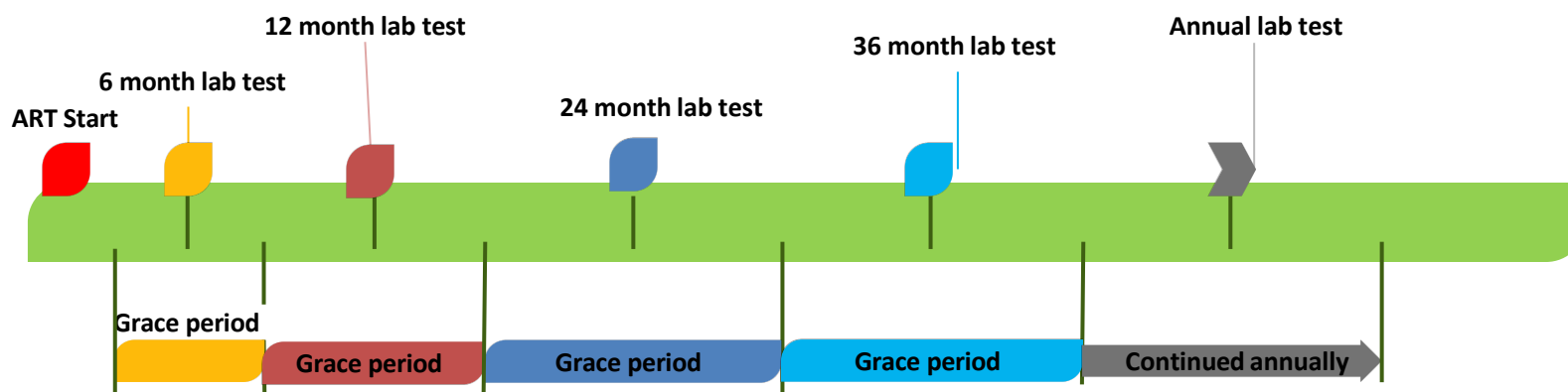
# Illustration of inclusion and exclusion criteria for Viral Load management in TIER.Net and allocation of results in ART cohort report



## Legend

**Milestone:** Routine Viral load monitoring test required in line with SA National ART guidelines

**Grace period:** Threshold rules allocate laboratory tests entered to the respective duration in ART



## Grace periods to the rules:

- (3-9months = 6VL), +/- 3 months for 6 months bloods
- (10-21months = 12 VL), - 2 months to + 9 months for 12 months bloods
- (22-31 months = 24 VL), - 2 months to +7 months for annual bloods

**Note:** The rules in TIER.Net summarize data in alignment with the routine laboratory tests as outlined in the National treatment guidelines. The rules in TIER.Net will allocate laboratory results entered in line with the durations and corresponding grace periods listed above. **No data will be excluded from the reports (except where a result is entered between 0 – <3 months from ART start).**

# Caveats to the Viral Load results management rules in TIER.Net



## Caveats to the rules in TIER.Net:

- **Caveat 1:**

If a person is **not on drugs (uLTF)** when the annual safety bloods are captured, then their bloods will be excluded.

This can be for 2 different reasons:

**1. Data quality/completeness:** if no visit is recorded (i.e., no regimen data) but a laboratory test is captured, the lab test will be excluded from the data as there is no corresponding visit to link to the requested test.

- **Reminder:** the denominator for **VLD is FLR+SLR.**

Thus, if no regimen is recorded then the laboratory result is excluded but this would also be excluded from the denominator. Data quality and completeness should be verified to ensure patient visits are captured.

**2. Clinical management:** Where a patient might be stopped treatment for clinical management reasons (i.e., this might happen if someone had hyperlactatameia and therefore had to stop drugs for their blood to normalise). This would be recorded as a patient visit with a 'stop' recorded and zero drugs issued. This too is excluded from the data collation.

- **NB:** Results are to be captured under the **visit** the bloods were drawn and not the date they were returned to the facility or the date they were filed.

**[Interpretation: if a regimen is not captured but a blood result is captured in the corresponding visit the blood result won't be included in the summary. Important to ascertain if this is a clinical management or data quality/completeness issue.]**

# Caveats to the Viral Load results management rules in TIER.Net



## Caveats to the rules in TIER.Net:

- **Caveat 2:**

- A patient with an **outcome** during the cohort summary duration being reported will be excluded from the summary data. Data is only reported on patients who are active on ART.
- e.g., reporting for 24 months, those patients with a viral load captured and an outcome between 12 and 24 months will be excluded from the data collation. But, again, the patient would not be included in the denominator so this would not affect the VLD data.

**[Interpretation: laboratory results are excluded where a patient has an outcome. Thus, this does not affect the data completeness due to the denominator definition for VLD which is FLR + SLR.]**

# Caveats to the Viral Load results management rules in TIER.Net



## Caveats to the rules in TIER.Net:

- **Caveat 3:**
  - Only one laboratory result per reporting duration is included. If more than one viral load or CD4 count is captured within the same duration (and grace period) only the latest result captured is included in the collated data per reporting duration.

**[Interpretation: only 1 test is counted per person, per reporting duration. Any additional tests done and entered for patient management and monitoring purposes are important but aren't included in the summarized data]**

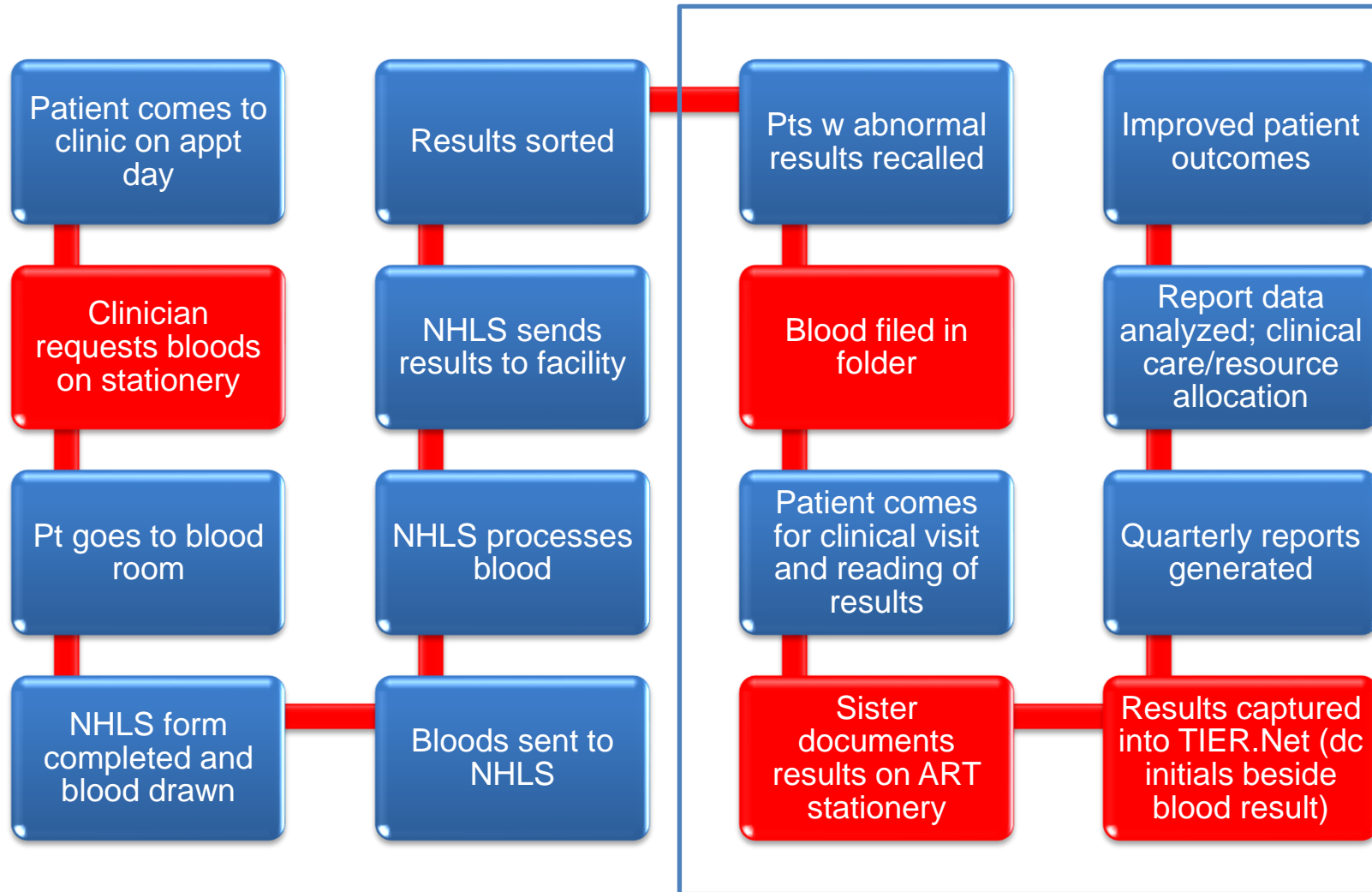
**Note:** The rules in TIER.Net summarize data aligned to the National treatment guidelines and are not meant to prescribe patient management. TIER.Net collates the data that is captured to assist with program monitoring.

# Management of Viral Load in TIER.Net

- Viral Load Journey
- TIER.Net Guidance
- VL Results in TIER.Net
- TIER.Net VL Capturing



# Viral load journey: making it to the Quarterly Reports...



# The diagram on the previous screen illustrates the journey of the laboratory request and results



- The **red blocks highlight** the key points where the VL might not be done or not captured, though all blocks are places where the results might drop off (i.e., not happen).
- This also illustrates the integrated role everyone plays to ensure the results are returned to the patient file and captured into TIER.Net.
  - If the laboratory request is done (sticker in the clinical stationery), but the result is not filed in the patient file, the clinician does not have the information to effectively manage the patient.
  - If the result is not captured in the stationery the data capturer cannot capture the result. This results in low proportions of VLD. And unreliable VLS.
- The implication of not filing the results is we are not effectively managing our patients, but we are also spending a lot of money on laboratory tests that aren't being acted on!
- Additionally – results **NOT** captured into TIER.Net are not included in the push button management reports.
- Refer to ART M&E SOP for further guidance.



## Management of normal and abnormal laboratory results in TIER.Net guidance

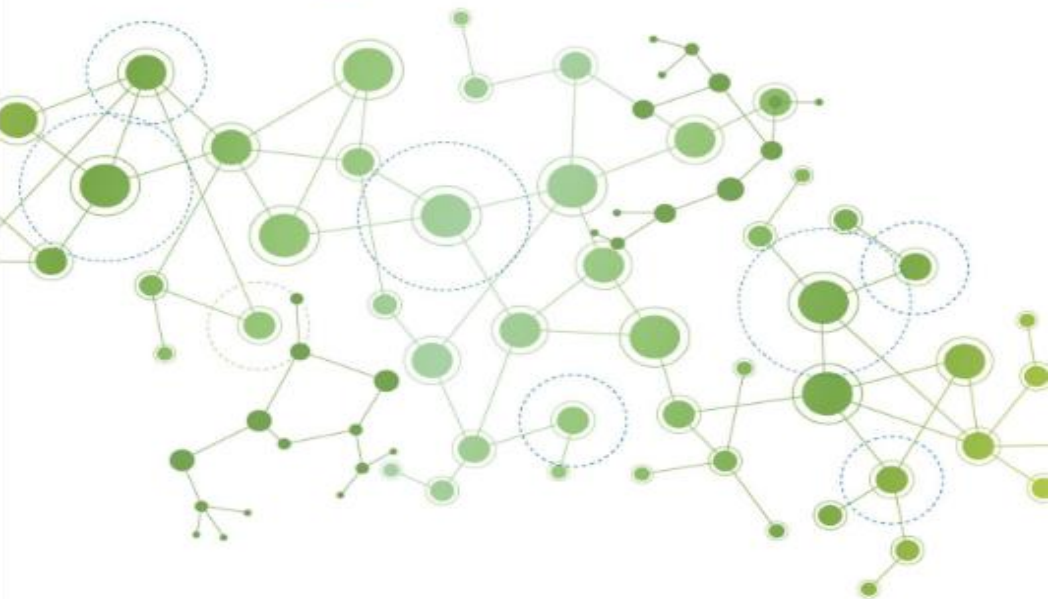
*This revised guidance includes step by step instruction for all activities relating to NHLS laboratory results as conducted by both the clinician and the administrative clerk (AC); including the requesting of laboratory tests, the triaging of results, recall of patients (if required), the capturing of results and recall intervention into TIER.Net, and the filing of the results in the patient folder.*

### Requesting diagnostic tests:

1. During the clinician consultation, the Clinician to indicate in the clinical stationery the requested tests.
  - 1.1. HIV/ART clinical stationery: Indicate the type of specimen requested in the visit column of the ART clinical visit summary corresponding to the clinical visit date.
  - 1.2. TB clinical stationery: Indicate in the laboratory tests and diagnostics section, or in the TB ID register the type of test requested.

*Note: If the test is requested by one clinician but referred to another for completion of the test, then the clinician conducting the specimen collection, will need to complete section 2 and 3 below.*

2. Clinician, who is conducting the test, to complete the NHLS Laboratory request form.
  - 2.1. Place the barcoded lab specimen number sticker from the corresponding NHLS form on each specimen tube/jar and in the clinical stationery or TB ID register next to the requested test.
3. Clinician to record results from point of care (POC) instruments in the clinical stationery, indicating the type of test, the result, date, and document using 'POC' to indicate that the test was conducted using a POC machine.



# VL Results in TIER.Net



#	Date: 10 / 05 / 2012
	N / D :
History and examination	Weight
	Temp / Height
	Months on ART
	Months on regimen
Investigation	Notes
	OTI months
	PD conditions
	Months on TB Rx
	TB M / C / S
	CD4 (CD4%)
	Viral Load
	ALT
	HB / WCC / PLT
	Other investigation results (incl. XR)
Assessment	HIV conditions / O/S, TB & other conditions
	Adverse event / grade
	Adverse event / grade
	Adverse event / grade

Data clerks get this information from clinical stationery

FIGURE 1. TEST REQUEST CAPTURING IN TIER.NET

## Capturing of requested tests:

1. AC (using the patient folders and TB Identification register) to capture **requested** lab tests into TIER.Net.
  - 1.1. Open patient record, and in TIER.Net, capture the test requested against the corresponding visit.

## Management of laboratory test results:

**Note:** All results (normal and abnormal) must be captured into the TB/HIV information system on the same day they are triaged by the clinician.

## Triaging of Results:

1. Clinician to triage **all** test results as soon as they are received (via NHLS hard copy or SMS printer).
2. Document **all** TB case finding results in the TB ID register, irrespective of result.
3. Return **all** triaged results to the admin clerk.
  - 3.1 Clinician to request patient folder from the admin clerk for **all** abnormal results received.
    - 3.1.1 Once folders are received; clinician to review and document intervention in clinical stationery.
    - 3.1.2 Clinician to open TB blue card for all TB positive patients.

# TIER.Net VL Capturing



When a clinician requests a viral load, as indicated in the clinical stationery, click on the New button in the Test Results grid



This will open the Test Details window. The test date will automatically be populated with the visit date.

Select the Test type. - Enter the Lab reference number if available.  
Click on Save to save the test request

Test Details

Specimen details

Test date: 23 Jan 2020

Test type: VL

Specimen type:

Lab reference number: Lab 0001

Result returned:  Result confirmed NA:

Result returned within 48 hours:

Test result: 19 LDL

Absolute Percentage

Save Close

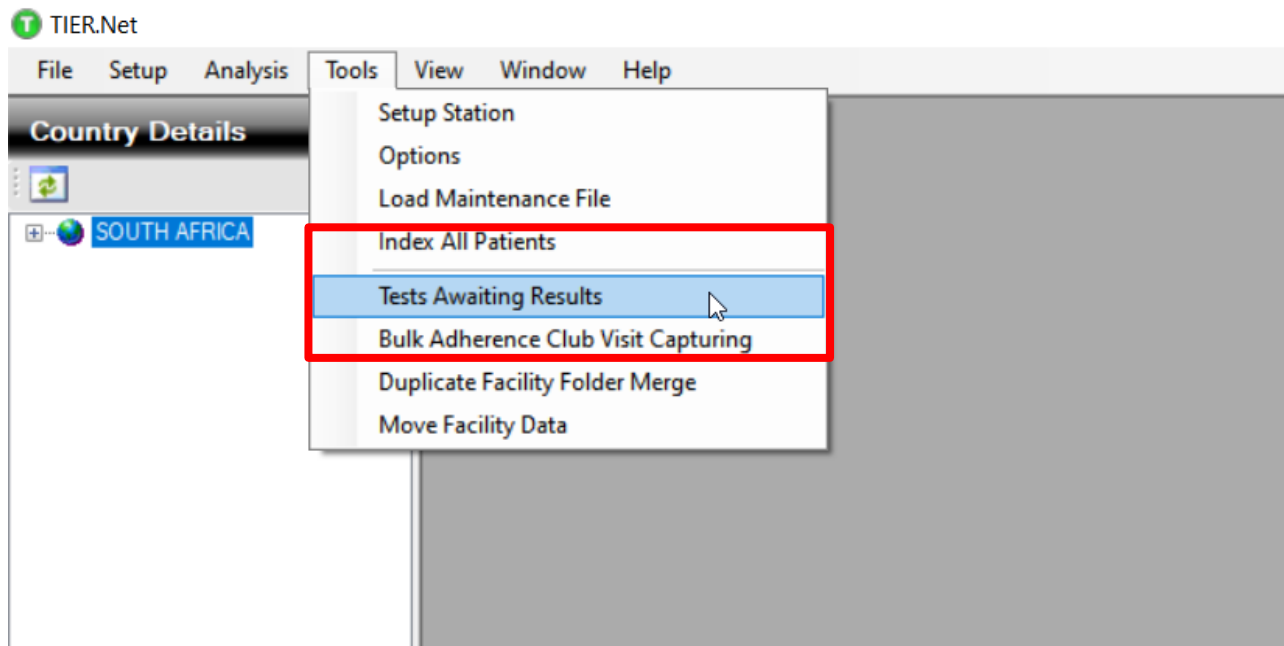
Once the visit has been saved, the next time the user opens the patient record, the visit dates where the tests were requested will appear in **bright orange**. This indicates that there are blood results against this visit that have not been captured

Treatment Visits							
					0 (Nov 19)		
					ITFE	VL	CD4
1 (Dec 19)	2 (Jan 20)	3 (Feb 20)	4 (Mar 20)	5 (Apr 20)	6 (May 20)	VL	CD4
7 (Jun 20)	8 (Jul 20)	9 (Aug 20)	10 (Sep 20)	11 (Oct 20)	12 (Nov 20)	VL	CD4

# Bulk capturing of returned (normal) results



- Once results have been returned, and triaged by a clinician, all NORMAL and INITIALLED results can be captured in bulk
- Under **Tools** click 'Tests Awaiting Results' (renamed from 'pending tests')



- Bulk capturing functionality was designed to drive efficiency (speeds up capturing)
- Not universally utilised in facilities
  - Missed opportunity to alleviate the AC workload
- Clinicians **MUST** document test in clinical stationery (affix sticker) – Good Clinical Practice
- Tests **MUST BE** captured
  - Non-capturing of tests limits usefulness of bulk capturing

**Critical prescriptions - all laboratory results must be triaged by a clinician on same day that results arrive**

# Bulk capturing of returned (normal) results (2)



- Search by folder number, or by lab reference number
- Or, click on headings to sort any column
- Double-click to open the patient record

Tests awaiting results

Search

Folder number  Lab reference

Number of records: 39

	Folder number	Name	Surname	Test type	Test date	Lab reference
▶	890909ZUL	ZOE	ZULU	GeneXpert	31 Aug 2018	AKK01152
	FOLDER_100728	Xandra	Guthrie	VL	21 Aug 2018	ABPJ0299P
	FOLDER_100728	Xandra	Guthrie	CD4	21 Aug 2018	ABPJ0299P
	FOLDER_100126	Medge	Howe	CD4	08 Aug 2018	ABOP4832P
	FOLDER_100126	Medge	Howe	VL	08 Aug 2018	ABOP4832P
	FOLDER_100161	Scarlet	Hamison	CD4	08 Aug 2018	ABOP4825P
	FOLDER_100161	Scarlet	Hamison	VL	08 Aug 2018	ABOP4825P
	FOLDER_100399	Maia	Gilliam	VL	08 Aug 2018	ABOP4829P
	FOLDER_100450	Kelsey	Foreman	VL	08 Aug 2018	ABOP4826P
	FOLDER_1001101	Giselle	Joyner	VL	08 Aug 2018	ABOP4827P
	FOLDER_1001229	Vielka	Rivera	VL	08 Aug 2018	ABOP4820P
	FOLDER_1001257	Sonya	Eve	VL	08 Aug 2018	ABOP4823P

Close

# Test results capturing window (1)



Test Details

Specimen details

Test date: 09 Jan 2023

Test type: VL

Specimen type: [dropdown]

Lab reference number: **ABTN2212345**

Result returned:  Result confirmed NA:

Result returned within 48 hours:

Test result: [text box] LDL

Absolute  Percentage

Save Close

- Bulk capture is 'short cut' to test results capturing window
- Tick '**Result returned**' to activate box for 'Test result'

Test Details

Specimen details

Test date: 09 Jan 2023

Test type: VL

Specimen type: [dropdown]

Lab reference number: ABTN2212345

Result returned:  Result confirmed NA:

Result returned within 48 hours: [text box]

**Test result: [text box] LDL**

Absolute  Percentage

Save Close



# Test results capturing window (2)



Test Details

Specimen details

Test date: 09 Jan 2023

Test type: VL

Specimen type: [dropdown]

Lab reference number: ABTN2212345

Result returned:  Result confirmed NA:

Result returned within 48 hours:

Test result: [text box] **LDL**

Absolute  Percentage

Save Close

For VLs, button for LDL auto populates test result with 19

Test Details

Specimen details

Test date: 09 Jan 2023

Test type: VL

Specimen type: [dropdown]

Lab reference number: ABTN2212345

Result returned:  Result confirmed NA:

Result returned within 48 hours:

Test result: 19 **LDL**

Absolute  Percentage

Save Close

# Common error: capturing test result in box for lab reference number



Tests awaiting results

Search

Folder number  Lab reference

Number of records: 39

Folder number	Name	Surname	Test type	Test date	Lab reference
FOLDER_1001766	Nasim	Romero	VL	2018/08/06	
FOLDER_100892	Jaquelyn	Holden	CD4	2017/01/02	200
FOLDER_100728	Xandra	Guthrie	VL	2018/08/21	389
900706KHO	MANDLA	KHOZA	Smear	2018/01/02	AAPP2474POF
FOLDER_100628	Nayda	Mcclure	CD4	2018/08/06	ABOP4803P

Our reports can be a reflection of how well the system is functioning?



Therefore, it is essential the quality of the data is good in order to adequately interrogate the program.

# Poll Question 3



1. Which Option below will allow you to access the Data Validation List ? *Ans. Analysis*




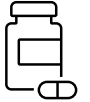


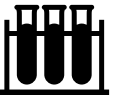
- A. Setup*
- B. Tools*
- C. View*
- D. Analysis*

2. What List can be used to Identify clients who may need to be switched to 2nd line or who need another viral load? *Ans. Two Consecutive Unsuppressed Viral Load List*

- A. Viral Load Overdue List*
- B. Monthly Report*
- C. Facility Management Report*

# Conclusion



New terminology	Clinical changes 	Impact on TIER.net 	Data Capturer's role
<b>TLD/ALD 1</b>  	DTG-containing regimen, who have never failed any other regimen ( <b>previous “first-line”</b> )	Capture ART regimen as <b>“First-Line Regimen”</b>	✓ Ensure that the regimen number and 3 ARV drugs (with additional drugs if indicated) are captured correctly
<b>TLD/ALD 2</b>  	DTG-containing regimen, who have failed an earlier regimen ( <b>previous “second-line”</b> )	Capture ART regimen as <b>“Second-Line Regimen”</b>	
<b>VL monitoring according to dispensing cycles (DCs)</b> 	<ul style="list-style-type: none"> <li>1<sup>st</sup> VL <u>after</u> 3 DCs:                             <ul style="list-style-type: none"> <li>→ <b>6-month cohort</b></li> </ul> </li> <li>2<sup>nd</sup> routine VL <u>from</u> 10 DCs:                             <ul style="list-style-type: none"> <li>→ <b>12-month cohort</b></li> </ul> </li> <li>3<sup>rd</sup> and subsequent routine VLs <u>from</u> 22 DCs in intervals of 12 DCs thereafter:                             <ul style="list-style-type: none"> <li>→ <b>24-month, 36-month cohort etc</b></li> </ul> </li> </ul>	VL cohorts will remain unchanged	✓ Ensure all VL results are captured

# Thank you for your time

## Questions / Comments

