VL MANAGEMENT ON ART

AWACC 2023 – 20/10/23

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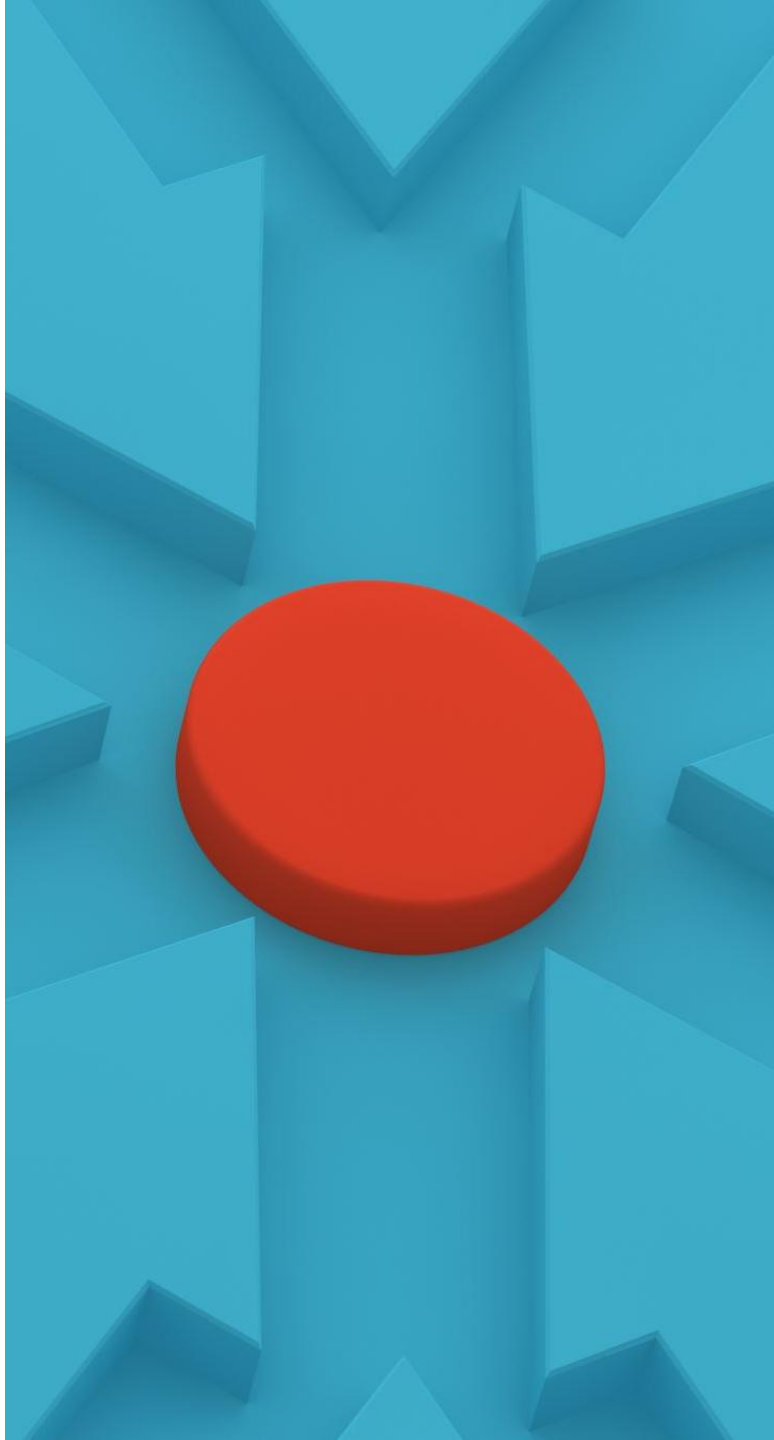


OPERATION PHUTHUMA

NERVE CENTRE SUPPORT HANDBOOK

VERSION TWO
01 MARCH 2022

HIV PRIORITY INDICATORS

The handbook focuses on the HIV priority indicators listed below. It is important to note however, that all principles taught in this handbook, can and should be applied to all indicators in any programme. These are the HIV programme priority indicators:

1. Total HIV tested
2. Total HIV positive
3. Total naive start ART
4. Total remaining on ART (TROA)
5. TLD Transition
6. ART Viral Load Suppressed
7. Differentiated Models of Care (DMOC)

OUTLINE OF PRESENTATION

LATEST STATISTICS ON 95-95-95

LESSONS LEARNT FROM STRATEGIES TO IMPROVE VL MANAGEMENT IN KZN

THE VL CHAMPION MODEL

- 1. MAKING VL MONITORING ROUTINE AND IMPROVE VL COVERAGW
- 2. IMPROVING THE VL FAILURE CASCADE MANAGEMENT

DTG BASED REGIMENS –NEW NDOH GUIDELINES = TOOLS AND SOP

VL MANAGEMENT -OVERVIEW OF GUIDELINES

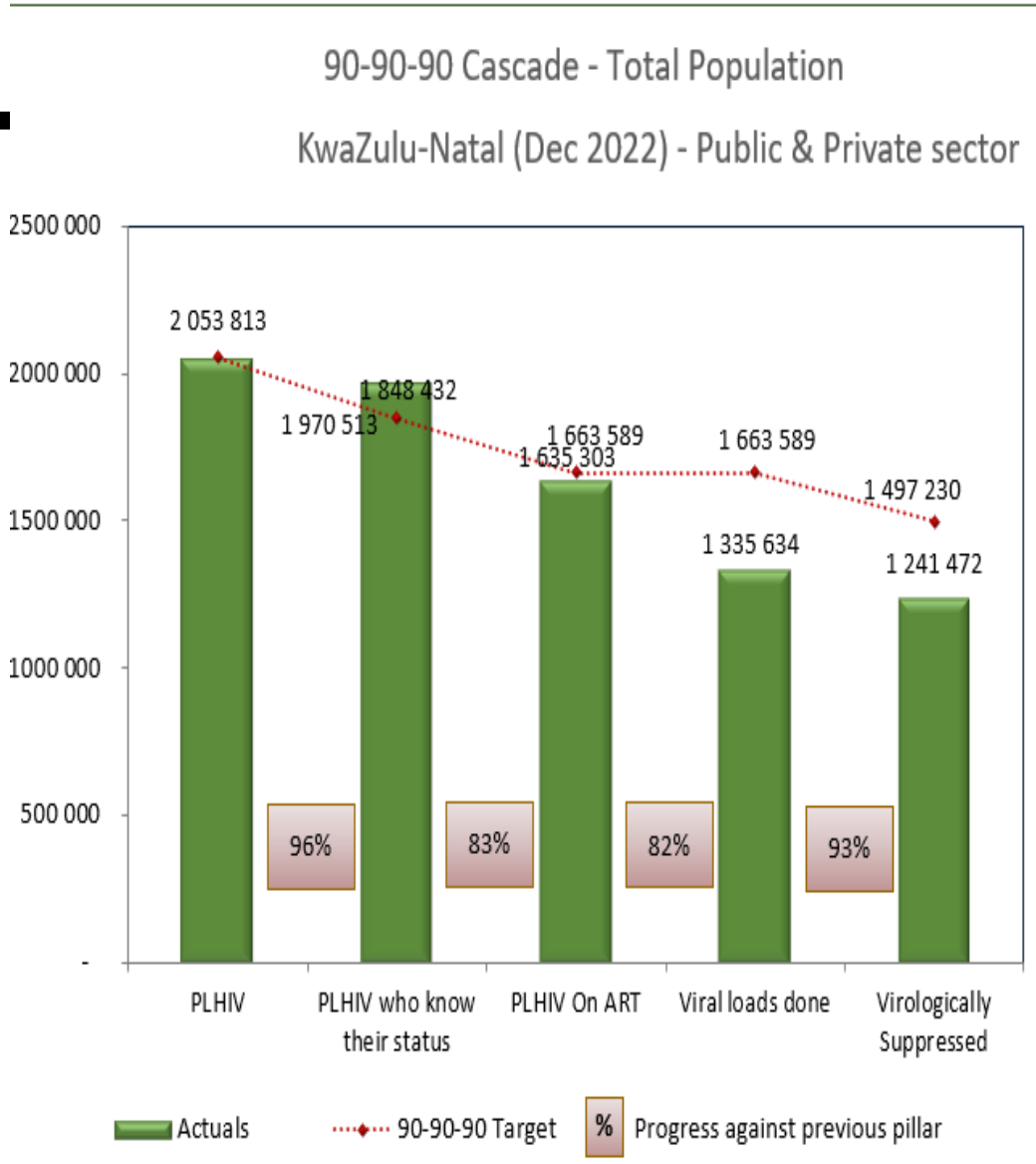
LOW LEVEL VIRAEMIA

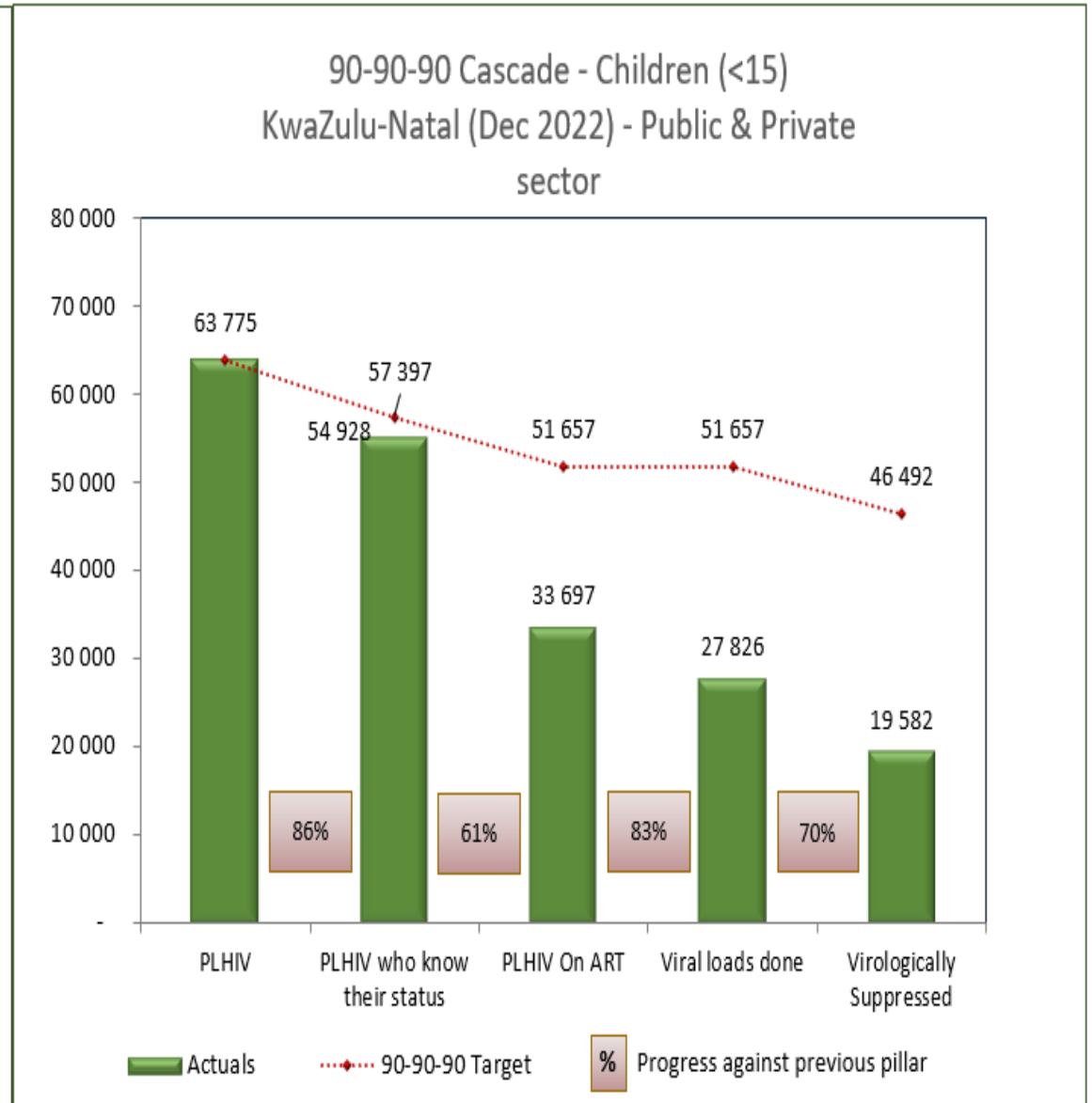
District graduation table as of Dec 2022 (Public & Private sector)

Province	District	95-95-95		
		1st 95 Source: Thembisa 4.5	2nd 95 Source: DHIS & CMS	3rd 95 Source: DHIS - VLS rate 12 mth cohort
KwaZulu-Natal	Umkhanyakude	96%	97%	95%
KwaZulu-Natal	Umzinyathi	96%	93%	93%
KwaZulu-Natal	Harry Gwala	96%	91%	92%
KwaZulu-Natal	Zululand	96%	88%	92%
KwaZulu-Natal	Uthukela	96%	89%	90%
KwaZulu-Natal	King Cetshwayo	96%	84%	94%
KwaZulu-Natal	Ugu	96%	82%	93%
KwaZulu-Natal	eThekwini	96%	80%	93%
KwaZulu-Natal	uMgungundlovu	96%	81%	92%
KwaZulu-Natal	Amajuba	96%	74%	96%
KwaZulu-Natal	iLembe	96%	73%	92%

Q1

- WHAT WAS THE VL COVERAGE IN KZN AMONG ALL DISTRICTS in DEC 2022?
- 1. > 95 %
- 2. 63.5 %
- 3. 76%
- 4 .83%


90-90-90 Cascade - Total Population
KwaZulu-Natal (Dec 2022) - Public & Private sector
2500 000
2000 000
1500 000
1000 000
500 000
-
2 053 813
1 970 513
1 848 432
1 635 303
1 663 589
1 663 589
1 335 634
1 497 230
1 241 472
96%
83%
82%
93%
PLHIV
PLHIV who know their status
PLHIV On ART
Viral loads done
Virologically Suppressed
Actuals
90-90-90 Target
%
Progress against previous pillar


90-90-90 Cascade - Children (<15)
KwaZulu-Natal (Dec 2022) - Public & Private sector
80 000
70 000
60 000
50 000
40 000
30 000
20 000
10 000
-
63 775
57 397
54 928
51 657
51 657
46 492
33 697
27 826
19 582
86%
61%
83%
70%
PLHIV
PLHIV who know their status
PLHIV On ART
Viral loads done
Virologically Suppressed
Actuals
90-90-90 Target
%
Progress against previous pillar

Duration		D012 months				
Data		Oct to Dec 2018	Jan to Mar 2019	Apr to Jun 2019	Jul to Sep 2019	Jan to Mar 2020
ART adult viral load done rate	kz Amajuba District Municipality	68,1	76	76,9	68,6	62,4
	kz eThekwini Metropolitan Municipality	80,4	83,7	81,1	73,6	73,9
	kz Harry Gwala District Municipality	87,4	87,6	86,2	81,1	77,7
	kz iLembe District Municipality	67,8	71,8	70,5	68,2	67,6
	kz King Cetshwayo District Municipality	83,9	87,2	90,4	87,4	80,8
	kz Ugu District Municipality	84	86,9	84,8	80,2	76,2
	kz uMgungundlovu District Municipality	74,3	80,8	83,3	80,7	74
	kz Umkhanyakude District Municipality	71,4	79,7	79,6	74	65,2
	kz Umzinyathi District Municipality	78,3	78,7	77,8	74,9	76,1
	kz Uthukela District Municipality	80,5	75,8	78,7	74,6	71,7
	kz Zululand District Municipality	82,8	80,3	81,6	76,4	73,9
	kz KwaZulu-Natal Province	78,8	82	81,7	76,3	73,5
Duration		D012 months				

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VL MANAGEMENT -OVERVIEW OF GUIDELINES

LOW LEVEL VIRAEMIA

Viral Load Monitoring for People Living with HIV in the Era of Test and Treat: Progress Made and Challenges Ahead – A Systematic Review

Minh D. Pham Huy V. Nguyen David Anderson Suzanne Crowe Luchters

Posted Date: November 30th, 2021 /DOI: https://doi.org/10.21203/rs.3.rs-1091142/v1

- **VL coverage studies (11 in South Africa)**

4 in Cape Town with high VL coverage of **72–89%.**

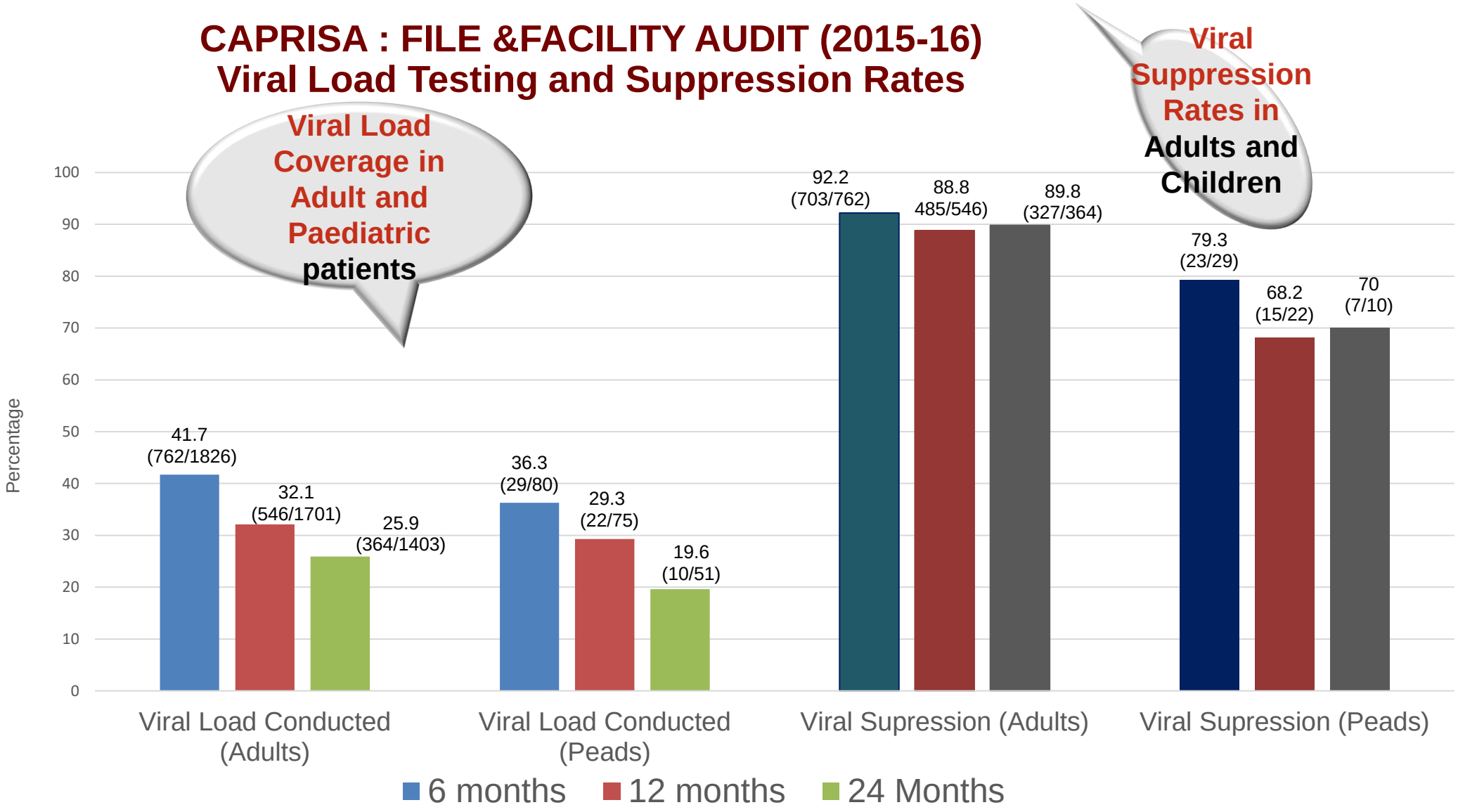
6 in KZN , EC and Gauteng and 1 from all 9 provinces - VL coverage **range** of **25%-81%.**

- **Few studies with interventions to improve quality of ART program had a VL coverage of >90%**
- The highest VL coverage at 6 months (94%) and 12 months (96%) after ART initiation were reported from a study in South Africa **assessing the impact of an intervention program to improve VL monitoring in which trained nurses were designated to the role of "VL champion" to follow-up on VL testing for PLHIV on ART** (30)

Sunpath, H., et al., Targeting the third '90': introducing the viral load champion. Public Health Action, 2018. 8(4): p. 225–231.

BACKGROUND TO VL CHAMPION STUDY

CAPRISA : FILE &FACILITY AUDIT (2015-16)
Viral Load Testing and Suppression Rates

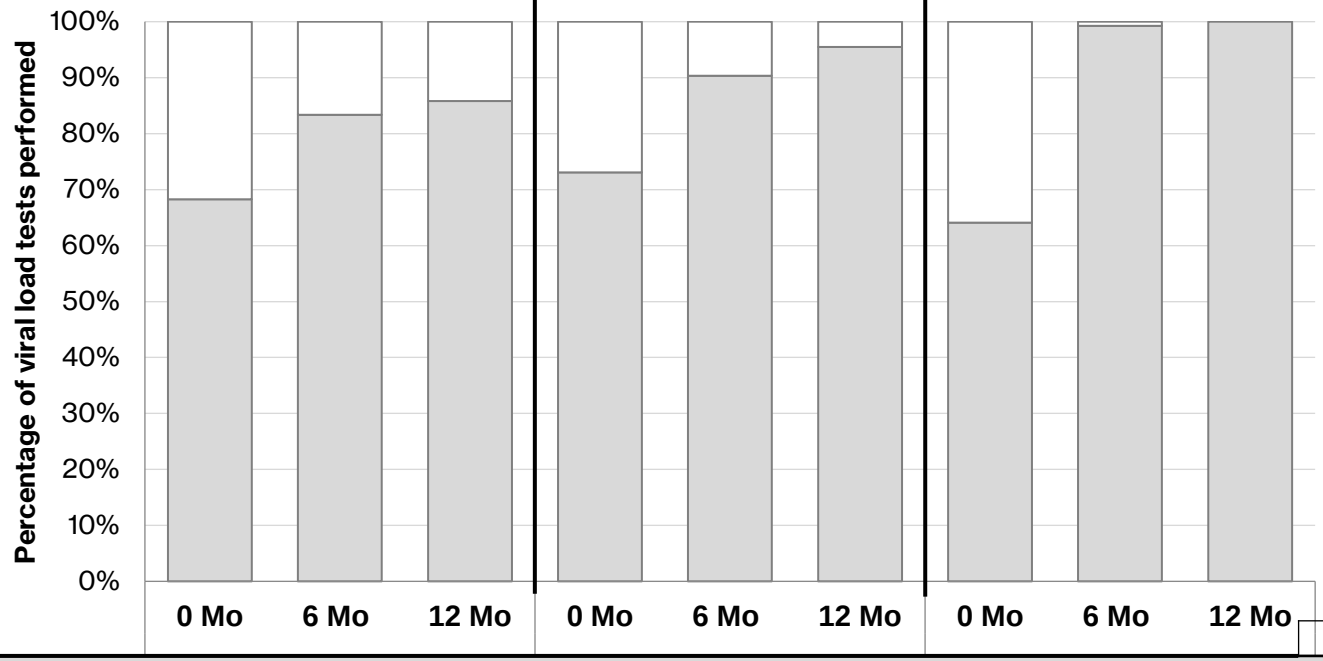


1.1. Naidoo K, Sunpath H. CAPRISA Advanced Clinical Care: strategies to optimize identification of unsuppressed viral load in patients on second-line antiretroviral therapy. Data Use Innovations and Best Practices Workshop. ([https://za.usembassy.gov/wp-content/uploads/sites/19/S11_1425_NaidooK_Strategies-to-optimize-ID.pdf

IMPLEMENTATION SCIENCE RESEARCH –*CAPRISA ACC PROGRAM (PEPFAR –CDC)*

Viral Load Tests Performed Among Those eligible for VL Testing -3 pilot ART sites (eThekwini 9872 pts)

Sunpath H, Hatlen TJ, Naidu KK, Msimango P, Adams RN, Moosa M-YS, et al. Targeting the third "90": introducing the viral load champion. Public Health Action. 2018 Dec 21;8(4):225–3



Cochran-Armitage Trend Test for viral load tests performed per site:

Site 1: p < 0.0001
Site 2: p < 0.0001
Site 3: p < 0.0001
Cumulative: p < 0.0001

□ VL Expected
▨ VL Performed

							Cumulative	
0 Mo								
VLP/VLE	140/205	68%	84/115	73%	323/504	64%	547/864	63%
VLS/VLP	112/140	80%	78/84	93%	307/323	95%	497/547	91%
6 Mo								
VLP/VLE	995/1194	83%	793/878	90%	3101/3124	99%	4889/5196	94%
VLS/VLP	840/995	84%	758/793	96%	2996/3101	97%	4594/4889	94%
12 Mo								
VLP/VLE	2262/2636	86%	1742/1824	96%	6636/6636	100%	10640/11096	96%
VLS/VLP	1920/2262	85%	1646/1742	94%	6519/6636	98%	10085/10640	95%

ADRENERGY RESEARCH INNOVATIONS

CAPRISA

CENTRE FOR THE AIDS PROGRAMME OF RESEARCH IN SOUTH AFRICA

UNAIDS

CAPRISA is the UNAIDS Collaborating Centre for HIV Research and Policy

LAUNCH OF THE KZN HIV VL AND DR MONITORING PROJECT

INTRODUCING THE VL CHAMP

MAKING VL MONITORING ROUTINE AND MANAGING HIGH VL

Dr.Henry Sunpath

Infectious Diseases Unit –NRMSM –UKZN

DIRECTOR MEDICATE –AIDS NPC T/A AWACC

CONSULTANT CAPRISA - ACC

AWACC 2017 -2019

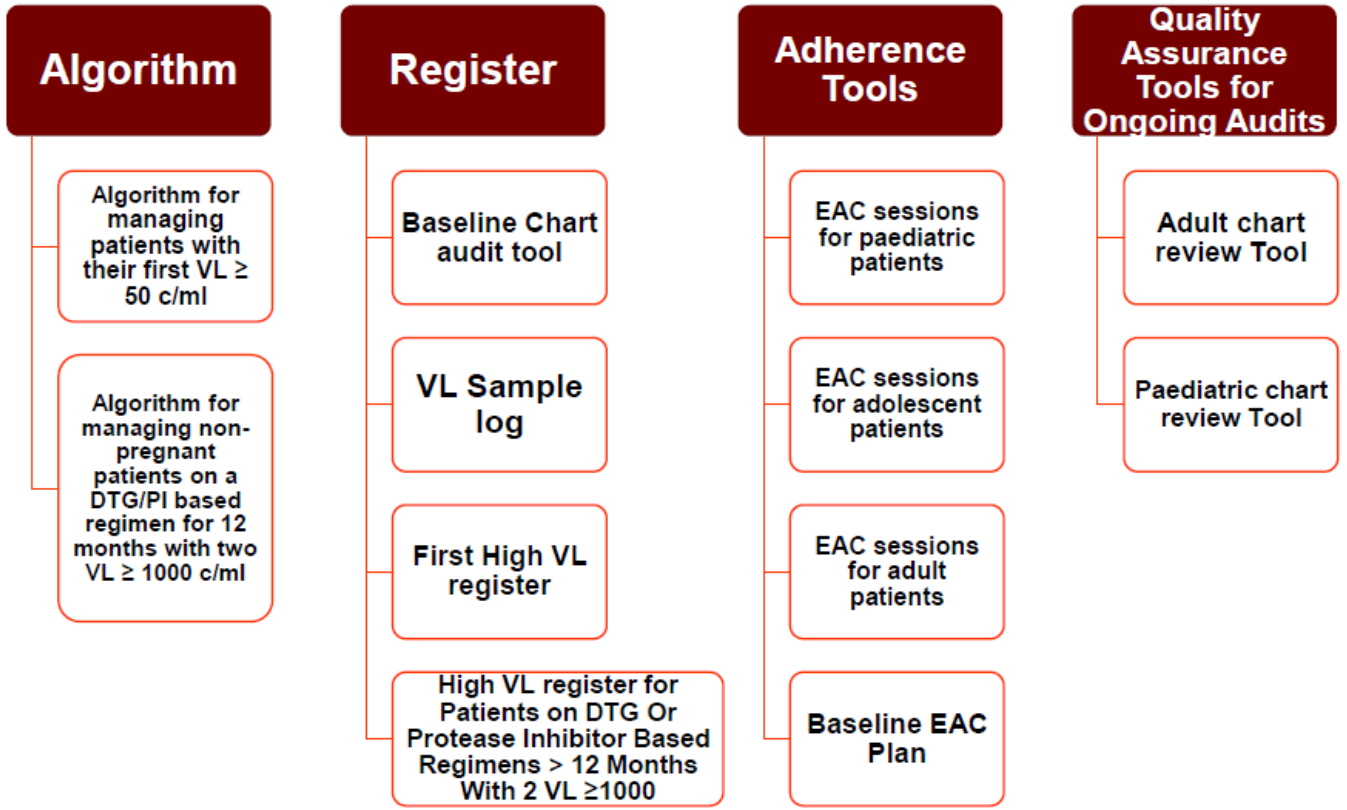
PROVINCE OF KWAZULU-NATAL
ISIFUNDAZWE SAKWAZULU-NATALI

DEPARTMENT OF HEALTH & HUMAN SERVICES · USA

CDC CENTERS FOR DISEASE CONTROL AND PREVENTION

CAPRISA CENTRE FOR THE AIDS PROGRAMME OF RESEARCH IN SOUTH AFRICA

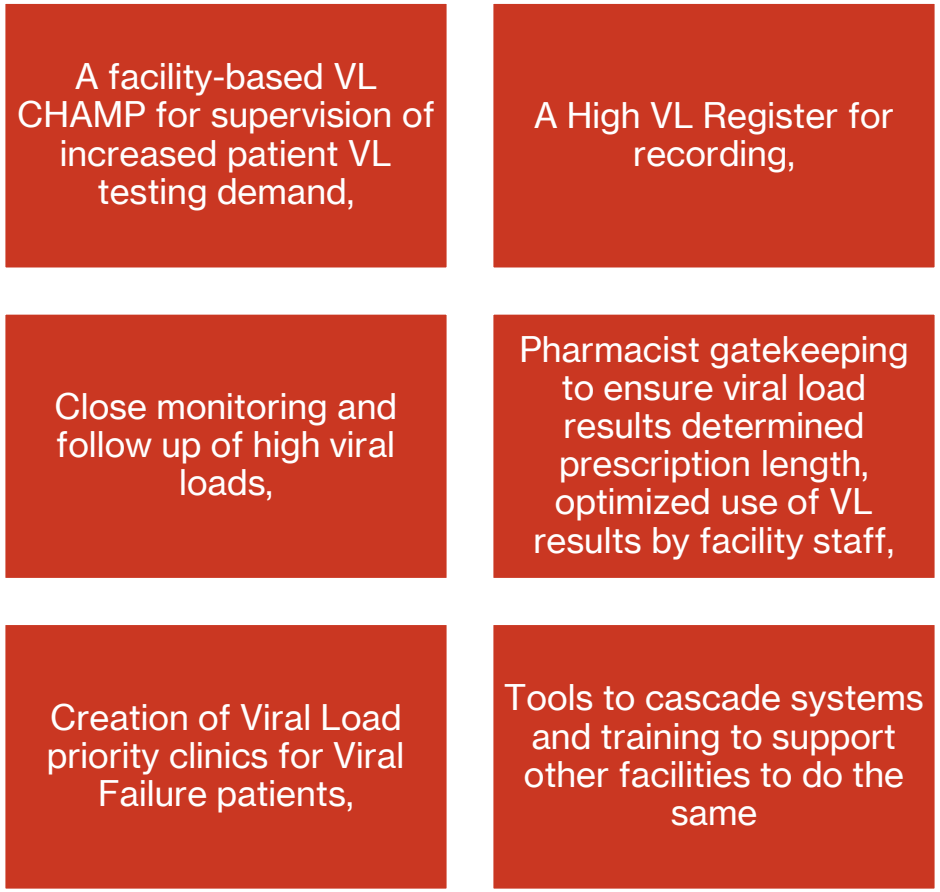
Algorithms, Registers, SOP's, Tools for VL Monitoring and Management



Roles and Responsibilities of QA team members
VL Champion activities
Standard Operating Procedure for First Line Viral Load Management
Standard Operating Procedure for the Management of high viral load in non-pregnant adolescents and adults on an INSTI- based or Protease Inhibitor (PI) - based antiretroviral therapy

CAPRISA

Sustained improvements in Viral Load Monitoring with Health Systems Strengthening: Experiences from the KwaZulu Natal ART Programme …NDOH research day 2021 …Authors: Jaqueline Ngozo[1], Marothi Letsoalo[2], Farzana Osman[2], Henry Sunpath[4], Kogieleum Naidoo[2,3]



Targeted health systems strengthening intervention with the VL champion model demonstrated significant improvements in VL monitoring compared to the pre-intervention period.

Results. :

KZN –Among 616 facilities in 11 health districts,=

VL testing coverage was 75.5% - improved by almost 10% during the intervention versus pre-intervention period, p<0.001, IRR 1.095 (CI: 1.05 – 1.14). 2017-2018

In the eThekwini District =

VL testing coverage was 78.6% improved by 5% during the intervention versus pre-intervention period p=0.1178, IRR 1,046 (CI: 0.98 – 1.11).

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Posted Date: November 30th, 2021 /DOI: https://doi.org/10.21203/rs.3.rs-1091142/v1

- **Suboptimal uptake of follow-up VL after** initial elevated VL (median 66%, IQR: 38–77%);
- **High proportion of confirmed treatment failure those who had a follow-up VL** (median 62%, IQR: 50–75%)
- **Low switching rate** among those with confirmed treatment failure (median 45%, IQR: 36–71%).
- Possible causes - **inadequate EAC and/or poor implementation of VF cascade**

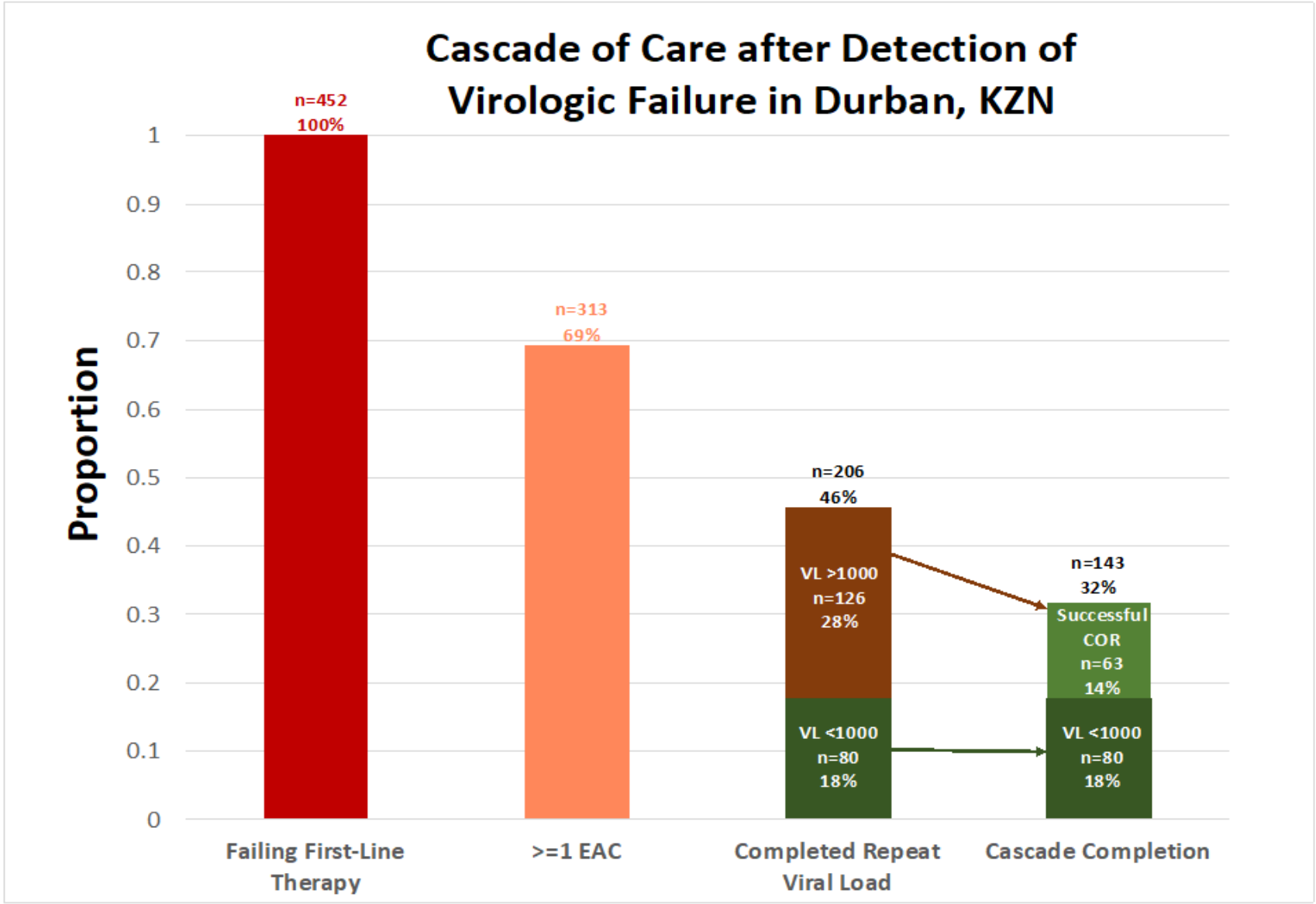
Operations research and intervention strategies (facilty and community based)- needed to address the failure cascade and preserve the efficacy of first/second-line ART

BASELINE DATA :

Three months observational cohort (March –June 2017)

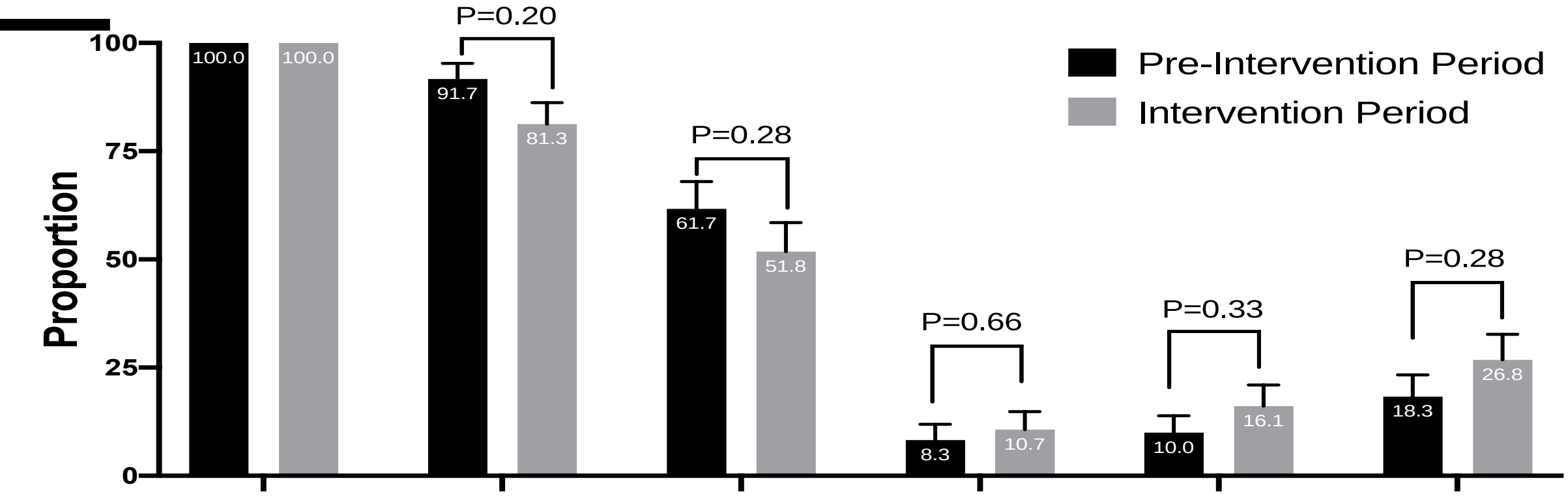
Only 32% (143/452) of patients with FLART failure re-suppressed or were changed to SLART

- Only 27% (117/452) and 8% (35/452) did so within 180 and 90-days, respectively



Sunpath H, Naidu K,Pillay S ,Naidoo K ,Seidner M ,et al The Second Cascade: Management of Patients with High Viral Loads in Public HIV Clinics in Durban, South Africa. 22nd International AIDS Conference (AIDS 2018): Abstract A-899-0219-07643. www.aids2018.org

Second-Line Cascade of Care Prior to and after Implementation of a Nurse-Led Viral Load monitoring and Management Program

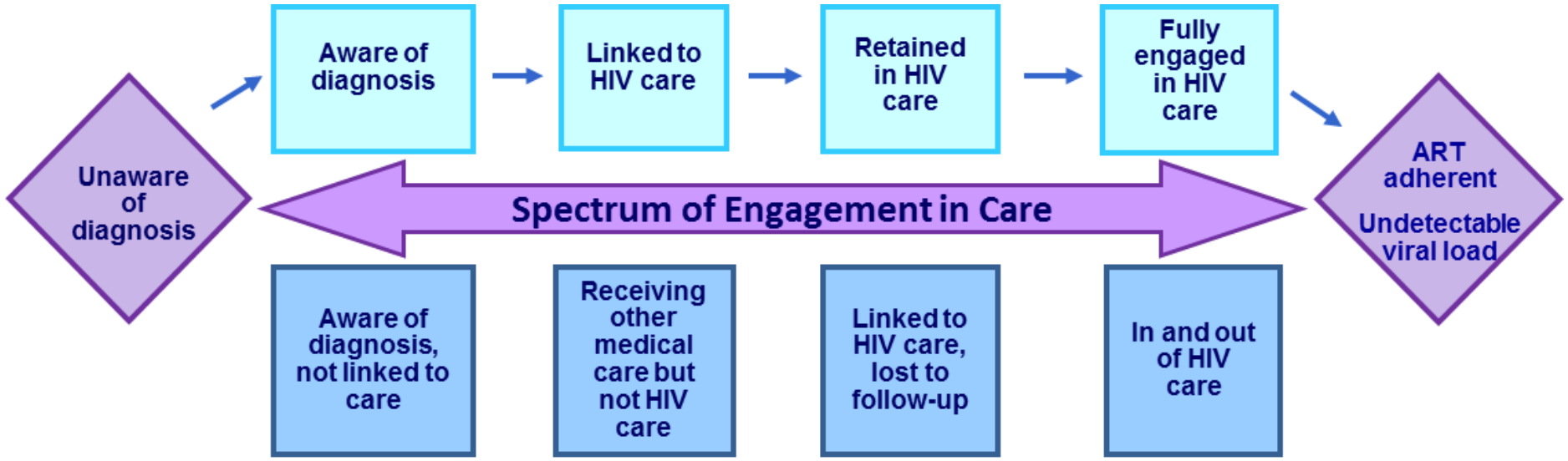


*Successful outcome defined as a repeat VL <1000 copies/mL or a change to second= line ART after a repeat VL>1000 copies/mL within 6 months of first-line ART virologic failure

USE OF A SOP and TOOLS to manage VF as part of the VL champ model

Sunpath H, Pillay S, Hatlen TJ , Murphy RA, Marconi VC, Moosa MYS, Naidoo K, Mark J. Siedner MJ . A nurse-led intervention to improve management of virologic failure in public-sector HIV clinics in Durban, South Africa: A pre-post implementation evaluation. SAMJ .April 2021

The Cascade /Continuum of CARE
Ideal vs. poor engagement in HIV care



REVISED CASCADE

Stage 1 –HIV + diagnosis/HIV+ re-diagnosis ===Linked /Re Linked

Interval from HIV test to enrolment in ART program or re initation

Stage 2 –Linked –Re linked ===Initiated /Re Initiated

From enrolment in ART program as new or returning patient to receiving ART

Stage 3 –Initiated reinitiated ==Early retention (until first VL result received or max of 6 months post ART)

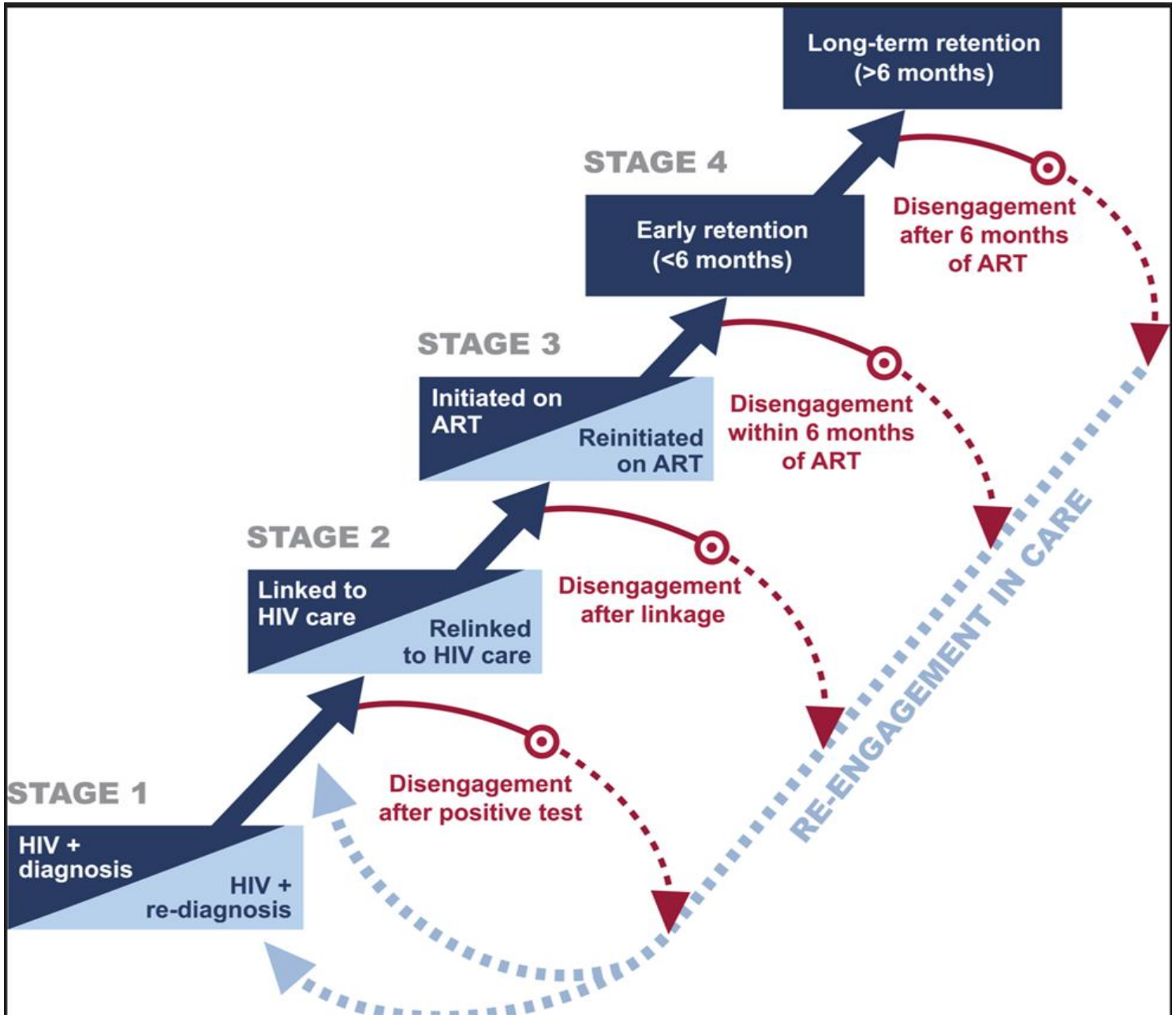
From first dose ART to initial VL test result (WHO : 6 months)

Stage 4 –Early retention===Long term retention (beyond first VL ,often > 6 months)

From first VL result (6 months) to final disengagement and/or death

DISENGAGEMENT – GAP of >30 days without ART

NB .SDI monitoring



The revolving door of HIV care: Revising the service delivery cascade to achieve the UNAIDS 95-95-95 goals

Peter Ehrenkranz, Sydney Rosen, Andrew Boulle, Jeffrey W. Eaton, Nathan Ford, Matthew P. Fox, Anna Grimsrud, Brian D. Rice, …PLOS . Version 2 Published: May 24, 2021.https://doi.org/10.1371/journal.pmed.1003651

- **REALITY - complex cycle of engagement, disengagement, temporary disuptions, reengagement, and transitions in care of PLWH**.

- REVISED CASCADE - inform and prioritize efforts by communities, healthcare workers, implementers, program managers, policymakers to
- **prevent missed clinic visits,**
- **overcome barriers to care reentry,**
- **minimize onset of advanced HIV disease.**

Focusing interventions on anticipating, and then reducing, the duration of gaps in care.

Improving data management to improve clinical monitoring

Taking it further …addressing the data management

Iwuji et al. BMC Infectious Diseases (2021) 21:1266
https://doi.org/10.1186/s12879-021-06952-5

BMC Infectious Diseases

STUDY PROTOCOL Open Access

Optimised electronic patient records to improve clinical monitoring of HIV-positive patients in rural South Africa (MONART trial): study protocol for a cluster-randomised trial

Collins Iwuji[1,2*], Meg Osler[3], Lusanda Mazibuko[2], Natalia Hounsome[1], Nothando Ngwenya[2], Rujeko Samanthia Chimukuche[2], Thandeka Khoza[2], Dickman Gareta[2], Henry Sunpath[4], Andrew Boulle[3,5] and Kobus Herbst[2,6]

Abstract

Background: There is poor viral load monitoring (VLM) and inadequate management of virological failure in HIV-positive individuals on antiretroviral therapy in rural KwaZulu-Natal, South Africa. This could be contributing to increasing HIV drug resistance in the setting. This study aims to investigate the clinical and process impediments in VLM within the health system and to evaluate a quality improvement package (QIP) to address the identified gaps. The QIP comprises (i) a designated viral load champion responsible for administrative management and triaging of viral load results (ii) technological enhancement of the routine clinic-based Three Interlinked Electronic Register (TIER.Net) to facilitate daily automatic import of viral load results from the National Health Service Laboratory to TIER.Net (iii) development of a dashboard system to support VLM.

NDOH – service delivery priorities

DATA MANAGEMENT TO IMPROVE PROGRAMOUTCOMES

Necessary admin staff – operate IT systems ,procure equipment and ensure connectivity

Functional filing system with reduced time for file retrieval and waiting times

Patient identification –SA ID ,passport , permanent residence or refugee number. Contact NDOH re implementation of Health Patient Registration System (HPRS) as unique identifier

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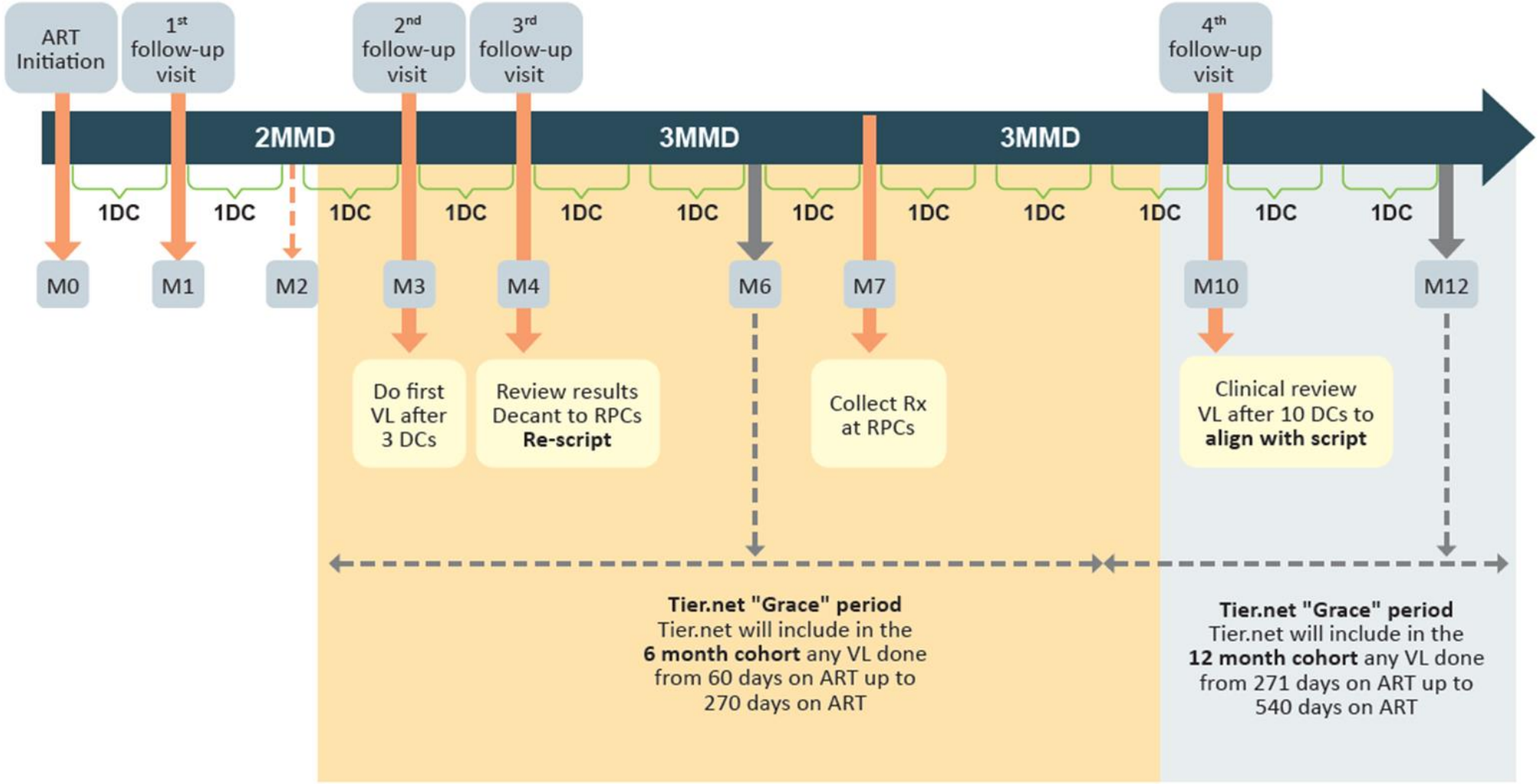

- For the 1st VL taken after 3 dispensing cycles, clients should be requested to return to the facility one DC later to review results and so that the client can be assessed for RPCs eligibility.
- For all subsequent VL monitoring (and other routine monitoring investigation) in clinically well clients: Clients should be rescripted at the same visit that their VL is taken. Clients should not be required to come back to the facility the following month for VL result review prior to rescript. Rather, recall to the facility only those clients with an elevated VL or other abnormal result.
- Facilities should ensure that results management processes are in place to ensure that results are reviewed by a clinician, that

List of Appendices to Proposed SOP for VL management in TLD 1 ,TLD2 and TLD2F regimens

- VL register for TLD 1 and TLD 2 and adherence <80 % with first VL> 60 c/ml
- VL register for TLD 2 and adherence > 80% and VL > 1000 c/ml and 500 -999 c/ml
- VL register for TLD2F regimens

SOP for VL management in the era of DTG regimens

Patient flow pathway in the clinic

Responsibilities of VL champion

Specialist /Expert Consultation For Complex Cases –KZN

Adult or Paediatric Infectious disease Hotline (King Edward VIII Hospital):

- Adult Infectious Disease Unit:
  - **080 011 1740**
- Paediatric Infectious Dise
  - **031 360 3111 or 031**

- Ngwelezane Hospital:
  - **0800 222 500**

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LOW LEVEL VIRAEMIA

Low level viraemia(LLV)

- **DEFINITIONS:**
- Much of the challenge in interpreting the significance of LLV comes from the discrepancies between various studies, including **the lack of uniformity in definitions of LLV and VF.**
- **Defined as two or more consecutive HIV RNA of at least 50 copies/mL,**
- Estimated prevalence of between 4 and 30%
- After achieving VL less than 50 copies/ml, most (more than half) of PLWH on ART maintain a residual HIV viremia at very low levels (1–10 copies/ml)
- Both transient and persistent increases in VL are frequently seen .
- *Rapid Response Service. Low-level HIV viremia: Definitions, predictors, mechanisms, and clinical outcomes. Toronto, ON: The Ontario HIV Treatment Network; January 2022. Prepared by David Gogolishvili*

The World Health Organization (WHO) 2016

- **Virologic failure** : detectable VL exceeding 1,000 copies/mL (two consecutive VL measurements within a 3-month interval with adherence support between measurements) after at least 6 months of using ART .**based on the fact that the risk of HIV transmission and disease progression is very low when VL is lower than 1,000 copies/mL**

- Below this threshold, **viral blips or intermittent low-level viremia** (50–1,000 copies/mL) can occur during effective treatment but have not been associated with an increased risk of treatment failure

- Recent studies from these settings suggest that lowering the threshold for switching to second-line ART to 100 copies/mL led to a higher proportion of participants with low-level viremia achieving viral suppression (<50 copies/mL) These studies support a lower threshold for defining virologic failure and switching to second-line ART in future WHO guidelines as well as incorporating of provisions for management of low-level viremia in them

Brown JA, Amstutz A, Nsakala BL, Seeburg U, Vanobberghen F, Muhairwe J, et al. Extensive drug resistance during low-level HIV viraemia while taking NNRTI-based ART supports lowering the viral load threshold for regimen switch in resource-limited settings: a pre-planned analysis from the SESOTHO trial. Journal of Antimicrobial Chemotherapy. 2021;76(5):1294-8.

Amstutz A, Nsakala BL, Vanobberghen F, Muhairwe J, Glass TR, Namane T, et al. Switch to second-line versus continued first-line antiretroviral therapy for patients with low-level HIV-1 viremia: an open-label randomized controlled trial in Lesotho. PLoS Medicine. 2020;17(9):e1003325.

NHLS DATA –VL TESTS DONE AND RESULTS –SEPT 2023

Age Range	Number of Tests	Number of Tests (<1000 cpml)	% Tests (<1000 cpml)	Number of Tests (<50 cpml)	% Tests (<50 cpml)	Number of Tests LY	Number of Tests (<1000 cpml) LY	% Tests (<1000 cpml) LY	Number of Tests (<50 cpml) LY	% Tests (<50 cpml) LY
0-4 yrs	646	397	61,5%	243	37,6%	670	389	58,1%	235	35,1%
5-9 yrs	1 062	829	78,1%	605	57,0%	1 169	846	72,4%	563	48,2%
10-14 yrs	1 999	1 597	79,9%	1 216	60,8%	2 429	1 834	75,5%	1 307	53,8%
15-19 yrs	3 813	3 062	80,3%	2 435	63,9%	4 285	3 299	77,0%	2 407	56,2%
20-24 yrs	7 893	6 824	86,5%	5 768	73,1%	9 049	7 632	84,3%	6 278	69,4%
<15 yrs	3 707	2 823	76,2%	2 064	55,7%	4 268	3 069	71,9%	2 105	49,3%
>=15 yrs	158 114	147 779	93,5%	126 169	79,8%	165 601	152 609	92,2%	126 438	76,4%
0-4 yrs	29	18	62,1%	8	27,6%	39	24	61,5%	17	43,6%
5-9 yrs	50	43	86,0%	35	70,0%	69	46	66,7%	31	44,9%
10-14 yrs	86	72	83,7%	53	61,6%	94	81	86,2%	69	73,4%
15-19 yrs	158	119	75,3%	104	65,8%	133	113	85,0%	97	72,9%
20-24 yrs	373	334	89,5%	306	82,0%	362	315	87,0%	293	80,9%
<15 yrs	165	133	80,6%	96	58,2%	202	151	74,8%	117	57,9%
>=15 yrs	7 268	6 881	94,7%	6 412	88,2%	6 788	6 381	94,0%	5 904	87,0%
0-4 yrs	179	111	62,0%	67	37,4%	204	117	57,4%	71	34,8%
5-9 yrs	263	211	80,2%	150	57,0%	306	233	76,1%	149	48,7%
10-14 yrs	499	402	80,6%	280	56,1%	613	488	79,6%	333	54,3%
15-19 yrs	964	778	80,7%	587	60,9%	1 182	945	79,9%	663	56,1%
20-24 yrs	2 380	2 056	86,4%	1 635	68,7%	2 772	2 326	83,9%	1 872	67,5%
<15 yrs	941	724	76,9%	497	52,8%	1 123	838	74,6%	553	49,2%
>=15 yrs	50 413	46 661	92,6%	37 224	73,8%	54 571	50 200	92,0%	39 342	72,1%

aZulu-Natal) FID (KwaZulu-Natal) eGK (KwaZulu-Natal) +

Number of Tests	Number of Patients	Number of Patients (<1000 cpml)	% Patient Tests (<1000 cpml)	Number of Patients (<50 cpml)	% Patient Tests (<50 cpml)	Number of Tests LY	Number of Patients LY	Number of Patients (<1000 cpml) LY	% Patient Tests (<1000 cpml) LY	Number of Patients (<50 cpml) LY	% Patient Tests (<50 cpml) LY
7 220	5 521	3 621	65,6%	2 462	44,6%	7 365	5 808	3 877	66,8%	2 611	45,0%
12 793	9 690	7 795	80,4%	5 888	60,8%	14 268	10 966	8 663	79,0%	6 471	59,0%
26 642	20 243	16 674	82,4%	13 143	64,9%	29 837	22 438	17 666	78,7%	13 387	59,7%
49 061	36 384	29 723	81,7%	23 646	65,0%	50 985	37 468	29 436	78,6%	22 883	61,1%
96 188	70 797	61 806	87,3%	52 819	74,6%	103 756	75 903	65 226	85,9%	55 089	72,6%
46 655	35 454	28 090	79,2%	21 493	60,6%	51 470	39 212	30 206	77,0%	22 469	57,3%
1 874 741	1 521 898	1 434 752	94,3%	1 234 336	81,1%	1 839 280	1 485 348	1 384 169	93,2%	1 181 437	79,5%
342	244	172	70,5%	110	45,1%	355	259	167	64,5%	100	38,6%
630	452	382	84,5%	281	62,2%	707	510	428	83,9%	324	63,5%
1 036	794	690	86,9%	548	69,0%	1 126	866	729	84,2%	593	68,5%
1 987	1 439	1 211	84,2%	1 066	74,1%	2 044	1 514	1 248	82,4%	1 061	70,1%
4 029	2 908	2 550	87,7%	2 323	79,9%	4 414	3 130	2 702	86,3%	2 405	76,8%
2 008	1 490	1 244	83,5%	939	63,0201342281879 %	2 188	1 635	1 324	81,0%	1 017	62,2%
79 782	64 052	60 939	95,1%	57 271		79 021	62 828	59 157	94,2%	54 989	87,5%
2 183	1 688	1 120	66,4%	731	43,3%	2 260	1 795	1 229	68,5%	812	45,2%
3 353	2 562	2 091	81,6%	1 498	58,5%	3 737	2 868	2 283	79,6%	1 691	59,0%
6 747	5 153	4 284	83,1%	3 191	61,9%	7 706	5 786	4 691	81,1%	3 502	60,5%
13 432	9 912	8 233	83,1%	6 166	62,2%	13 469	9 917	7 892	79,6%	5 955	60,0%
29 598	22 167	19 416	87,6%	16 024	72,3%	30 966	23 135	19 855	85,8%	16 428	71,0%
12 283	9 403	7 495	79,7%	5 420	57,6%	13 703	10 449	8 203	78,5%	6 005	57,5%
616 071	496 125	466 091	93,9%	378 121	76,2%	586 868	476 929	443 091	92,9%	366 258	76,8%

Low level Viraemia –KZN > 15 years

VL = 158114 tests –Sept 2023

VS <1000 = 93.5 %

VL 50-999 = 13.7% (21661)

VL< 50 =79.8%

VL > 1000= 6.5 %.

- VL = 1874741 tests –over last year
- VS <1000 = 94.7 %
- VL 50-999 = 13.6 % (254964)
- VL<50 = 81.1 %
- VL>1000 = 5.3 %

Comments

- Viral suppression rates are good from a population level viewpoint
- Is this viral suppression rate a true reflection of VL done per patient ie. what is the VL completion rate? Check Tier .net at facility and district level
- How many tests did each patient have ?
- Are the tests at 6, 12 ,24 time points months VL
- How many patients had repeat VL test after first high VL?
- How many TLD1 and TLD2 or TLD2F –available on Tier,net only

What is low level viraemia as per SA NDOH guidelines

- 1.< 50 c/ml
- 2. < 200 c/ml
- 3.200 -999 c/ml
- 4.50-999 c/ml
- 5.< 1000 c/ml

Source(s) and mechanisms of persistent LLV on ART.

Evidence suggests that it probably largely arises from

- Clonally expanded infected CD4+ T-cells - produce virions but do not infect new cells - protected by ART
- Ongoing viral replication in sanctuary sites (reservoirs) with suboptimal drug penetration
- Adherence issues
- Viral blips (intermittent LLV -50 -1000 copies/ml)
- Viral resistance
- Consider Drug interactions -

Hermans LE, Moorhouse M, Carmona S, Grobbee DE, Hofstra LM, Richman DD, et al. Effect of HIV-1 low-level viraemia during antiretroviral therapy on treatment outcomes in WHO-guided South African treatment programmes: A multicentre cohort study. The Lancet Infectious Diseases. 2018;18(2):188-97.

- Not genetic evolution of the virus

. Vancoillie L, Hebberecht L, Dauwe K, on ART shows no indications for genetic evolution of the virus. Virology. 2017;510:185-93Demecheleer E, Dinakis S, Vaneechoutte D, et al. Longitudinal sequencing of HIV-1 infected patients with low-level viremia for years while

- NB

1. Blips, an isolated HIV RNA of at least 50 copies/mL that is immediately preceded and followed by virologic suppression, have been found in between 10 and 50% of people living with HIV

2. LOW LEVEL VIRAEMIA WITH LOW CD4 COUNT –NOT ON ART – ELITE CONTROLLERS

Management of low-level viremia

- Very few clinical trials on the management
- Guidelines often reflect expert opinion.
- Several studies support the supposition that virologic failure (VF) is more likely to occur in patients with viral load (VL) ≥200 copies/ mL than in those with low-level viremia between 50 and 199 copies/mL.
- However, other studies have suggested that detectable viremia at this low level (<200 copies/mL) or even lower (<50 copies/ mL) can be predictive of virologic failure and can be associated with the evolution of drug resistance

Hermans LE, Moorhouse M, Carmona S, Grobbee DE, Hofstra LM, Richman DD, et al. Effect of HIV-1 low-level viraemia during antiretroviral therapy on treatment outcomes in WHO-guided South African treatment programmes: A multicentre cohort study. The Lancet Infectious Diseases. 2018;18(2):188-97.

Conclusions

- It is possible, though not confirmed, that persistent low-level- and very-low-level viremia may predict higher risk of virologic failure, morbidity and mortality.
- These patients may be discussed with experts at the ID unit at King Edward Hospital

RECOMMENDATIONS FOR ACTION IN EACH ART SITE

1) Audit of all patients in the facility record who started ART
2) Take a note of all VL records in their file
3) Triangulate VL data sources from NHLS and patient charts and update Tier.net
4) Make a note of those who have not returned and investigate reasons
5) Follow guidelines for switching for those on PI regimens
6) Timely VL monitoring and ongoing adherence measures for those with VL within 50 – 999
7) Consider community-based models of care CCMDD and repeat scripts for those with VL<50 as per guidelines . Call back patients with VL >1000c/ml
8) Assess VL completion rates to ensure that reported VL suppression rates are an accurate reflection –at facility /district
9) Follow SOPs and use /adapt tools for VL monitoring –once approved
10) District partners to pilot tools and SOP in at least 2 sites and give feedback through HAST coordinators .

ART Viral Load Suppressed

Services delivery processes:

Functional Booking system

Effective processes to highlight patients due for VL

Effective blood result management process and actioning of abnormal results

Managing missed viral load appointments

Planned patient flow (Bloods prior consultation)

Staff competency and capability:

All clinicians to be trained on interpreting blood results

All clinicians cognisant of processes to support viral load management

NIMART trained nurses to adapt ART treatment due to abnormal results

Data System:

Print VL due reports to identify patients expected within the month

Print the VL outstanding results report to follow-up on expected blood results

Clinician to record results in patient files

Manage file flow processes between consultation rooms and data capturing point.

Resources and Supplies:

Lab materials

Access to Lab track

Teamwork:

Effective communication between facility and laboratory

Intergration and coordination of the multi-disciplinary team supporting viral load management processes

Patient Engagement:

Routine provision of health education

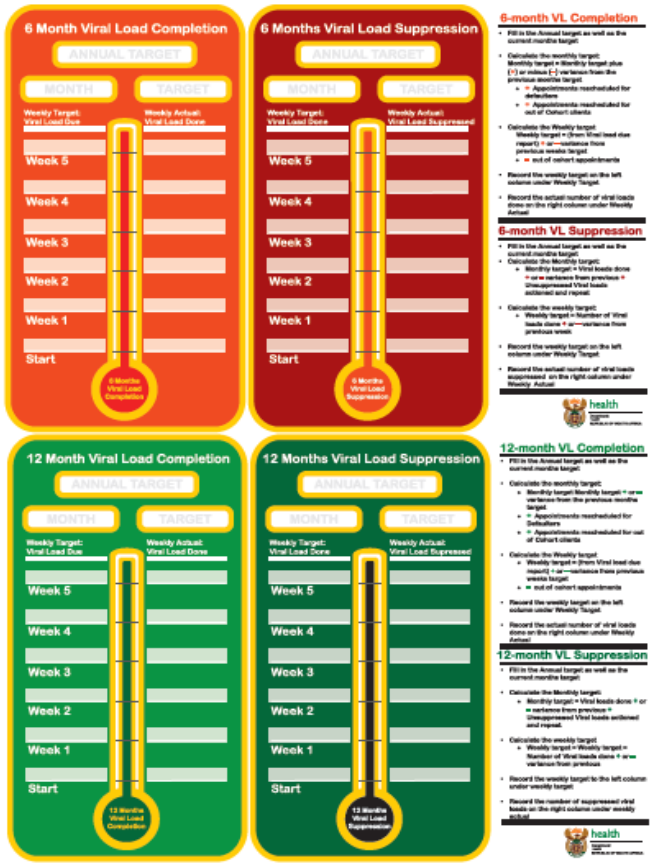
Patient reminders for viral load appointments

VIRAL LOAD MANAGEMENT				
Step 2	Viral load due previous week		TIER.Net VL Report	Assess the efficiency of the viral load management process.
Step 3	Retrieve files on VL Due report			
Step 4	# Files not found on VL report			
Step 5	Do you find evidence of Viral load done		Patient file	
Step 6	# of Viral load results recorded and available in patient file		Clinical stationary/ Lab Form	
Step 7	Identify the number of patients eligible for TLD switch		VL results (use guideline criteria)	
Step 8	What was the actual number that was switched to TLD		Count/TIER.Net	
Step 9	# Not switched to TLD: obtain the reasons for not switched		Patient file	
DATA MANAGEMENT				
Step 10	Weekly review # Transitioned to TLD # recorded in Clinical stationary		Patient file (from Audit)	Assess if data quality processes are in place to ensure TLD performance is collected, captured and reporting to reflect actual work done.
Step 11	# Transitioned to TLD # captured on TIER.Net		TIER.Net	
	Describe the file flow process from Transitioning to the Data room		Process Map	
TLD STOCK AVAILABILITY				

The 8 Steps Explained:

1. Complete the relevant **Barometers** (See How to Complete a Barometer page 185)

- **a.** Identify the variance
- **b.** Adjust the following weeks' target



Example of Changes	Process Measures
Reminder calls for Viral load due appointment: Professional nurse does reminder calls every Tuesday for the VL due appointments of the following week.	• # Viral due for the week • # Patients reached and promised to come • # Patients came for the bloods • # Bloods done

List of Appendices to Proposed SOP for VL management in TLD 1 ,TLD2 and TLD2F regimens

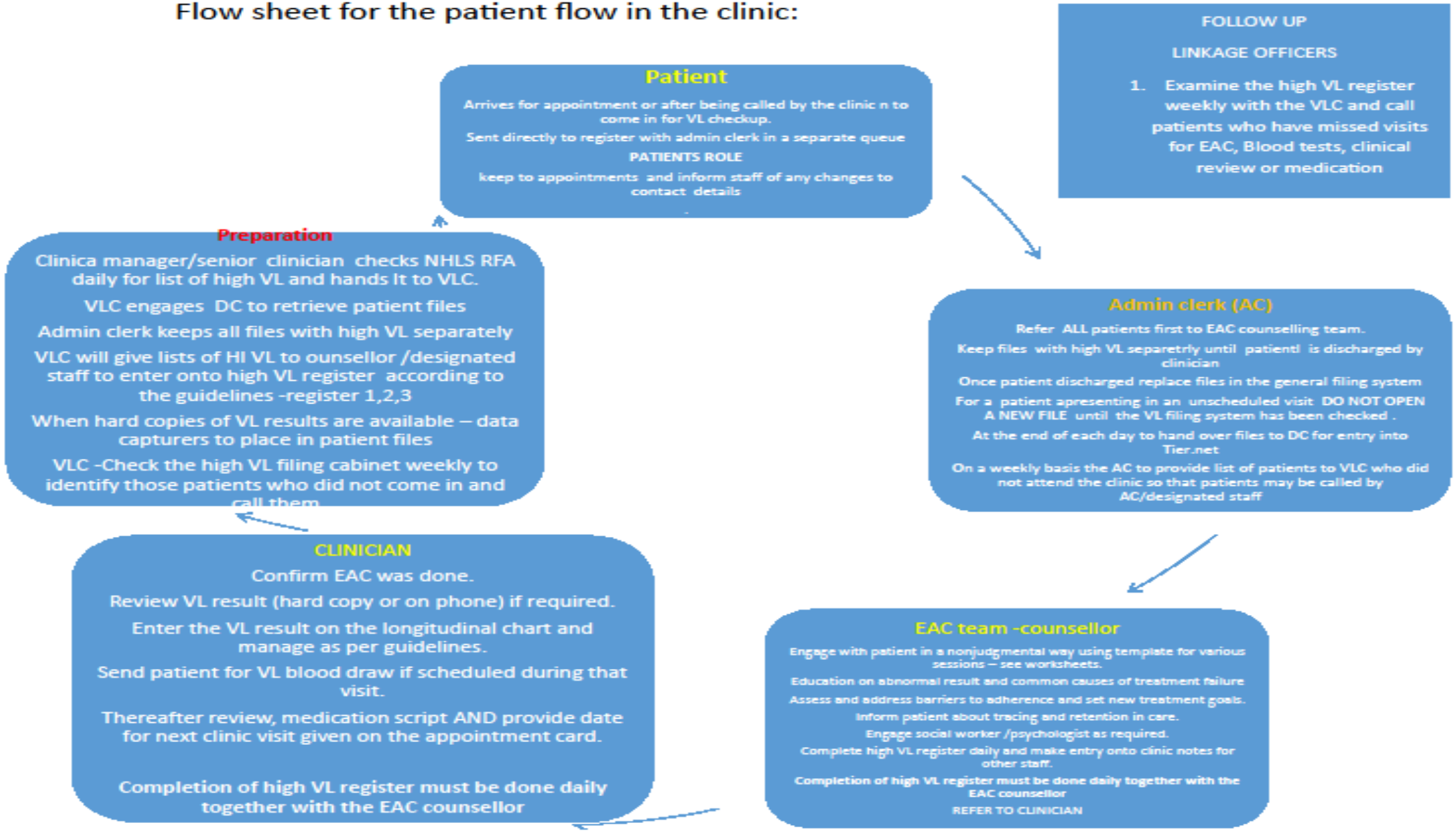
- VL register for TLD 1 and TLD 2 and adherence <80 % with first VL> 60 c/ml
- VL register for TLD 2 and adherence > 80% and VL > 1000 c/ml and 500 -999 c/ml
- VL register for TLD2F regimens

SOP for VL management in the era of DTG regimens

Patient flow pathway in the clinic

Responsibilities of VL champion

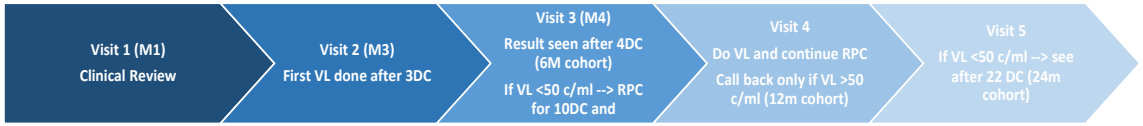
Flow sheet for the patient flow in the clinic:



REGISTER 1A: MANAGEMENT OF TLD 1 and TLD 2 WITH THE FIRST VL ≥ 50 c/ml after start /change of ART (M0)

On TLD 1 0r TLD2 (non PI regimen)-follow as per guidelines below

Patient Name	Clinic Number	ID Number	Contact number x 2	VL test M3 Date	VL result M4	EAC 1 Date	EAC 2 Date	EAC 3 Date	EAC 4 Date	EAC 5 & VL test Date	Outcome & Date:



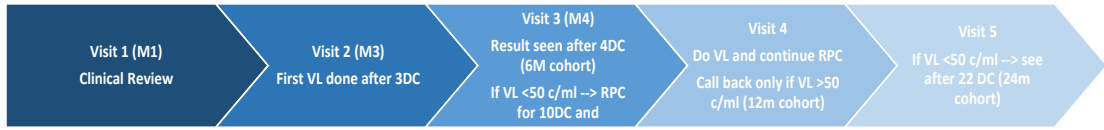
Developed in Partnership with: ADHERENCY

REGISTER 1 B : MANAGEMENT OF TLD 1 and TLD 2 WITH THE FIRST VL ≥ 50 c/ml after start /change of ART (M0)

NB.1. PI regimen for more than 2 years, VL < 1000 c/mL – -Switch to DTG-containing regimen. If VL in last 12 months > 50 c/mL, continue to switch same day, provide EAC if needed, and repeat the VL after 3 months and guidelines below

NB.1 Two or more VLs > 1000 c/mL more than 2 years ;-Adherence less than 80% - Switch toa DTG-containing regimen . Repeat the VL after 3 months and guidelines below

Patient Name	Clinic Number	ID Number	Contact number x 2	VL test M3 Date	VL result M4	EAC 1 Date	EAC 2 Date	EAC 3 Date	EAC 4 Date	EAC 5 & VL test Date	Outcome & Date:



Developed in Partnership with: ADHERENCY

REGISTER 2: MANAGEMENT OF PATIENTS WITH TLD2F

After GRT results and individualised regimen -VL after 3 months then as determined by clinician depending on VL

Two or more VLs ≥ 1000 c/mL taken two or more years after starting PI regimen - adherence more than 80%. Do a resistance test.

Discuss with an HIV expert to authorize and interpret a resistance test and provide individualized regimen. Repeat VL 3 months .

Patient Name	Clinic No	ID No	Contact no x 2	Regimen Date started	EAC 1 Clinical review Date	EAC 2 Date	EAC 3 Do VL Date	EAC 4 VL result Review Date	Date	Date	NEXT VL At 6 months annually	Outcome & Date:

Developed in Partnership with: ADDENDOV

QA Tool 1: ADULT ARV CHART REVIEW

Date: _____

ne of Reviewer		Designation	
ility Name		File No	

A. Initiation Visit for current regimen (Mark X to denote completed, ND to denote no evidence of completion or N/A if test was not required)

een	Done	Abnormal Test actioned	Blood Test/screen	Done	Abnormal Test actioned	Blood Test/screen	Done	Abnc Test actio
			Urine dipstix			Cr Cl		
			Preg test			ALT		
l			TB Screen			Hep B SAg		
O Stage			STI screen			Chol (f)		
umination			HB/FBC			Trig (f)		

B. TB Screening, Management and IPT Completion

	Was TB Screening completed?					YES		NO		
	% of visits TB Screening done	0%		<50%		>50%		All		
	Were they pregnant at baseline?	Yes		No		CD4 <100	Yes			
	GXP done in all pregnant patients	Yes		No						
	Was IPT initiated?	No - Active TB				YES		NO		
	If IPT started, number of Months of IPT completed									
	Any DSTB on Aluvia/DTG/Atazanavir/Darunavir					Yes		No		N
	Were the doses of Aluvia doubled during DSTB Rx?					Yes		No		N
	Were Aluvia doses reduced 2 weeks after DSTB Rx end?					Yes		No		N
	Were the doses of Dolutegravir doubled during DST Rx					Yes		No		N
	Did they get Rifabutin while on Atazanavir or Darunavir?					Yes		No		N

C. VL Coverage and Suppression (Mark appropriate column with an X)

Patients current ART regimen		Months on Regimen	

D. Mark with X if VL was done next to the month. Add result below if applicable

nth 6		Month 12		Month 24		Month 36		Most recent
ult		Result		Result		Result		Result
epeated if ≥ /N)		VL repeated if ≥50 (Y/N)		VL repeated if ≥ 50 (Y/N)		VL repeated if ≥ 50 (Y/N)		VL repeated if ≥50 (Y/N)
ult		Result		Result		Result		Result

E. Management of Switch from 1st Line ART to TLD

	VL result before switch to TLD in c/mL		VL completed within 6 months before switch to DTG? (Y/N)	
	Patient is ≥ 10 years of age	YES		NO
	Patient is ≥ 35kg	YES		NO
	Creatinine clearance result			
	Documentation of Counselling about DTG for women	YES		NO
	Pregnancy excluded before starting DTG	YES		NO

2023 ART Clinical Guidelines

for the Management of HIV in Adults, Pregnancy and Breastfeeding, Adolescents, Children, Infants and Neonates

April 2023

Republic of South Africa National Department of Health