QUALITY ASSURANCE THROUGH MONITORING EARLY WARNING INDICATORS AND INTEGRATED CARE FOR PLHIV

Dr Henry Sunpath
Infectious Diseases Unit :Nelson Mandela School of Medicine –UKZN
HAST Technical Working Group Team : Ethekwini District Health Office

AWACC2016

FIGHTING DISEASE, FIGHTING POVERTY, GIVING HOPE

Agenda

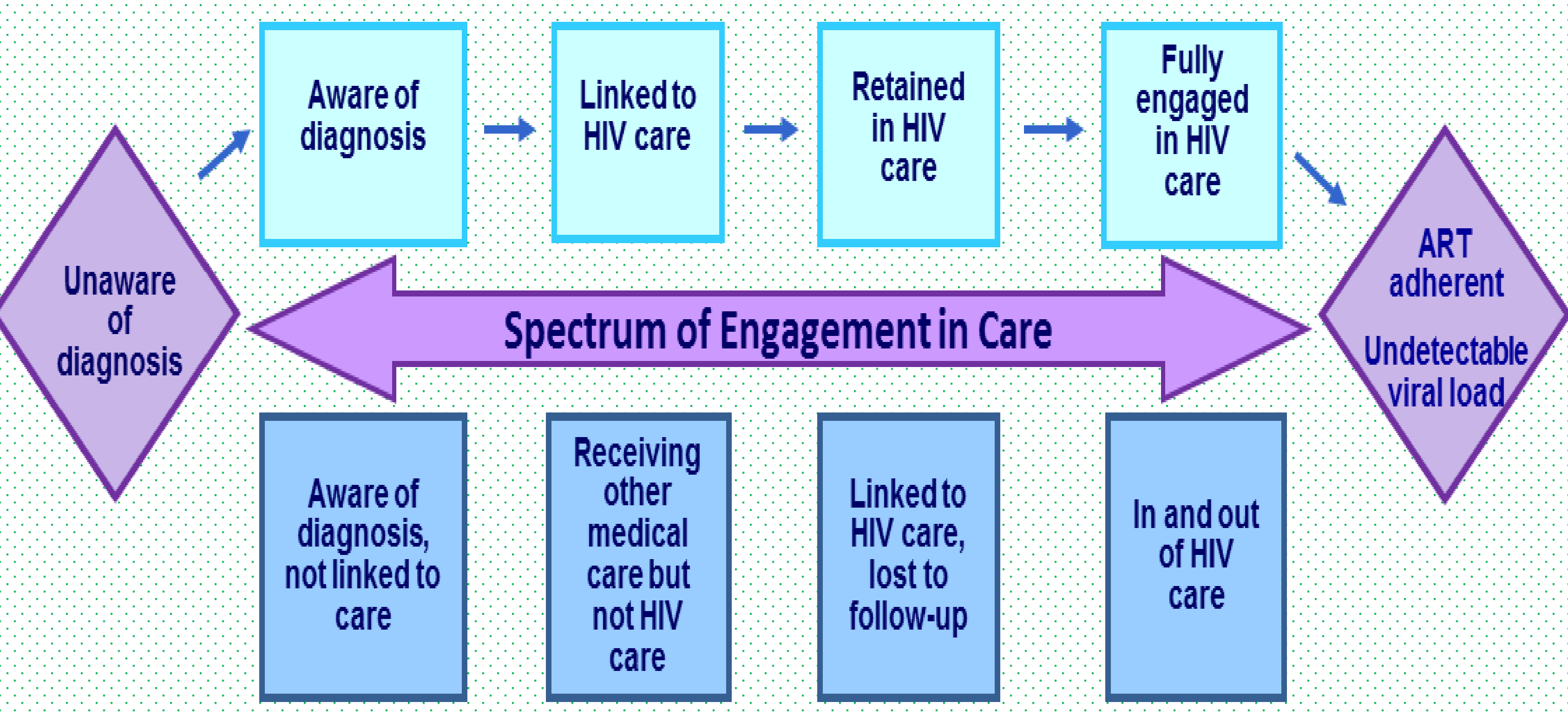
- Introduction –
- VL completion and Suppression data
- Early warning indicators –Viral load monitoring
- Making viral load monitoring routine
- Managing virological failure

In order for a person to benefit from HIV treatment success it is necessary to:

- ✓ Diagnose their HIV infection
- ✓ Link infected individuals to outpatient care
- ✓ Start antiretroviral therapy
- ✓ **Have patients adhere to therapy**
- ✓ **Retain patients in care**

Emphasis should be placed on "adherence" to care and not just medications

Ideal vs. poor engagement in HIV care



Question 1

How many patients in KZN had 6 months Viral load done in 2013-2014.

1. 80 %
2. 70%
3. 60%
4. 50%
5. 40%

Question 2

How many patients in KZN had 6 months Viral load done in 2014-2015.

1. 80 %
2. 20%
3. 70%
4. 50%
5. 40%

Question 3

How many patients in Ethekwini had 6 months Viral load done in 2015-2016.

1. 80 %
2. 20%
3. 70%
4. 50%
5. 40%

Question 4

- Which district in KZN had the highest number with 6 months VL in 2013-2014?
- 1. Harry Gwala
- 2.ilembe
- 3. Uthukela
- 4. Amajuba
- 5.Ethekwini

Question 5

Which facility in Ethekwini has the highest viral load completion rate?

- 1.King Edward hospital
- 2.Clairwood PHC
- 3.Kwa Dabeka CHC
- 4. Goodwins PHC

Question 6

- Which district in KZN has the lowest VL completion rate?
- 1. Zululand
- 2. Uthuhgulu
- 3.Umgungundlovu
- 4. Ugu

Agenda

- Introduction –
- VL completion and Suppression data
- Early warning indicators –Viral load monitoring
- Making viral load monitoring routine
- Managing virological failure

WHO-recommended HIVDR EWIs

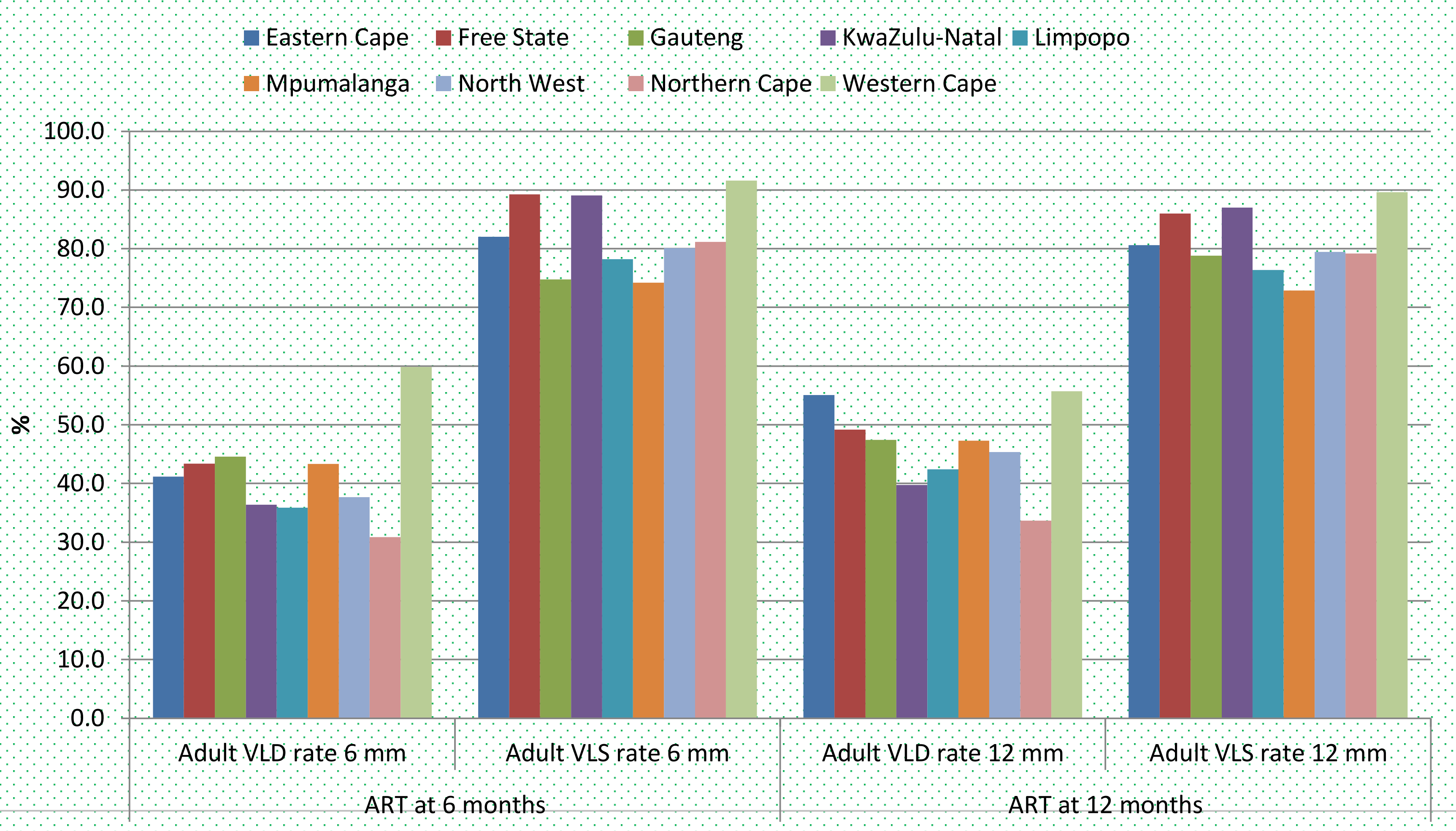
EWI	EWI Target
1. Prescribing practices	100%
2. Lost to follow-up at 12 months	≤ 20%
3. Retention on first-line ART at 12 months	≥ 70%
4. On-time drug pick up	≥ 90%
5. On-time appointment keeping	≥ 80%
6. Drug supply continuity	100%
8. Viral load <1000 copies/ml at 12 months	≥ 90%(adapated)

Bennett DE et al., *Antivir Ther* 2008

Agenda

- Introduction –
- VL completion and Suppression data
- Early warning indicators –Viral load monitoring
- Making viral load monitoring routine
- Managing virological failure

VLD and VLS at 6,12 months on ART 2012/13



Adult with Viral load completion rate at 6 months

District	NDoH Target FY 2014/15	FY 2011/12	FY 2012/13	FY 2013/14	Progress Q3	VLD at 6m FY 2013/14
Amajuba District Municipality	**80**	54.0	47.9	48.4		11,678
eThekwini Metropolitan Municipality	**80**	64.6	64.4	67.4		4,872
Harry Gwala District Municipality	**80**	65.1	55.3	44.1		1,148
iLembe District Municipality	**80**	50.2	44.0	42.6		23,041
Ugu District Municipality	**80**	38.6	36.2	32.4		1,178
uMgungundlovu District Municipality	**80**	26.5	30.6	29.6		4,888
Umkhanyakude District Municipality	**80**	41.4	39.4	35.4		1,888
Umzinyathi District Municipality	**80**	33.0	43.8	0.0		0
Uthukela District Municipality	**80**	37.7	42.9	53.4		4,318
Uthungulu District Municipality	**80**	38.6	35.2	28.4		1,083
Zululand District Municipality	**80**	43.4	37.6	32.0		2,064
KwaZulu-Natal	**80**	**17.4**	**15.4**	**19.3**		**397**

Adult with Viral load suppressed rate at 6 months

District	Target FY 2014/15	FY 2011/12	FY 2012/13	FY 2013/14	Progress Q3	VLS at 6m FY 2013/14
Amajuba District Municipality	**96.5**	92.5	94.5	94.1		1,108
eThekwini Metropolitan Municipality	**96.5**	90.2	92.9	92.8		4,535
Harry Gwala District Municipality	**96.5**	74.4	78.9	83.5		1,577
iLembe District Municipality	**96.5**	90.3	91.7	0.0		0
Ugu District Municipality	**96.5**	92.1	93.2	91.3		3,941
uMgungundlovu District Municipality	**96.5**	80.2	80.9	84.5		915
Umkhanyakude District Municipality	**96.5**	92.5	90.5	91.3		1,884
Umzinyathi District Municipality	**96.5**	82.7	94.5	92.9		369
Uthukela District Municipality	**96.5**	87.6	89.7	93.1		1,676
Uthungulu District Municipality	**96.5**	67.5	78.2	83.9		4,250
Zululand District Municipality	**96.5**	83.3	87.1	92.6		718
KwaZulu-Natal	**96.5**	**84.9**	**87.7**	**89.4**		**20,973**

CAPRISA is the UNAIDS Collaborating Centre for HIV Research and Policy

Improving Viral Load Monitoring and Outcome File and facility Audit 2 hospitals/3 CHCs/5 PHCs

Viral Load Testing and Suppression Rates

Viral Load Coverage in Adult and Paediatric patients

Viral Suppression Rates in Adults and Children

Percentage

100
90
80
70
60
50
40
30
20
10
0

41.7 (762/1826)
32.1 (546/1701)
25.9 (364/1403)

36.3 (29/80)
29.3 (22/75)
19.6 (10/51)

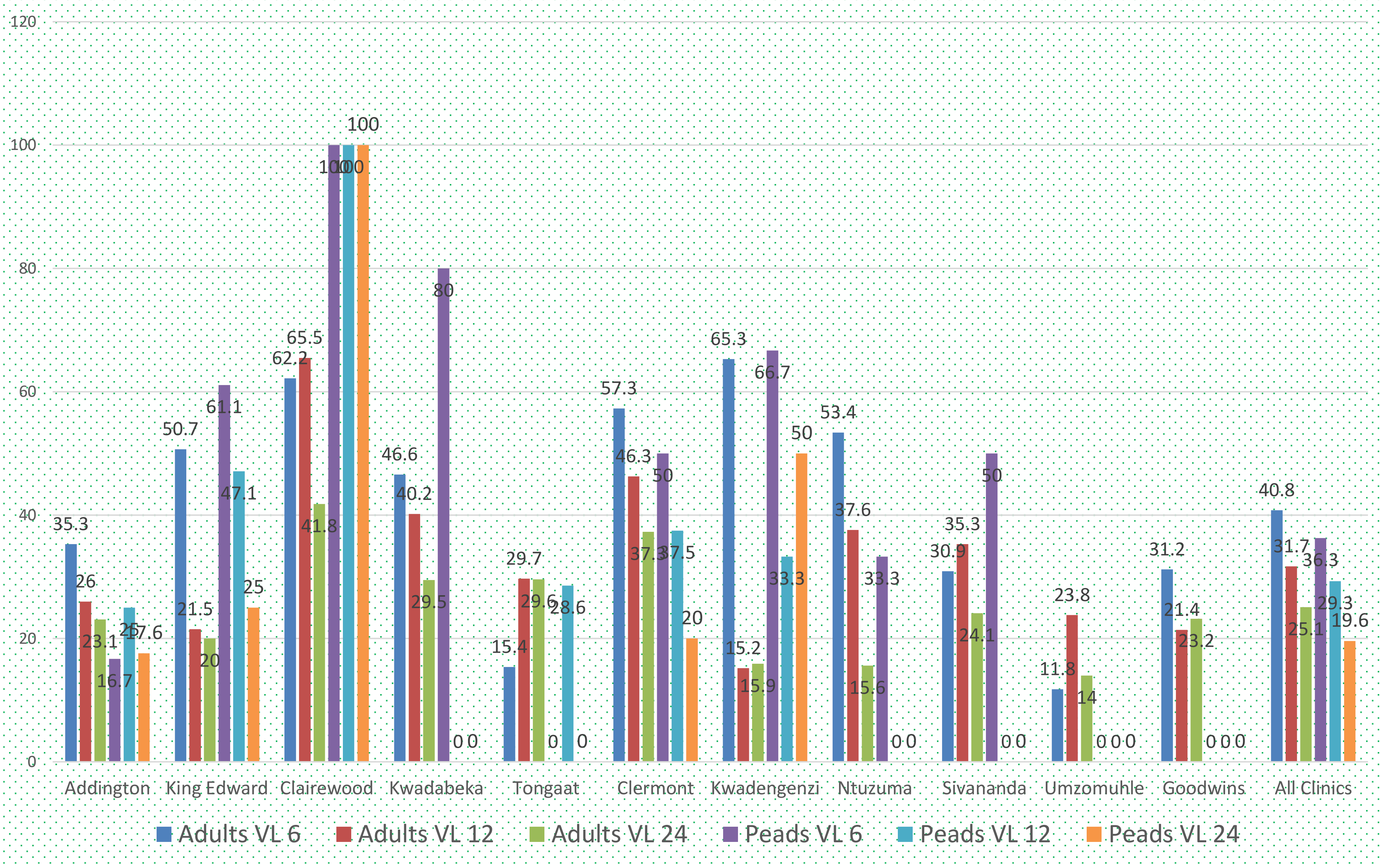
92.2 (703/762)
88.8 485/546)
89.8 (327/364)

79.3 (23/29)
68.2 (15/22)
70 (7/10)

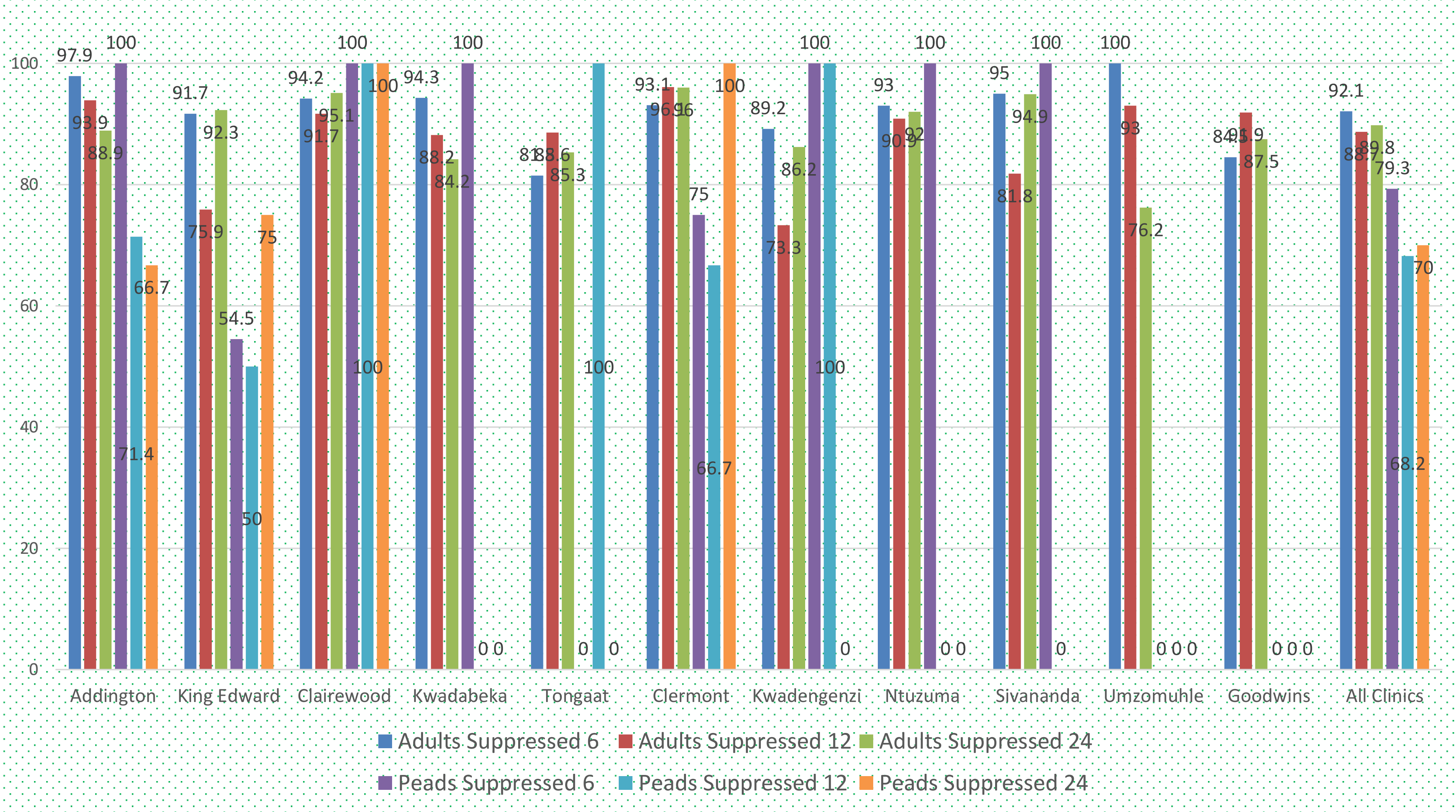
Viral Load Conducted (Adults)
Viral Load Conducted (Peads)
Viral Supression (Adults)
Viral Supression (Peads)

6 months
12 months
24 Months

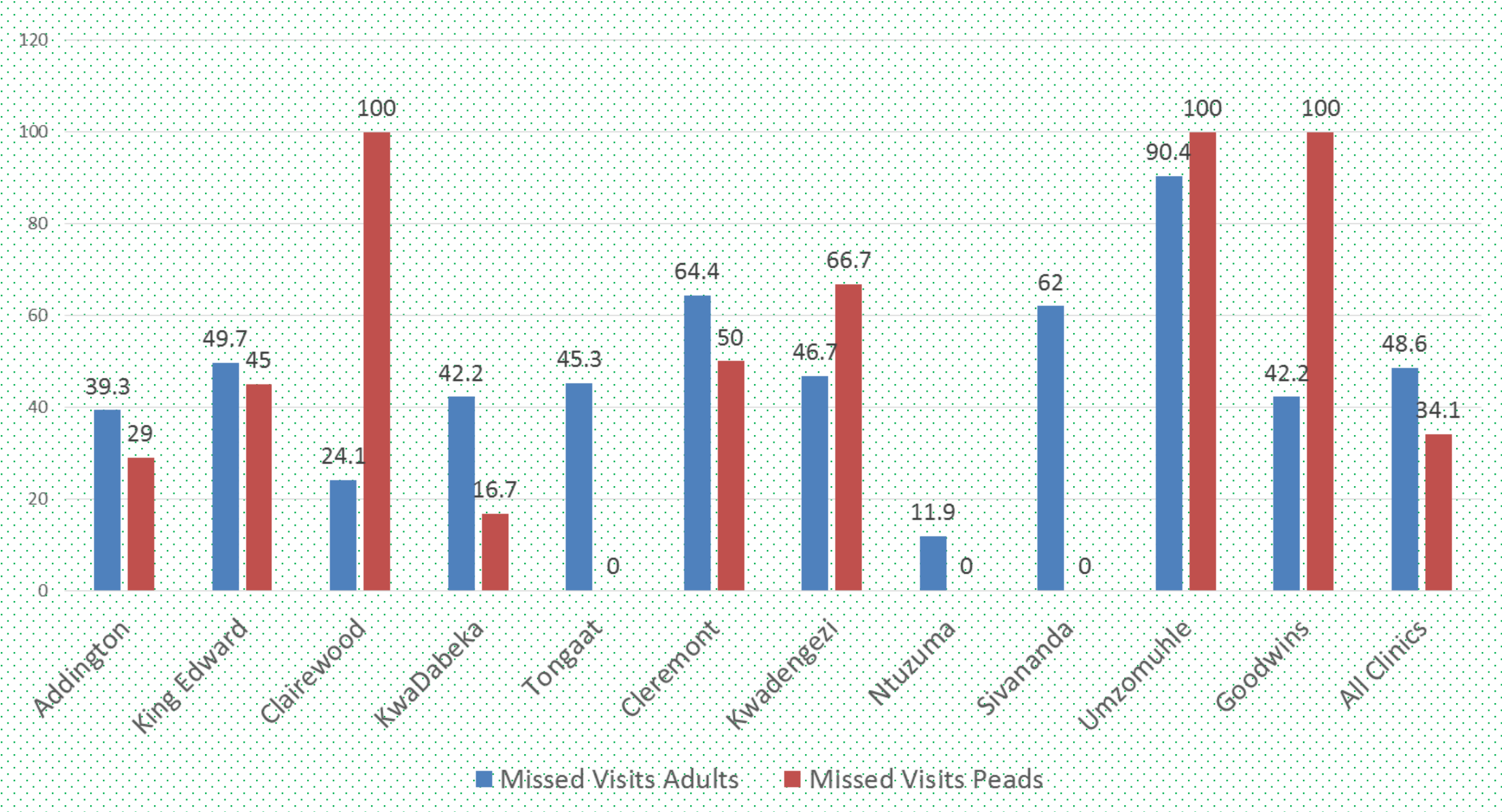
Viral Load Coverage at 6, 12, 24 Months



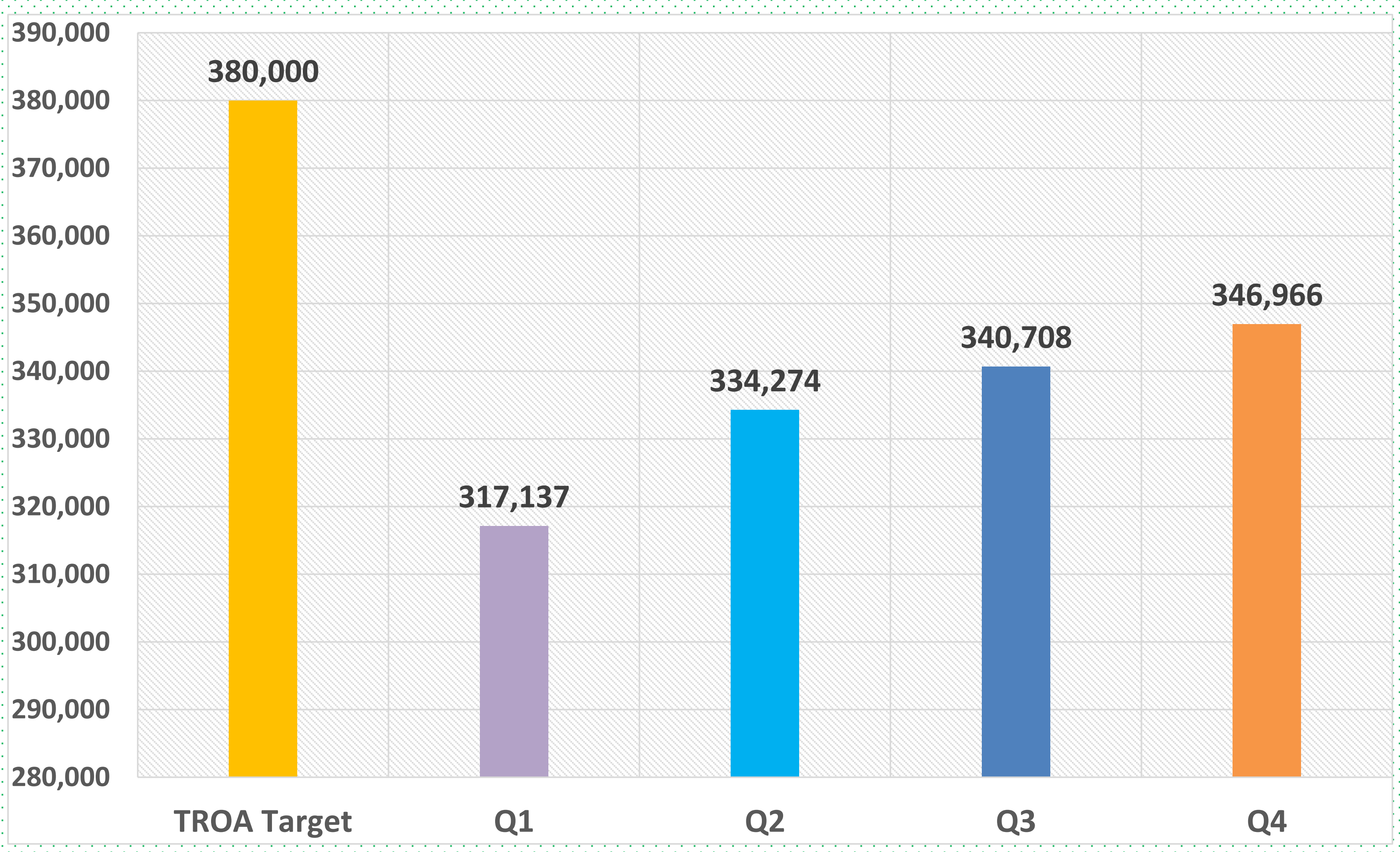
Viral Suppression at 6, 12, 24 Months



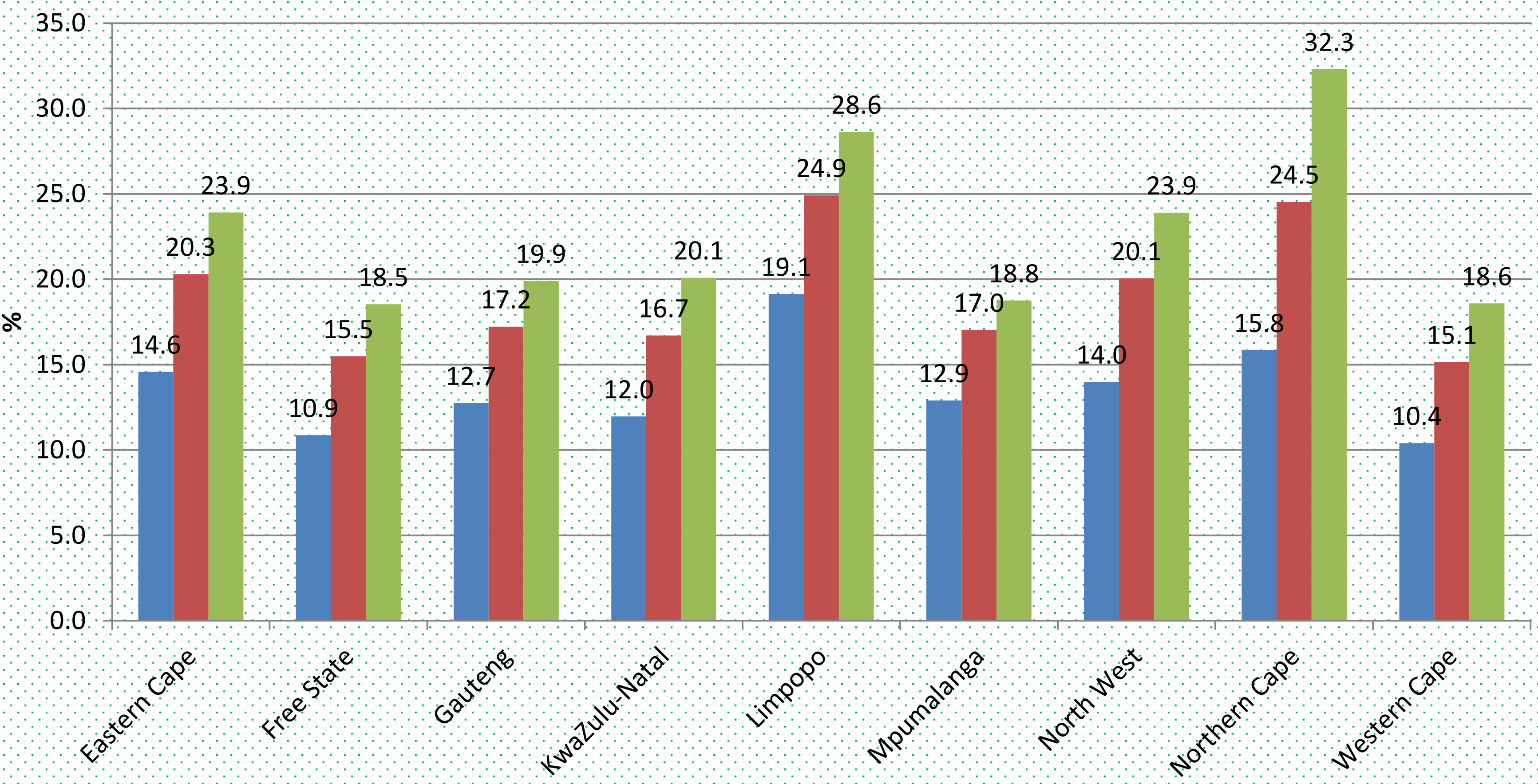
Retention in Care



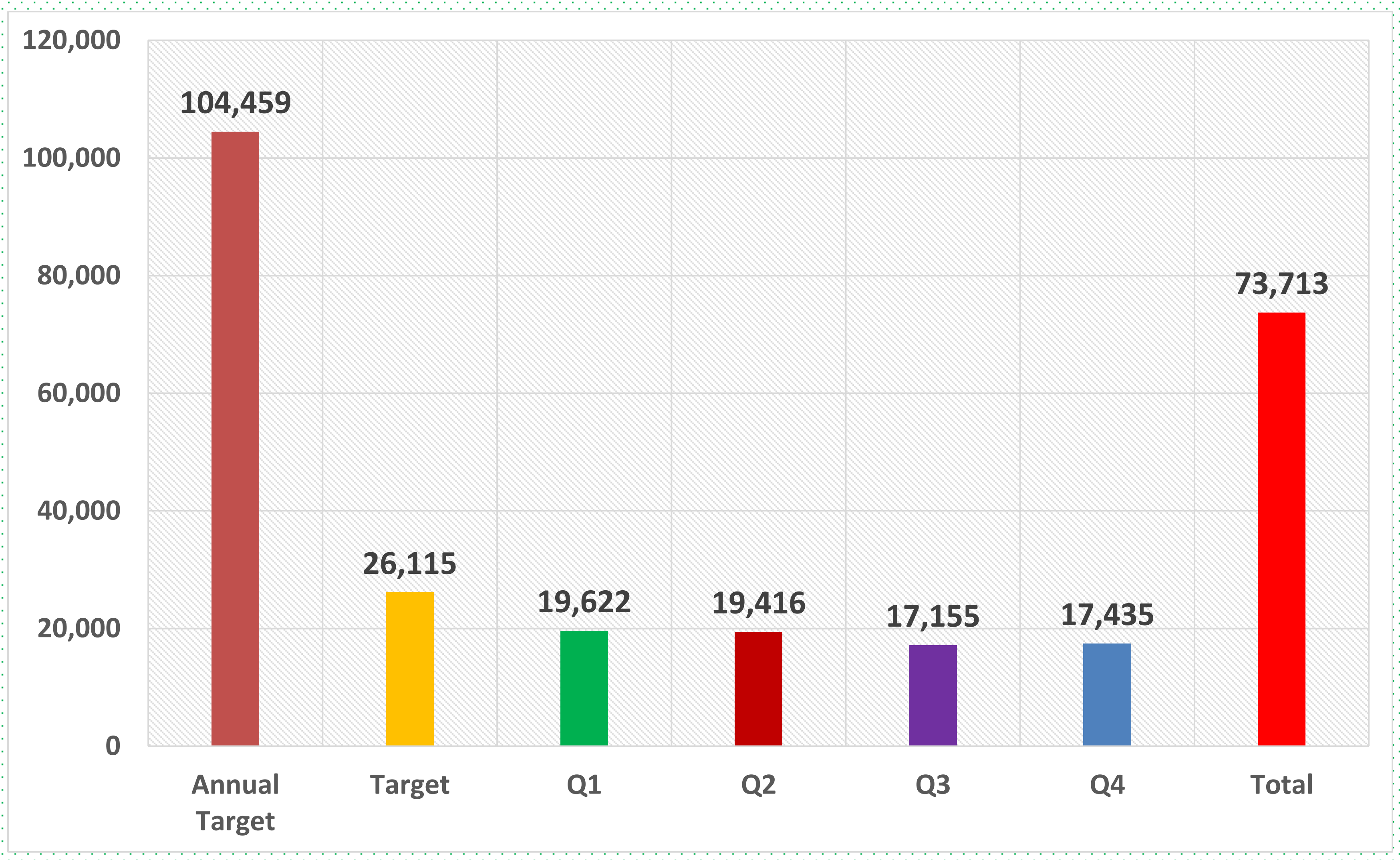
Total Remaining in care 2015-16



Adult lost to follow-up at 3,6,12 months Started ART Jan - Dec 2013



ART total initiation 2015-16



Agenda

- Introduction –
- VL completion and Suppression data
- Early warning indicators –Viral load monitoring
- Making viral load monitoring routine
- Managing virological failure

Information collected as part of HIVDR EWIs

- **Viral load done and viral load suppression rates at 12 months after ART initiation**
- Remaining/Retention on ART 12 months after initiation

Greater role for pharmacy

- On time patient appointment /drug pick up time
- ART prescribing and dispensing practices
- Drug stock availability

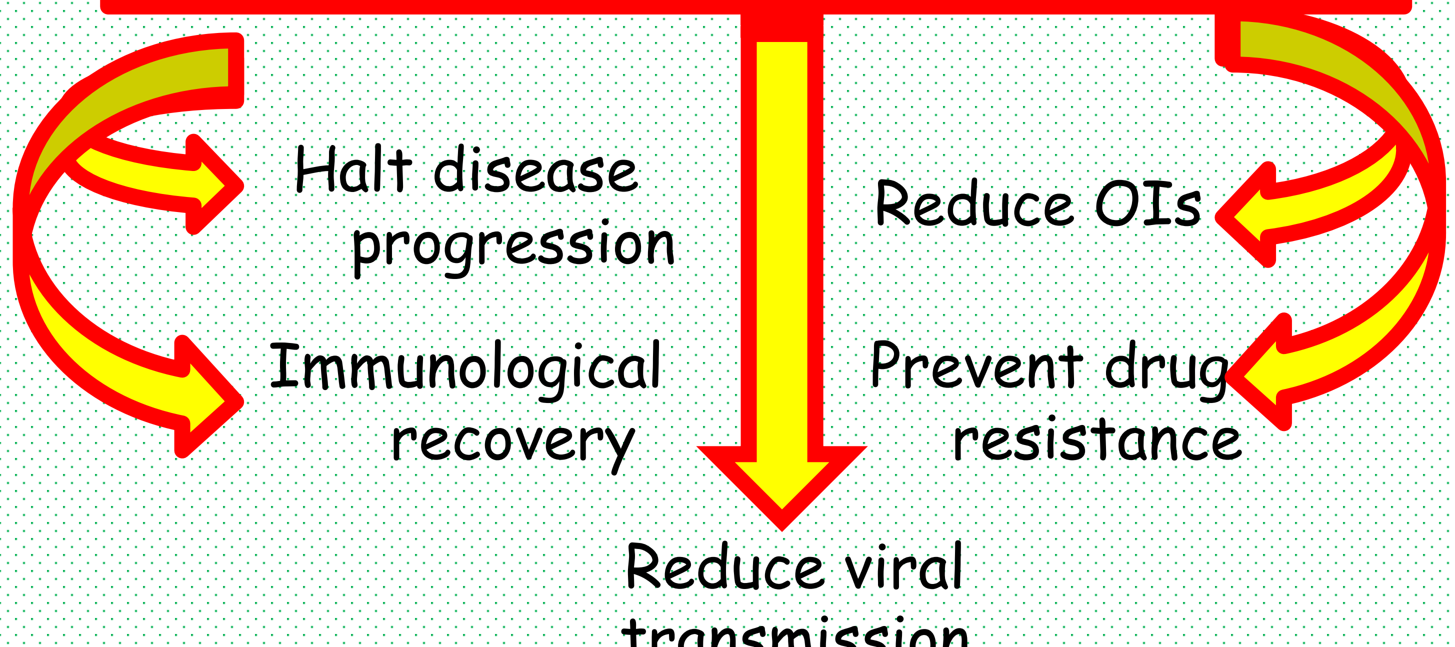
ART Program Use of EWI Results

1. **Strengthened record keeping systems**
   - Formation of clinic specific care optimizing committees[1]
   - Validation of existing electronic record keeping systems[1, 2,3]
   - Adjustments in pharmacy record keeping to permit on time pill pick up assessments[3]
   - Pilot of enhanced defaulter tracing to identify patients missing drug pick-ups with the goal of reengaging in care within 48 hours[1]
   - General strengthening of records[4,5,6,7,8]

2. **Seek funding support from partners to scale-up EWI[9]**
3. **District teams to support adherence and trace patients LTFU[1,10,11]**
4. **Regular review of patient pill pick-up and establishment of formal referral system to document transfers-in/out[6]**
5. **Scale-up viral load testing[5]**

[1]Hong et al. *JAIDS* 2010; 2 Anna Jonas, MoHSS Namibia, personal communication; [3]Dawn Pereko, MSH Namibia, personal communication; [4]Jack N et al. CID (in press); [5]Ye M et al. *CID* (in press); [6]Daonie e et al. *CID* (in pres); 7Nhan DT el al. *CID* (in press); Hedt BL et al., *Anti Viral Ther* 2008; 9Paula Mundari, Uganda National ART Programme, IAS 2010, Vienna; 10Evelyne B, National ART Program, Burundi, personal communication; 11Anna Jonas, MoHSS Namibia, personal communication.

Goal of HAART



Viral Load

Plasma HIV RNA load is the most representative and sensitive laboratory test for monitoring:

- Response to antiretroviral therapy
- Failure of treatment from any cause

1.Drug resistance

2. Adherence

Adherence monitoring:

Use the viral load.

- WHO recommends **VL monitoring** with other adherence measures.
- Raised viral load indicates a risk of failure, so **DO** something.
- 56-68% can re-suppress with an adherence intervention.

Consequences of viraemia

- Poor immunological recovery- risk of recurrent OIs and increase mortality
- Increased risk of transmission of infection – poor prevention and control of the epidemic
- Risk of resistance to ART and need to change to more expensive regimens
- Increased risk of transmission of resistant virus
- Disease progression – increased risk of comorbidities viz. DM; HPT; IHD due to chronic immune activation with increasing age

Virology failure (SA)

- HIV RNA >1000 check for:
  - Adherence
  - Tolerability
  - Dosing schedule
  - Drug interactions
- Repeat VL in 2 months
- Repeat VL >1000 change regimen

Major challenges for VL monitoring

- **Ownership**

Clinical and lab monitoring

- **Mentorship**

R**ecording and reporting**

ADULT HIV PROGRAM OVERVIEW (1) Viral Load Done at 12 months –Ethekwini DIP

Critical Issues for Indicator Improvement	Innovations	Ethekwini
Data Management (includes data capturing) Monitoring cohort on Tier.net Patient tracing Results filling Availability of clinical stationary Sticker system	SMS system for follow-up	Need to: Quantify activities e.g. no. of facilities Find baseline data Specify no. of facilities targeted for SOP

TIER.NET UPDATE-eTHEKWINI

FY 2015/16 Quarter 2 status:

- 121 facilities initiating ARVs

- Tier 1: 3
- Tier 2: 118

– **Phase 1:**0 **Phase 2:** 0 **Phase 3:** 08

– **Phase 4:** 15 **Phase 5:** 01 **Phase 6:** 97

– 78%

– Training of ONMs and M&E managers has been conducted.

Early Warning Indicators (EWIs) for Drug Resistance

EWI implementation and monitoring: South Africa context

South Africa context: Starting with EWIs

- District Implementation Planning (DIP) and 90-90-90 targets:
  - **Viral load**
  - **Retention in care/lost to follow up**
- **Routine implementation of cascade approach –identify bottleneck**
- Clinical Mentorship system
  - On time pill pick up
  - Prescription/dispensing practices
  - Pharmacy stock
- **National Adherence strategy –Training**
- Consolidated HIV National Technical Guidelines 2015
- Monitoring and Evaluation Systems (Tier.net, DHIS, …)

WHO Proposed HIVDR Early Warning Indicators and targets –In selected Sites

Early Warning Indicator	Targets
1. On-time pill pick-up	• Red: <80% • Amber: 80–89% • Green: ≥90%
2. Retention in care	• Red: <80% retained after 12 months of ART • Amber: 80–93% retained after 12 months of ART • Green: ≥90% retained after 12 months of ART
3. Pharmacy stock availability	• Red: <100% of a 12-month period with no stock-outs • Green: 100% of a 12-month period with no stock-outs
4. Prescription and Dispensing practices	• Red: <100% dispensing of triple therapy • Green: 100% dispensing of triple therapy
5a. Viral load completion	• Red: <70% of patients with a 12-month VL test result available • Amber: 70-79% patients with a 12-month VL test result available • Green ≥ 80% of patients with a 12-month VL test result available
5b. Viral load suppression at 12 months	• Red: <75% viral load suppression after 12 months of ART • Amber: 75-89% viral load suppression after 12 months of ART • Green: ≥90% viral load suppression after 12 months of ART

EWI 5

- Data Source: Tier.net (Tier 2)
- TIER.NET uses a viral load suppression threshold of <400 copies/mL.
- Viral load suppression will be calculated as “on-treatment”, meaning the denominator will be **patients who had viral load done at 12 months.**
- Viral load completion will be calculated as the percent of viral load results available among patients who were active at 12 months (+/- 3 months).

EWI 5a: Improving viral load completion-done

- Use tier-net system to generate the list of patients due for viral load
- Retrieve the patient files
- Put a sticker on the patient file to remind the nurse
- Include the laboratory form on the file
- Mark with red pen in the patient file "viral load due", next to the space where the date of next appointment is written.

EWI 5b: Viral load suppression monitoring

- Use tier-net system to generate :
  - the list of patients - with viral load done
  - the list of patients with viral load suppressed (<400 copies) and not suppressed.
- Calculate the percentage of patients with viral load suppressed
- Use existing reporting system (DHIS) to report on "viral load suppression"
- Monitoring viral load with focus at 6, 12, 24 and 36 months

Agenda

- Introduction –
- VL completion and Suppression data
- Early warning indicators –Viral load monitoring
- Making viral load monitoring routine
- Managing virological failure

MAKING VL ROUTINE

Success and challenges in the implementation of routine HIV viral load monitoring

THE VIRAL LOAD CASCADE

STEP 1 Achieving Coverage of Viral Load Testing

STEP 2 Acting on the results

STEP 3 Switching to Second Line ART

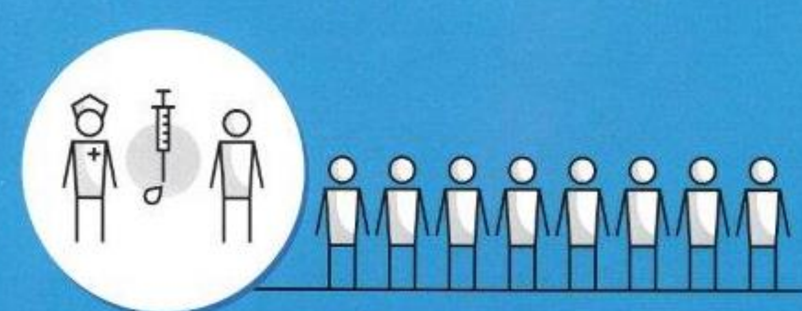
THE ROLE OF DIFFERENTIATED ART DELIVERY

- Using VL to differentiate ART delivery (resulting in clinic decongestion) as this may act as a motivating factor for VL to be taken.
- Differentiated ART delivery models where patients attend in groups for annual clinical review and VL testing achieve higher coverage of VL= VL anniversary.

KEY IMPLEMENTATION STRATEGIES TO MAKE VIRAL LOAD ROUTINE

- A VL focal person dedicated to identifying those in of need of VL and enhanced adherence counselling greatly facilitated uptake at all steps of the VL cascade.
-
- Systems to flag patients in need of VL using paper based and electronic medical records improved
- A patient triage system, clinic flow and tools (EAC register and high VL form) adapted to identify patients in need of VL and enhanced adherence counselling improved uptake.
- Investing in patient education and demand creation for viral load should be at the foundation of any VL scale up strategy.

ACHIEVING COVERAGE OF VIRAL LOAD TESTING



Coverage of routine VL testing in MSF supported sites:

Steps …

Human Resources

- Healthcare workers require continuous training as to the benefits of VL monitoring and why it should be 'routine'.
- Setting monthly VL targets for each clinic is useful for supervision and provided motivation to enhance performance.

Identifying patients for Viral Load Testing

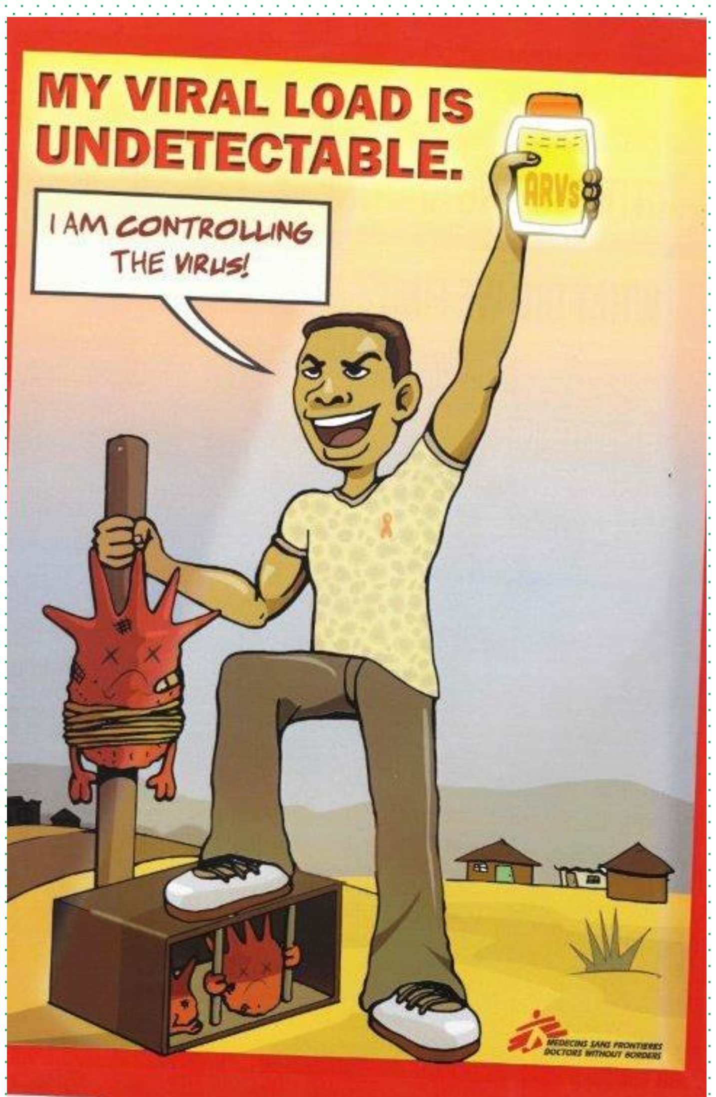
- Use existing documentation (ART cards/patient-held records) to identify those in need of VL according to time on ART.

- Where electronic medical records (EMRs) exist, they should be programmed to immediately flag a patient who is due VL testing or produce lists to support clinical management e.g. a weekly list to identify attendees due a VL test.

- Use hard copy of viral load register as a back up when EMRs not fully functional

CREATING DEMAND FOR VIRAL LOAD TESTING

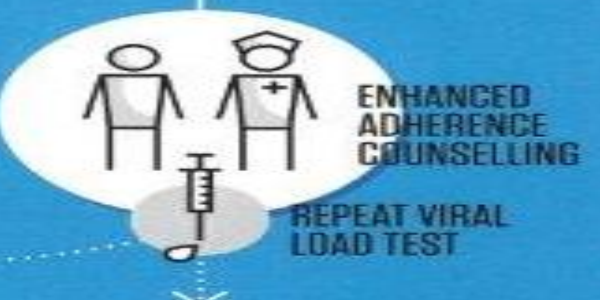
- Programmes should invest in the training of counsellors and development of educational material to ensure quality patient education on VL,
- Funding for civil society organisations to support VL awareness campaigns should be integrated into national VL scale-up plans.


MY VIRAL LOAD IS UNDETECTABLE.
I AM CONTROLLING THE VIRUS!
ARVs
MEDECINS SANS FRONTIERES
DOCTORS WITHOUT BORDERS

Agenda

- Introduction –
- VL completion and Suppression data
- Early warning indicators –Viral load monitoring
- Making viral load monitoring routine
- Managing virological failure

ACTING ON THE RESULT



LOW VIRAL
LOAD COUNT

Enhanced Adherence Documented:

56%

SHISELWENI
SWAZILAND 82%

Repeat Viral Load Taken:

23%

71%

ACTING ON A VL < 1000 COPIES/ML

- The positive impact of sharing a good result (< 1000 copies/ml) on adherence should not be forgotten,
- A VL < 1000 copies/ml can be used as a criteria to differentiate ART delivery and reduce the burden of clinic visits for both the patient and health system

ACTING ON A RESULT > 1000 COPIES/ML

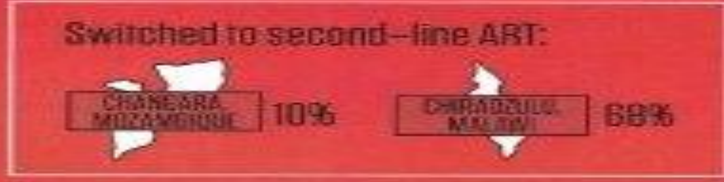
- The presence of a VL focal point focal complete point (a the dedicated enhanced staff adherence register and actively identify those in need of adherence counselling and repeat VL testing facilitated action. Additional staff were not added to perform these tasks. Rather, job descriptions of existing lay cadres were formally adapted
- Correct follow-up of a high VL result was more likely to occur if a triage system was in place.
- Flagging of results and automatic result lists (as described in the laboratory report) have facilitated identification of those with a high VL
- Using the high VL summary form to flag the patient files for action at each visit and use of the enhanced adherence register facilitated tracing of defaulters.

PERFORMING ENHANCED ADHERENCE COUNSELLING

- In most sites, EAC is performed by lay counsellors Training and on-job support for lay counsellors is needed to enhance their technical ability to deal with more complicated cases of treatment failure. In two sites counsellors with formal qualifications were employed to review these cases. However, such personnel are rarely available in these contexts.

Step l: Results arrive	Step 2: Trace patients with high viral load	Step 3: Patient is seen for first EAC session
High viral loads are separated ·Patients! details are entered into the high viral load register High viral load summary form is completed Normal viral loads are filed	Staff member is delegated to trace patients with high viral load via phone or through the community health workers Recently, SMS of high viral load results to both clinic and patients has been introduced as an additional means of contacting patients	Patient is identified through the high viral load form that flags the file and is triaged to EAC on arrival Patient is given l-month refill and booked for a second EAC session in month

SWITCHING TO SECOND-LINE ART



LESSONS LEARNED

- Rates of switch to second-line ART remain low in most sites
- Where patients are well or where adherence is not optimal, clinicians are reluctant to switch and 'give more time' for adherence support
- The optimal duration to allow for suppression before switch is not clear but may depend on the first VL result
- Factors that facilitated switch to second-line ART included:
  - *Decentralisation of second-line initiation*
  - *Task-shifting of second-line initiation to non-physician cadres*
  - *M-health strategies to allow remote clinical decision support for switching*
- Ensuring second-line drugs are available where the patient is accessing their first-line therapy should be a priority
- Ongoing adherence support following the switch to second-line ART is essential

Major challenges remaining include:

- Improving the knowledge and motivation of healthcare workers to recognise the benefits of VL testing through mentorship, clinical governance mechanisms and

- Increasing awareness of patients and CSOs to create demand and dispel myths around viral load testing

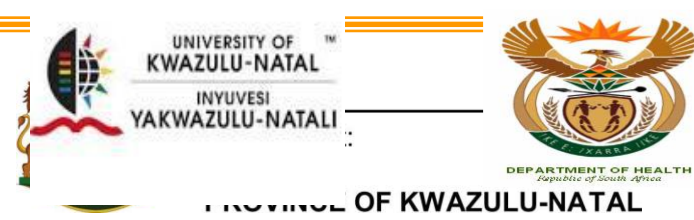
- Ensuring access to adequately trained and remunerated HR to perform enhanced adherence counselling
- Strengthening the skills of clinic managers to coordinate triage and patient flow

- Decentralisation and task shifting of second line ART initiation and follow up, with continuous access to second line drugs

Acknowledgements

- The Epicentre team led by Cherie Cawood
- The 11 facilities that participated in the File and Facility Audit
- The CAPRISA ACC Statistics & Data Management Team
- Dr Henry Sunpath (eThekwini District Specialist Clinical Team Leader)

This project was supported by the Grant or Cooperative Agreement Number U2G GH001142, funded by the Centers for Disease Control and Prevention. Its contents are solely the responsibility of the presenter(s) and do not necessarily represent the official views of the U.S. Centers for Disease Control and Prevention or the U.S. Department of Health and Human Services



QUALITY ASSURANCE THROUGH MONITORING EARLY WARNING INDICATORS AND INTEGRATED CARE FOR PLHIV

NDOH –DIRECTORATE HAST SERVICES

ETHEKWINI DISTRICT OFFICE –TWG

INFECTIOUS DISEASES –NRM SCHOOL OF MEDICINE –UKZN

KZN DRUG RESISTANCE STUDY

FIGHTING DISEASE, FIGHTING POVERTY, GIVING HOPE

Partners

- Harvard Medical School
- Emory University
- SA HIV clinicians Society
- MEDICATE –AIDS T/A AWACC