



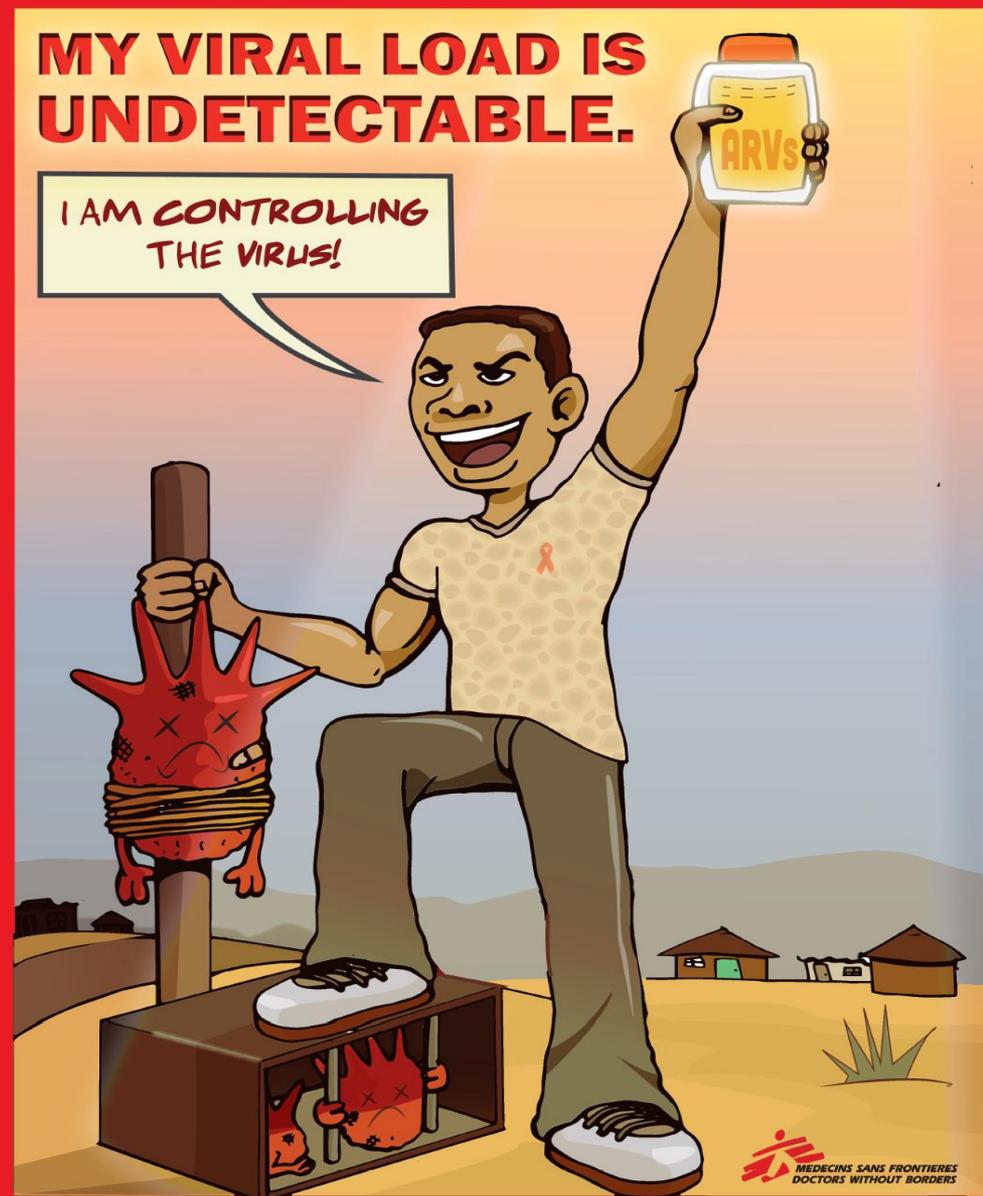
Making Viral Load Routine

A Focus on Programmatic Strategies

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HIV/TB Advisor MSF

ICAP Webinar Sept 20th 2016





MAKING VIRAL LOAD ROUTINE

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

PART 1: PROGRAMMATIC STRATEGIES



MAKING VIRAL LOAD ROUTINE

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PART 2: THE VIRAL LOAD LABORATORY





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PART 2: THE VIRAL LOAD LABORATORY



**PROGRAMMATIC AND LABORATORY TEAMS
HAVE TO SPEAK TO EACH OTHER**
www.msfaccess.org/makingviralloadroutine

TABLE 1: MSF SUPPORTED ART COHORTS: BACKGROUND AND VIRAL LOAD CASCADE OUTCOMES

10 ART Sites ; 189,795 patients on ART (Zimbabwe, Lesotho, Malawi, Mozambique, Swaziland, Uganda) Majority Rural Decentralised Districts 3-28 sites served

testing after 12 months on ART										
ART cohort eligible for VL testing	19 289	11 944	42 003	15 382	19 036	6 032	3 534	45 591	20 000	6 994
Number of ART sites with access to VL testing	28	19	28	14	5	10	10	7	25	3
Sample type used	DBS	DBS	DBS	DBS	PLASMA SAMBA 1	DBS	DBS	DBS	PLASMA	PLASMA SAMBA 1
Coverage of routine VL testing	91%	74%	58%	32%	60-80% (across 5 sites)	70%	62%	69%	85%	85%
VL > 1000 copies/ml	14%	15%	9%	20%	22%	10%	40%	27%	9%	21%
Threshold for triggering adherence intervention (copies/ml)	1000	1000	1000	1000	1000	1000	3000*	3000*	1000	1000
EMO documented for patients with VL above the threshold	57%	78%	62%	58%	NA	70%	70%	NA	62%	NA
Repeat VL test performed (VL2)	68%	67%	55%	40%	71%	42%	23%	36%	57%	64%
Suppressed to <1000 copies/ml	43%	38%	46%	32%	31%	50%	22%	26%	24%	24%
Threshold for switch to second line ART (copies/ml)	1000	1000	5000*	5000*	5000*	5000**	3000*	3000*	1000	1000
Eligible patients switched to second-line ART	37%	35%	15%	38%	68%	37%	10%	Not known: referred to tertiary centre	17%	41%

High VL = > 1000 copies/ml Suppressed VL = < 1000 copies/ml

TABLE 1: MSF SUPPORTED ART COHORTS: BACKGROUND AND VIRAL LOAD CASCADE OUTCOMES

Site	 BULAWAYO, ZIMBABWE	 GUTU, ZIMBABWE	 THYOLO, MALAWI	 NSANKHWE, MALAWI	 CHIRADZULU, MALAWI	 ROMA, LESOTHO	 CHANGARA, MOZAMBIQUE	 MAPUTO, MOZAMBIQUE	 SHISELWENI, SWAZILAND	 ARUA, UGANDA
HIV prevalence										
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Eligible patients switched to second-line ART	 37%	 35%	 15%	 38%	 68%	 37%	 10%	Not known; referred to tertiary centre	 17%	 41%

High VL = > 1000 copies/ml Suppressed VL = < 1000 copies/ml

Annual VL Except Malawi (every 2 years)

TABLE 1: MSF SUPPORTED ART COHORTS: BACKGROUND AND VIRAL LOAD CASCADE OUTCOMES

Sites										
HIV prevalence	15.7%	14.5%	14.5%	16.3%	17.0%	23.0%	7.0%	16.8%	31.0%	3.0%
Year routine VL testing started	2012	2013	2012	2013	2013	2014	2013	2013	2012	2013
Frequency of routine viral load testing after 12 months on ART	Annual	Annual	Every 2 years	Every 2 years	Every 2 years	Annual	Annual	Annual	Annual	Annual
ART cohort eligible for VL testing	19 289	11 944	42 003	15 382	19 036	6 032	3 534	45 591	20 000	6 994
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Sample type used	DBS	DBS	DBS	DBS	PLASMA SAMBA 1	DBS	DBS	DBS	PLASMA	PLASMA SAMBA 1

1 Site Plasma Biocentric
7 Sites DBS Biomerieux
2 Sites SAMBA 1

ELC intervention (copies/ml)										
EMO documented for patients with VL above the threshold	57%	76%	62%	56%	NA	70%	70%	NA	62%	NA
Repeat VL test performed (VL2)	68%	67%	55%	40%	71%	42%	23%	36%	57%	64%
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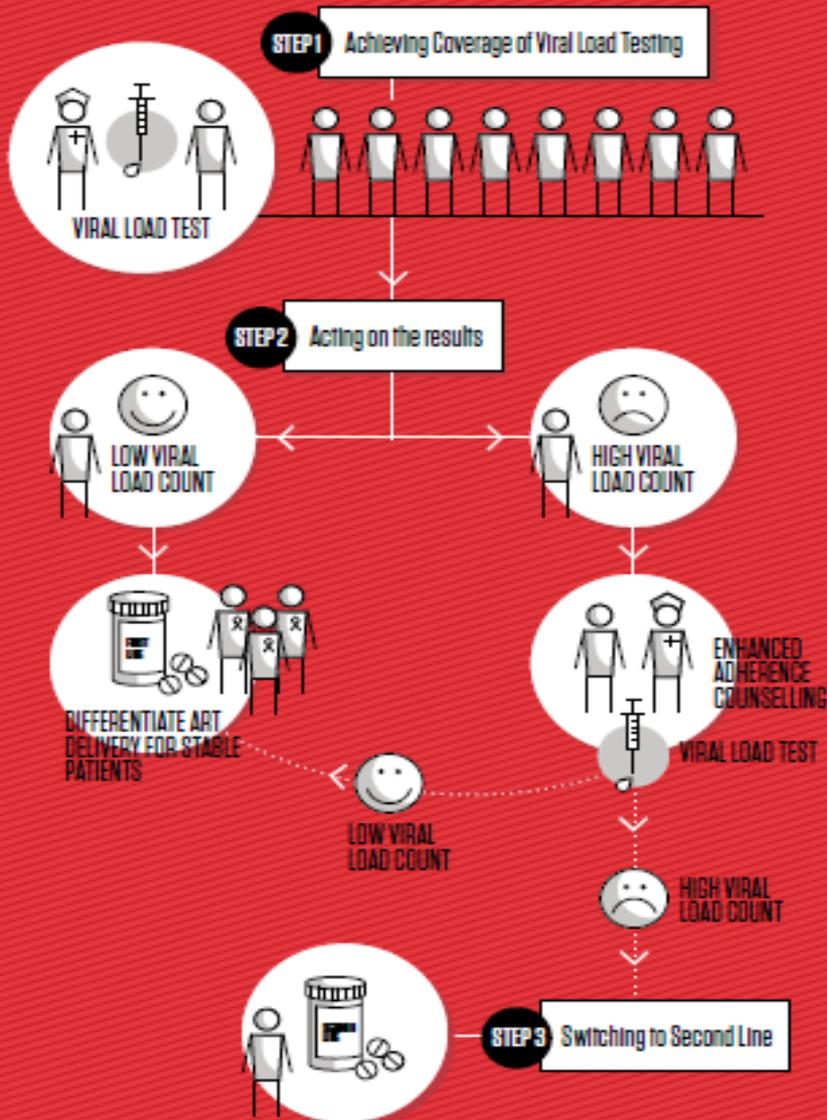
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HIV prevalence	 15.7%	 14.5%	 14.5%	 16.3%	 17.0%	 23.0%	 7.0%	 16.8%	 31.0%	 3.0%
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Sample type used	 DBS	 DBS	 DBS	 DBS	 PLASMA SAMBA I	 DBS	 DBS	 DBS	 PLASMA	 PLASMA SAMBA I

VL Cascade Data

THE VIRAL LOAD CASCADE



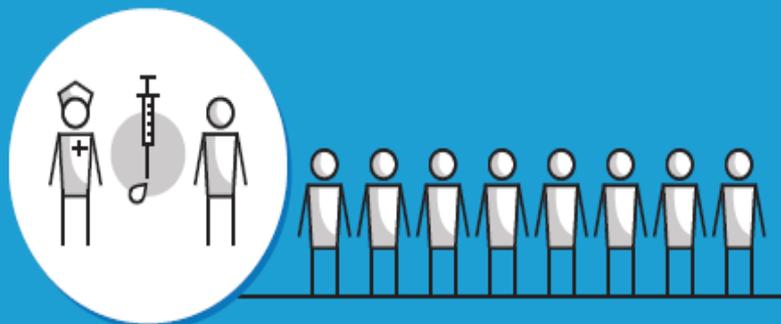
Objective

To go away with
some tips for
operational
strategies to
scale up Viral
load
Monitoring

STEP 1

ACHIEVING COVERAGE OF

VIRAL LOAD TESTING



Coverage of routine VL testing in MSF supported sites:



Demand Creation:

- Knowing when VL should be taken
- What VL means
- What action needed depending on the result
- Investing in client education material

32-91% Coverage of Routine Viral Load

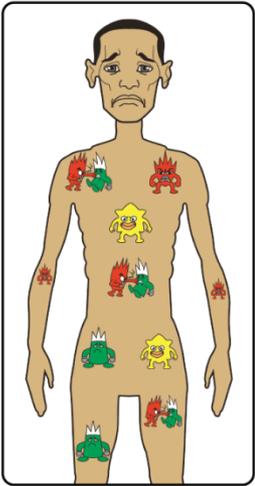
Step
1

Patient Education

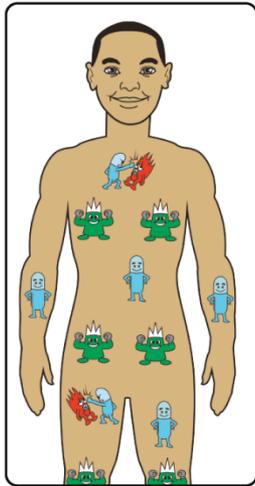
- Incorporating VL key messages into ART preparation counselling
- Pre-bleeding VL messages – by triaging patients in need of viral load on arrival this can be done as group
- Incorporate into general health education messages especially at start of scale up

Step
1

Viral Load IEC Material



High viral load > 1000



Low or undetectable viral load < 1000

When to have a viral load test?

The first viral load will be taken at 6 months, then again at 12 months. After that you will get a viral load yearly as part of the routine follow up of HIV+ patients on ART.

If your viral load is high, it is taken again 3 months later. During those 3 months you will work on your adherence with your counsellor and clinician.

Some common questions from our patients

“What is the best way to know my treatment is working: a CD4 count or a viral load test?”

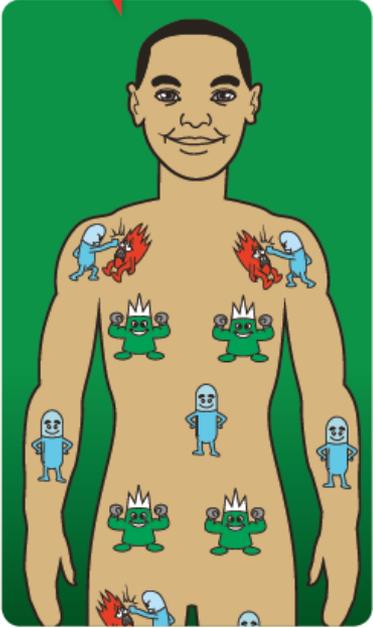
A viral load test.
We check whether your treatment was working by taking a CD4 count. A CD4 count measures the amount of soldiers in your blood and shows how strong your immune system is.

Now we have a better way of checking if your treatment works, which is the viral load test.

“Can unprotected sex be a reason for my high viral load?”

Unlikely.
There is only a very small chance that you may be infected with a resistant HIV virus through unprotected sex.
The most likely reason for a high viral load is an adherence problem. It remains however important for you to use condoms to avoid passing HIV to others.

I know my viral load I am in control of my HIV



It is your right to know your viral load result!
.....
Ask your health care worker for the test and for your results.



Step
1

Viral Load Posters





**The nurse told me
my blood test was
undetectable for
HIV so I stopped my
drugs**

ROUTINE VIRAL LOAD TESTING FOR HIV TREATMENT

Step
1

Working with Civil Society



**ACTIVIST
TOOLKIT**

Campaigning for Routine Viral Load Monitoring

 **ITPC**
INTERNATIONAL TREATMENT
PREPAREDNESS COALITION

APRIL 2016

Step
1

Health Systems Strategies

- The Role of lay workers in taking and preparing the samples- all sites except Zim
 - Making the DBS
 - Centrifuging the samples
 - Performing SAMBA analysis
- Education of health care workers to recognise value of viral load
- Setting clear monthly clinic targets for VL – **WITH FEEDBACK**
- Health system strengthening – triage and patient flow – **flagging** to identify clients in need of VL (Use of EMRs)

Impact of Group Differentiated ART delivery strategies

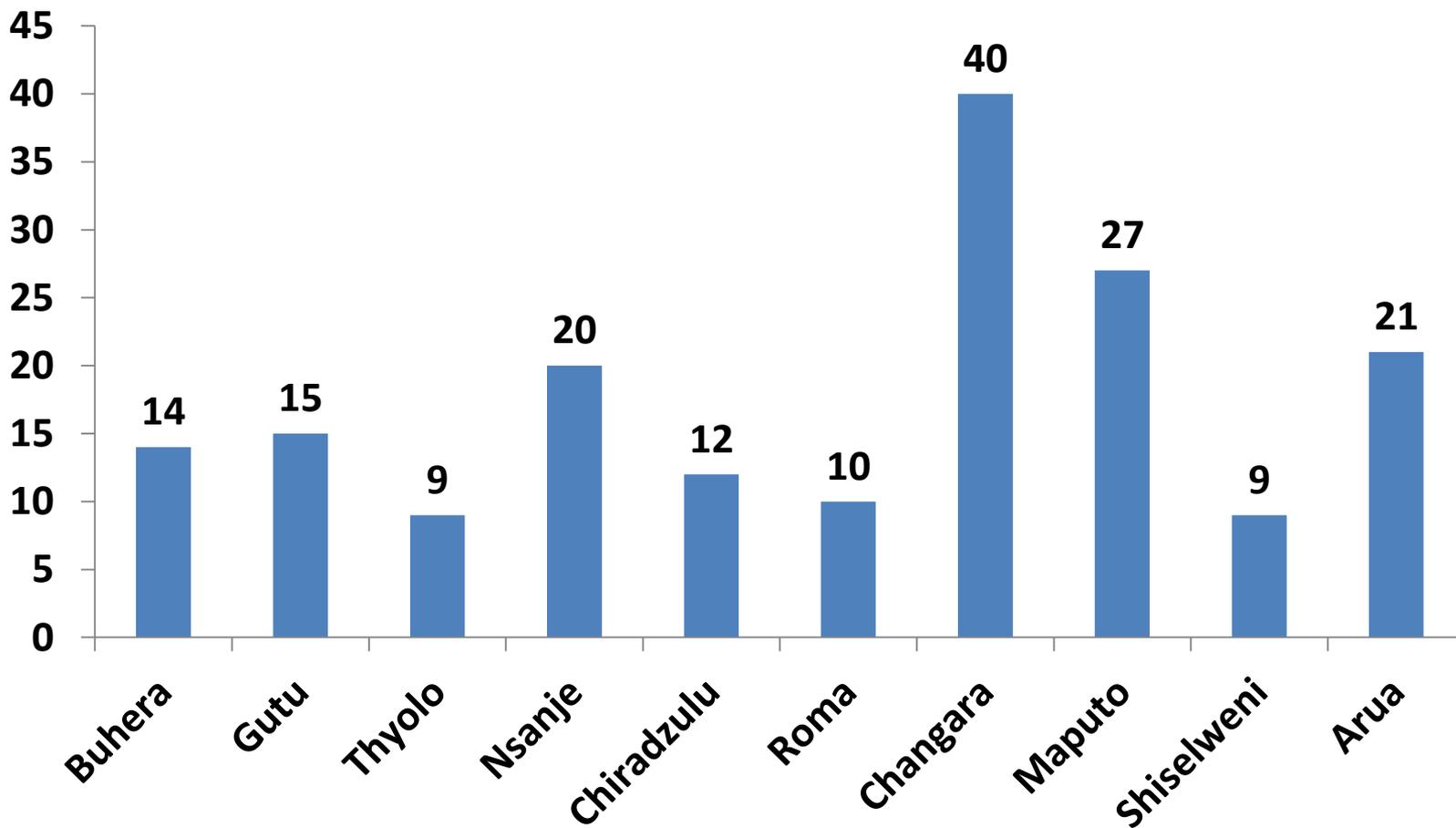
Step
1



**Adherence
Clubs:
VL uptake
67% v 49%**

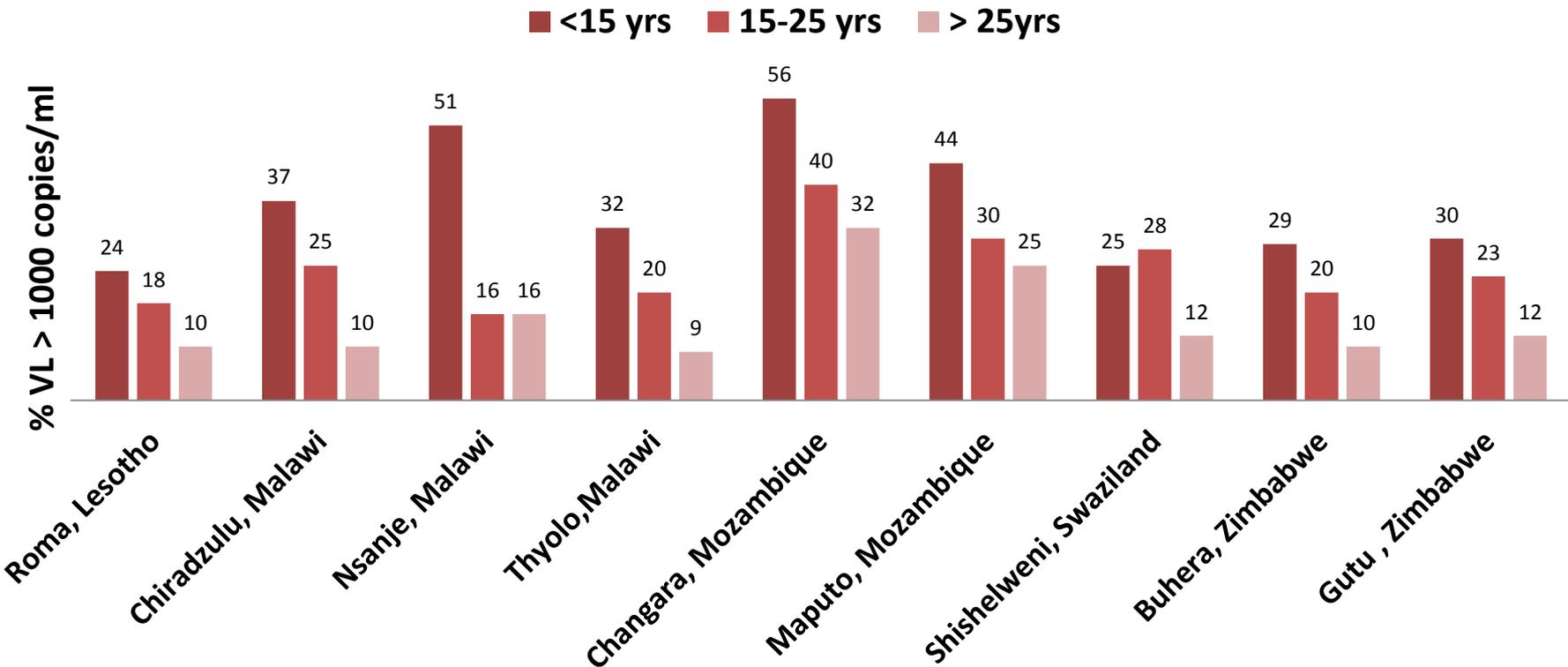
**CAGs
Mozambique:
VL uptake
72% v 47%**

What did we find ?



All VL performed % > 1000 copies/ml

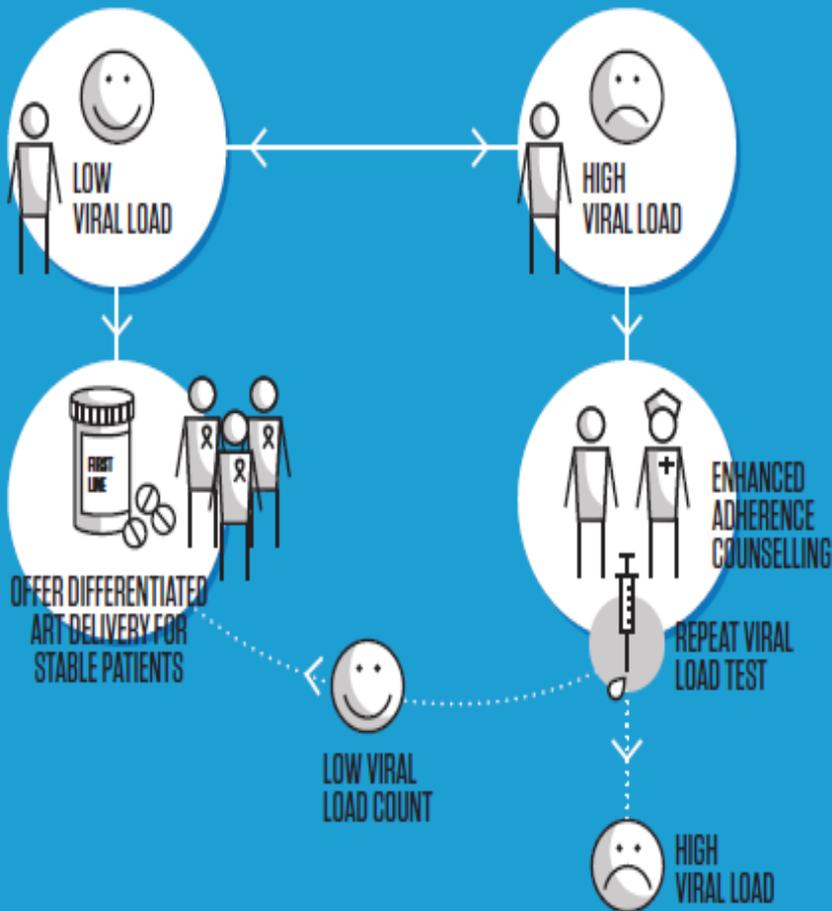
What did we find- VL > 1000 copies/ml by Age ?



More failure in children and adolescents

STEP 2

ACTING ON THE RESULT



**We need to get the Result
to the patient**

Email

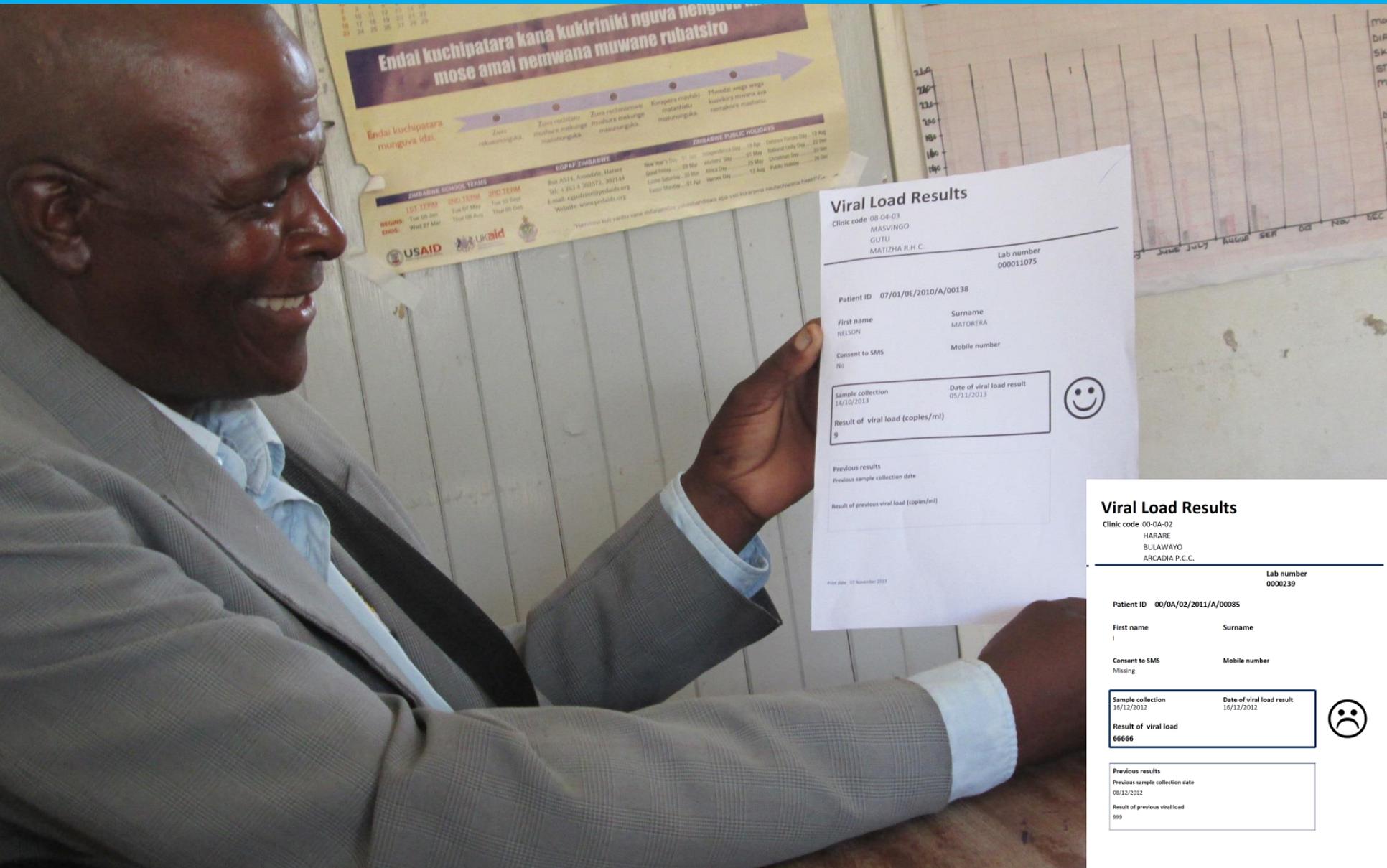
Paper Based

Filing –VL focal point

SMS

**Tracing those clients with
HVL**

Result delivery



Viral Load Results

Clinic code 08-04-03
MASVINGO
GUTU
MATIZHA R.H.C. Lab number 000011075

Patient ID 07/01/06/2010/A/00138

First name NELSON Surname MATOHERA
Consent to SMS No Mobile number

Sample collection 14/10/2013 Date of viral load result 05/11/2013
Result of viral load (copies/ml) 9



Previous results
Previous sample collection date
Result of previous viral load (copies/ml)

Print date: 12 November 2013

Viral Load Results

Clinic code 00-0A-02
HARARE
BULAWAYO
ARCADIA P.C.C. Lab number 0000239

Patient ID 00/0A/02/2011/A/00085

First name | Surname |
Consent to SMS Missing Mobile number

Sample collection 16/12/2012 Date of viral load result 16/12/2012
Result of viral load 66666



Previous results
Previous sample collection date 08/12/2012
Result of previous viral load 999

Viral Load Results Jan 2013

Clinic 00-0A-0F

HARARE

BULAWAYO

AVENUES CLINIC

Viral load results ≥ 1000

Sample date	Patient ID	First name	Surname	DOB	Age yrs	Age mths	Labno	Viral load date	Result
21/01/2013	00/0A/0F/2011/A/00055	MWALILINO	SIMOL	MWALILINO	01/01/2006		0000101	21/01/2013	4999

Sample date	Patient ID	First name	Surname	DOB	Age yrs	Age mths	Labno	Viral load date	Result
22/01/2013	00/0A/0F/2011/A/00097	KANYIMBO	KANYIMBO		40		0000342	22/01/2013	15000

Viral load results < 1000

Sample date	Patient ID	First name	Surname	DOB	Age yrs	Age mths	Labno	Viral load date	Result
10/01/2013	00/0A/0F/2011/A/00109	MUGHOGO	SAM	MUGHOGO	20		0000343	10/01/2013	800

No viral load results

Sample date	Patient ID	First name	Surname	DOB	Age yrs	Age mths	Labno	Viral load date	Result
22/01/2013	00/0A/0F/2012/A/00013	MWANKENJA	ANYIM	MWANKENJA	01/01/1960		0000334	22/01/2013	

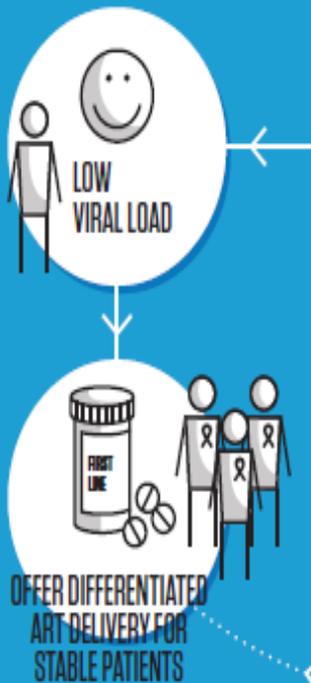
Laboratory error

Getting the result used

- Trying to get the result acted on
 - Person in clinic delegated to be responsible for filing
 - Person delegated to Trace high Viral load patients
 - Person in clinic delegated to enter VL > 1000 into EAC register

STEP 2

ACTING ON THE RESULT



"It encourages me to hold on and take my treatment as prescribed"
(Client Shishelweni Swaziland)

- Value of a “ Good Result”
 - Qualitative work Swaziland
(Horter et al IAS 2015)
 - Offer Differentiated Care – making VL cost effective
(Modelling consortium 2015)

STEP 2

ACTING ON THE RESULT



Approaches for Enhanced Adherence Counselling

Enhanced Adherence Counselling

- In most sites aim for 2 EAC sessions
- 1st Session on day VL results given- give 1 mth of drugs
- 2nd session one month later- give 2 months of drugs
- Repeat viral load taken 3 months (12 weeks) after first EAC session

Step

2

SESSION 1: 14/05/2013

Enhanced Adherence Worksheet

STEP 1: Review EDUCATION

Viral load is: *Pt knows*
High viral load is: *Pt unsure, explained again*
Suppressed viral load is: *Aiming for VL < 400*

STEP 2: PATIENT'S REASON FOR HIGH VL

Pt says she struggles with morning dose, she gets busy at work and then forgets to take meds

STEP 3: REVIEW TIME MEDS TAKEN

Problem with time: *Yes morning dose time*
Agreed upon time: *6am- before work and 7pm*
Late/missed doses: *Pt will take late doses asap*

STEP 4: STORING MEDS/EXTRA DOSES

Usual storage place: *Bedroom cupboard*
Emergency supply will be carried in: *handbag and locker at work*

STEP 5: MOTIVATION CARDS

Top 3 goals for the future: *Raise my kids*
Be a grandmother one day
Have a good job and be successful

Do you think your ARVs can help you achieve your goals for the future? *Pt says yes!*
Brainstorm places to put stickers & other reminders

STEP 6: PATIENT'S SUPPORT SYSTEM

Members of patient's support system
My husband and my parents

STEP 7: PLANNING FOR SUBSTANCE USE

Your plan to make sure you take your ARVs if you use alcohol or drugs: *Occasional alcohol user, pt says will still take ARVs even if using alcohol*

STEP 8: GETTING TO APPOINTMENTS

How do you get to clinic? *Local taxi*
Back-up plan to get to clinic *Walk*
Not able to come on date *Come asap- before ARVs finish*

STEP 9: HOMEWORK & WAY FORWARD

Your VL will be repeated in *July*
Next visit date: *11 June 2013*

DATE EAC SESSION 2 (Mth 1).....

DATE ADDITIONAL SESSION:.....

STEP 1: DISCUSS ADHERENCE

DIFFICULTIES/ PROBLEMS

Review homework

Adherence difficulties

STEP 2: MISTAKES

Thoughts to deal with

STEP 3: PLANNING

Update green appointment

Regular travel location

Remind pt to plan

STEP 4: REVIEW

Remind patient with

Give 2 months

for blood to be

mths time)

If further EAC needed

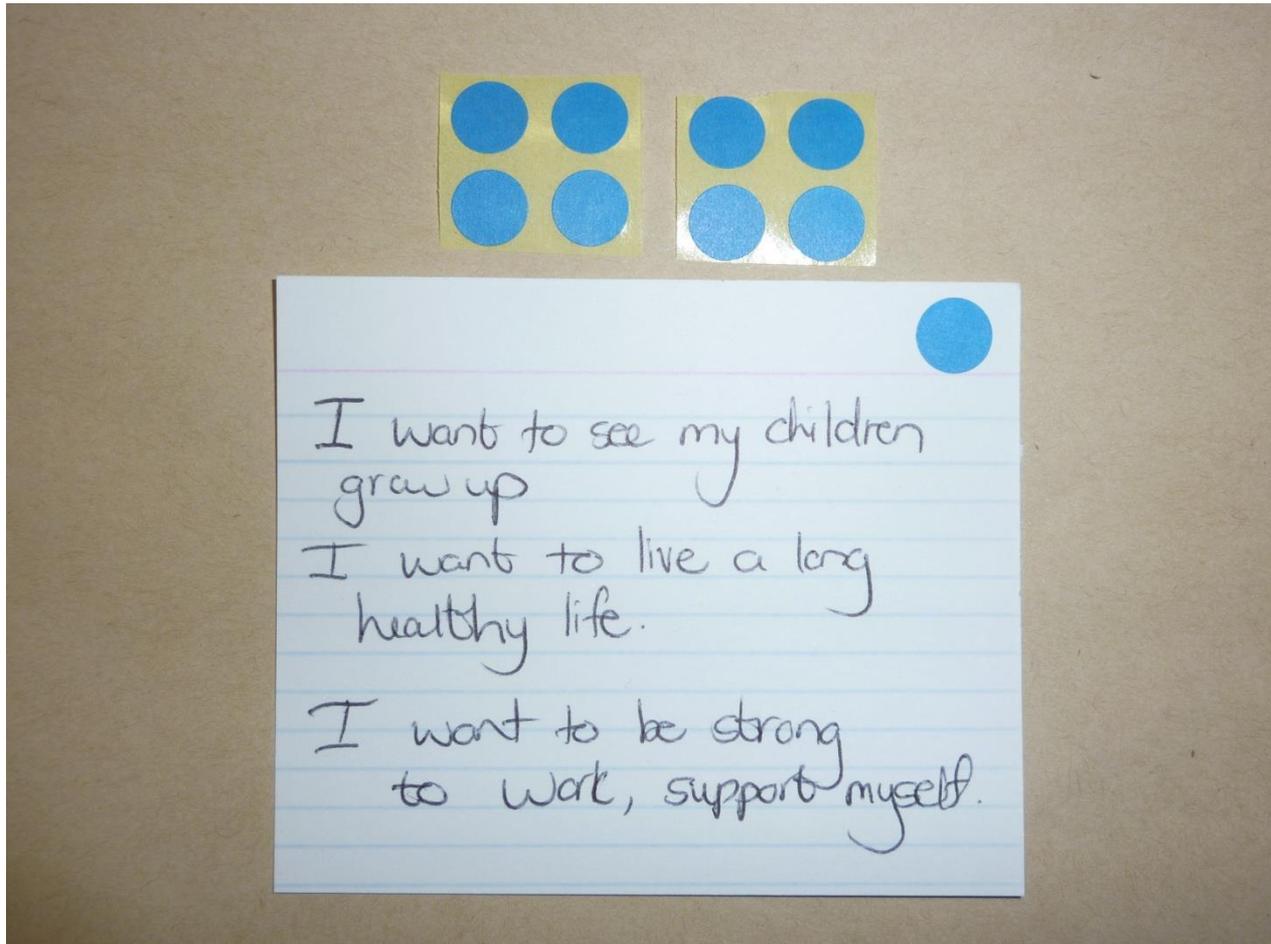
**Addressing , behavioural , social
and emotional barriers to
adherence
9 STEPS
Review Education
Patient's reason for High VL
Review time medications taken
Storing meds and extra doses
Motivations cards
Patient Support System
Planning for substance misuse
Getting to appointments
Making a plan until the next visit**

Date Next Visit or book for repeat VL:.....

Step
2

Practical adherence support

Note step 5, motivation cards



Community ART Groups and High Viral Load

“ We sat together with the Community ART group members of this patient with a high viral load.

The patient often forgot to take her drugs.

One of the CAG members is a neighbour who decided to pass by every morning, so they could take their drugs together”

Myth Busters

“One of my patients would never take drugs at the weekend.

- He said he was told he should not take ART and alcohol, but he always goes out with friends at the weekend.
- I clarified with him that it's better to take ART with alcohol than not taking them.
- Together we decided he would take his ARVs at the weekend a bit earlier, before leaving on a night out with friends”
- (**Counsellor, Khayelitsha, South Africa**)

- Alcohol Use
- Unprotected sex
- Taking drugs exactly on time

How did health workers deal with patients with high viral load ?

- Health practitioners assuming patient non-compliance
- Participants feeling blamed, abused, judged, interrogated and threatened
- Confidentiality breaches
- Impact

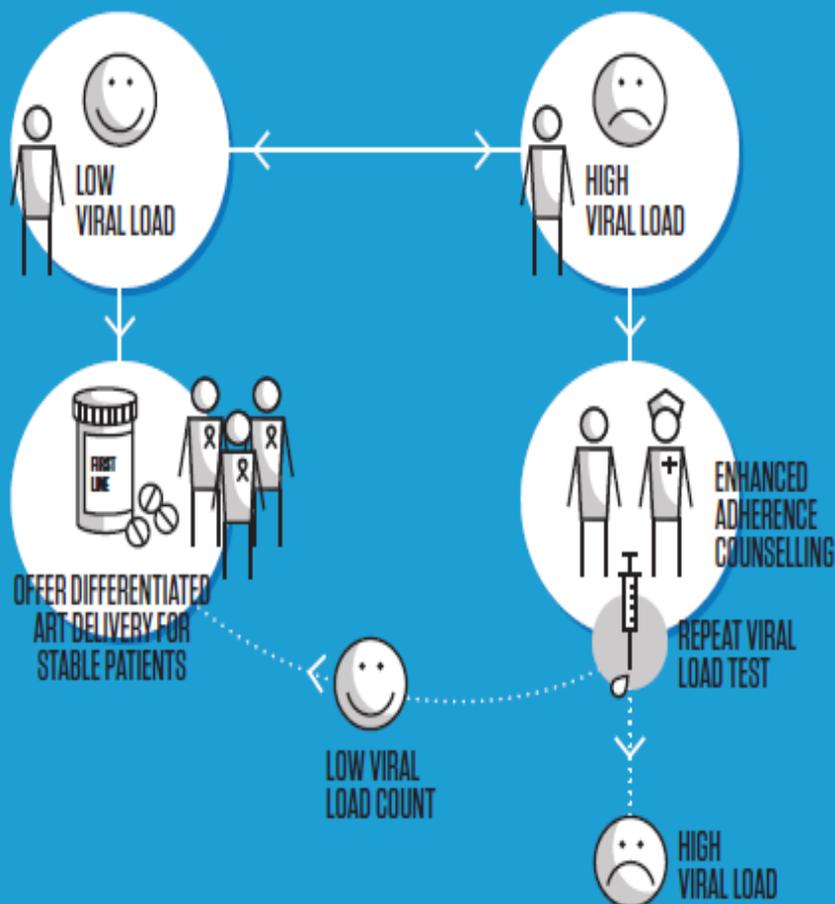
'In the clinic they were yelling at me... we ended up having a conflict and she said I should tell her the truth and I told her that the truth is what I am telling you' P12

'I didn't receive any support' P01

'They treated me bad' P06

STEP 2

ACTING ON THE RESULT



56-82% documented
Enhanced Adherence

23-71% repeat VL taken

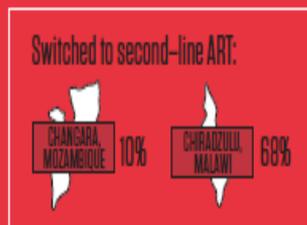
**24-50% suppressed after
EAC to < 1000 copies/ml**



STEP 3

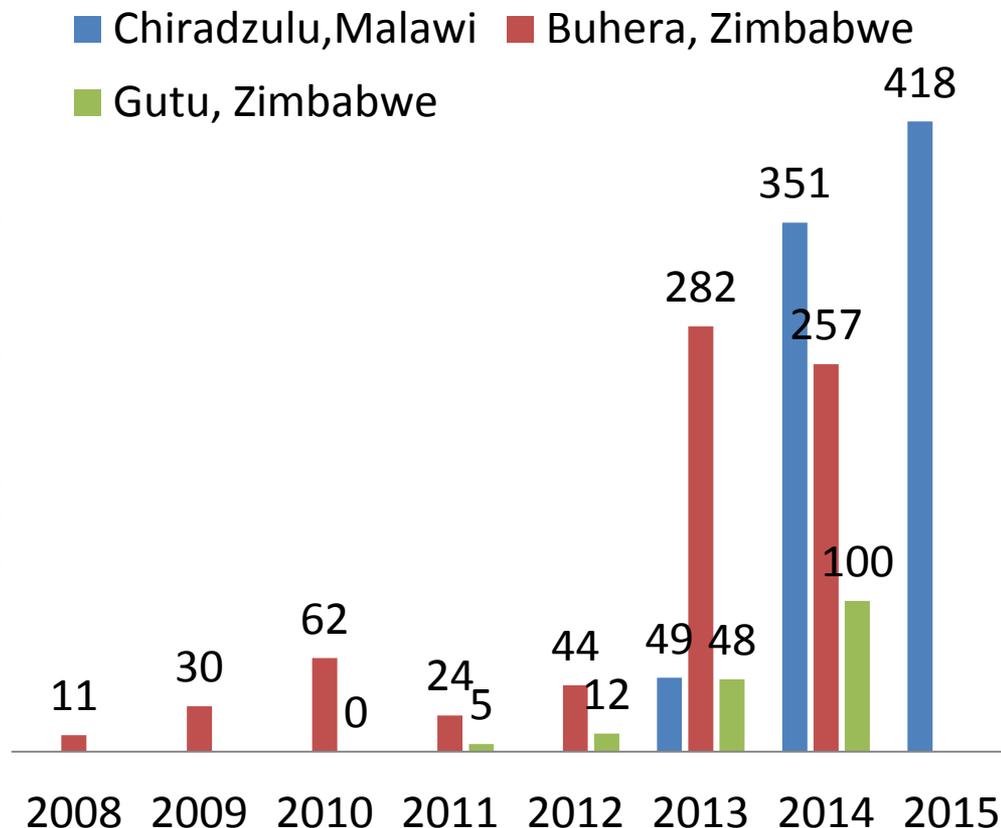
SWITCHING TO

SECOND-LINE ART



10-68% of those eligible switched to second line ART

Initiations on second line ART



Buhera 2012-2013

**Introduction of Routine VL on DBS > 6x
as many second line initiations**

Switching to Second Line

- Multidisciplinary Approach
- Access to second line drugs at district and primary care level
- WHERE? Decentralisation of second line switch
 - National committees ?
- WHO : Task shifting – what's the evidence?
- Training of HR
 - Malawi exam example
- Remote Switch decision support
 - Apps
 - Sending case summary to district level
- Perceptions of second line from HCW and Clients

M and E

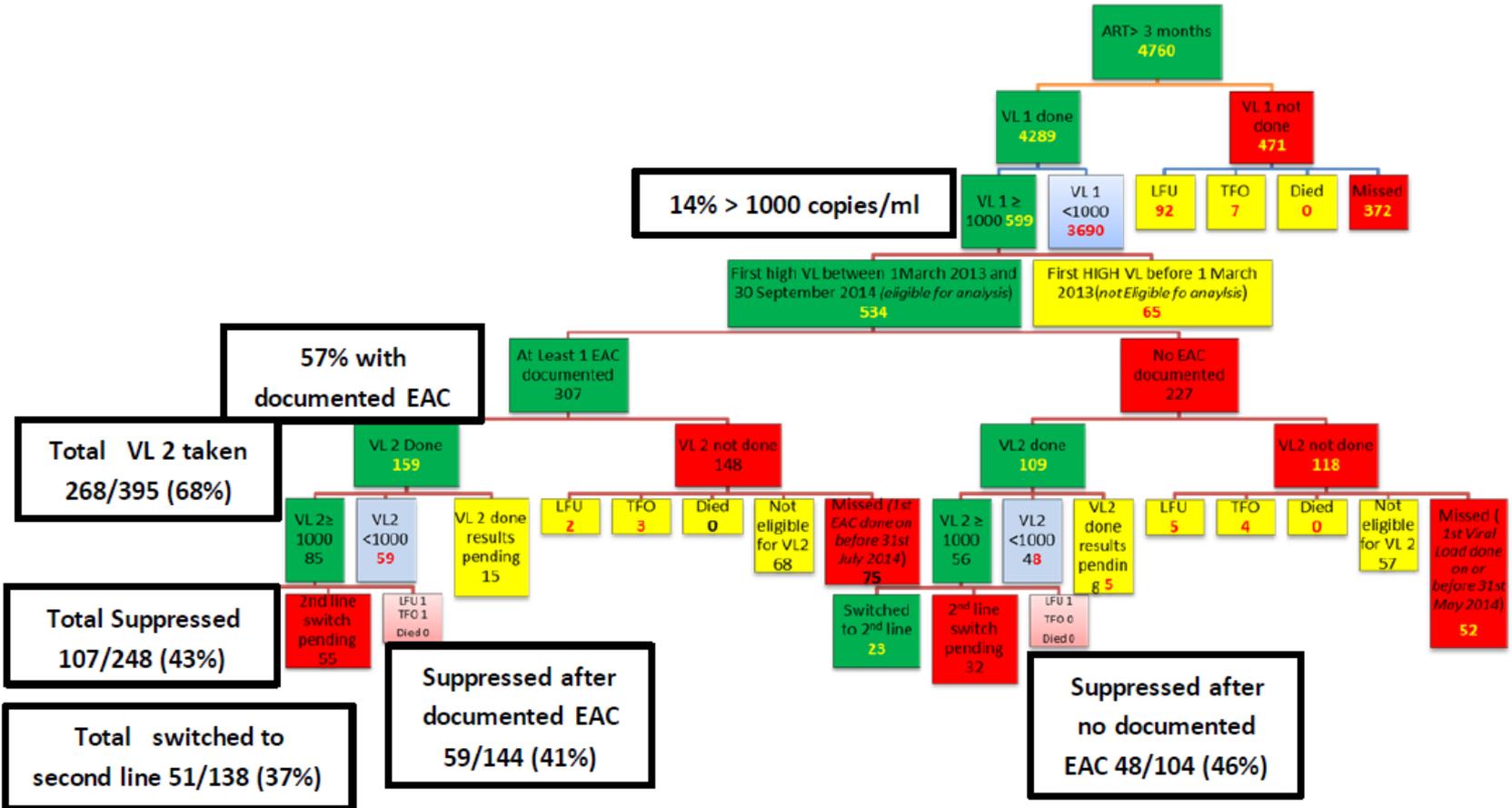
Evaluating the Cascade of Routine VL Monitoring

- Assessment of **quality of ARV treatment services**
- Assessment of **impact** of Routine VL monitoring (enhanced adherence counselling and treatment switching) for **patients with high VL.**

Suggested Indicators for VL Algorithm Monitoring

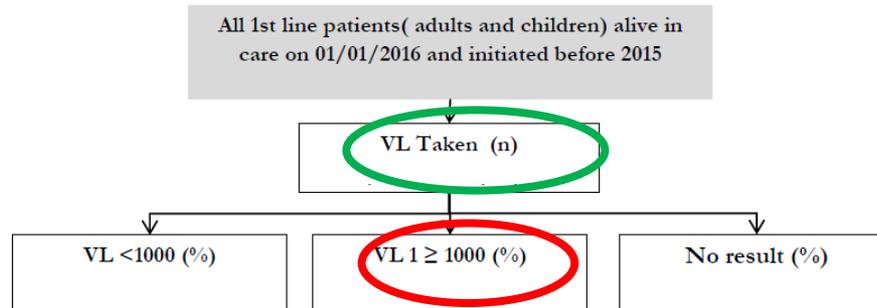
	Numerator	Denominator
% VL Performed	Number VL performed in time period	Number of patients eligible for routine viral load in time period
% VL with result	Number VL with result	Number VL performed
% VL > 1000	Number 1 st VL result > 1000	Number VL with result
% EAC received	Number with documented EAC	Number 1 st VL result > 1000
% Repeat VL performed	Number repeat VL performed	Number eligible (by time) for repeat VL 2 to be performed
% repeat VL > 1000 (not re-suppressed)	Number repeat VL > 1000	Number of repeat VL with result available
% switched to second line	Number switched to second line	Number of repeat VL > 1000 copies/ml

VL cascade



Viral Load Cascade: Monitoring and Evaluation

Coverage in previous year :

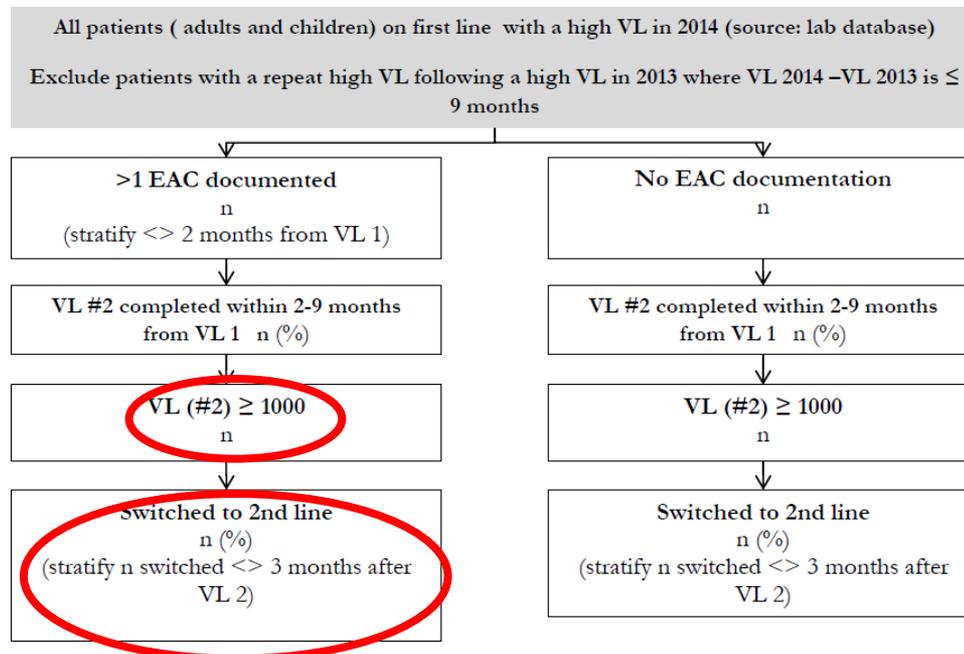


For patients with more than 1 VL, use last VL to classify VL distribution

Cascade analysis

For the cascade use cohort approach allowing max of 15 mths from VL1 to switch

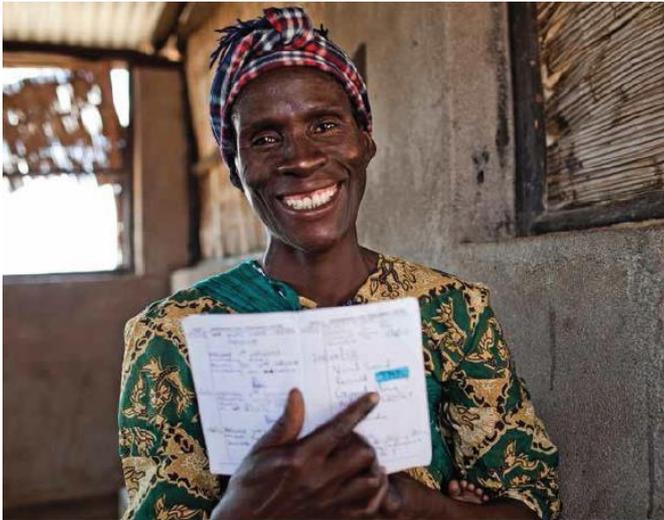
e.g Performing the analysis on 01/04/016



Some Questions Going Forward

- How do we best use centralised, near POC and true POC
- Coordination of donors across programmatic and laboratory needs
- Funding of layworkers crucial to coverage of VL and provision of enhanced adherence

Viral Load Toolkit



MÉDECINS SANS FRONTIÈRES
VIRAL LOAD TOOLKIT

AN IMPLEMENTER'S GUIDE TO INTRODUCING
HIV VIRAL LOAD MONITORING

- Tools
- Training powerpoints



samumsf.org

**Thanks to All the MSF Field Teams
Collaborating Ministries of Health
People Living with HIV in the MSF supported projects
UNITAID**



Strategies that have supported VL scale up



**DBS centralised platform
Biomerieux and Abbot**



**Plasma -Near POC
SAMBA 1
Xpert HIV -1 VL**

Lessons Learned

Setting Up Centralised VL Testing Platforms

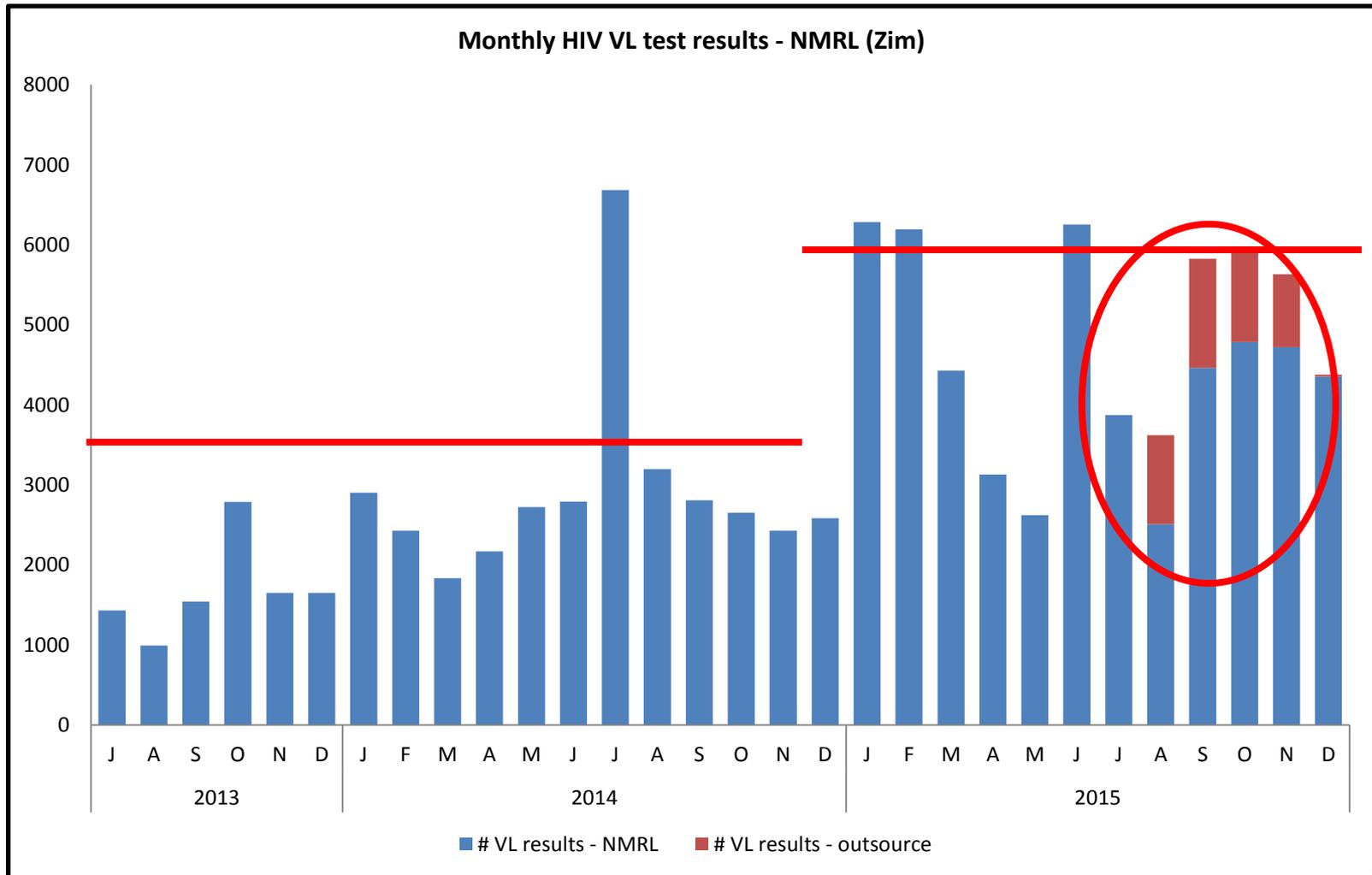
- **To purchase or lease**
 - Controls costs
 - Flexibility
 - Inclusion of maintenance in cost
 - Possible incentive for better maintenance
- **Infrastructure**
 - Adequate space
 - Power / water supply
 - Storage space for consumables
- **Retention of specialised laboratory technicians**
- Development of **laboratory information systems** for VL: programmed to produce clinically useful lists and triggers
- **WASTE MANAGEMENT**
 - No guidance
 - No regulation
 - 10mg cyanide from every kg of VL waste

Lessons Learned

Keeping a VL Laboratory Running

- Power supply : plan for longer UPS
- Maintenance
 - Training of local staff to perform maintenance
 - Availability of parts in country or regionally
- All machines underutilised (41-80%) - link between ART programme / VL cascade data and VL scale up planning
- HR management : Setting clear targets for throughput

Back Up Planning Must be Part of the Plan In or out of country : Public or private



Experience with Near Point of Care

- Allows **task shifting for sample processing** (Study Chiradzulu – excellent concordance of results lay worker v lab technician)
- SAMBA 1 (Malawi / Uganda) **80% of clients received results on the same day**
- Xpert – **polyvalency** – Study in Zimbabwe concurrent testing of VL , EID , TB , HPV on same platform in same clinic
- **Simpler to set up**
- **Down time much less – modular repairs**
- **Lower Error rates**



ICAP

GLOBAL. HEALTH. ACTION.

Columbia University
Mailman School of Public Health

GRANDROUNDS