Targeting the third ‘90’: introducing the viral load champion


Objective: To move closer to achieving the third target of the UNAIDS 90-90-90 goals, we prospectively implemented a viral load (VL) champion (VLC) program aimed at enhancing VL monitoring and recognition of treatment failure.

Design: Three clinics in eThekwini, Kwa-Zulu Natal (low-, medium- and high-volume, encompassing 9184 patients overall) were each assigned a VLC. We employed a descriptive analysis (chart audit) to compare the pre-intervention period to a 1-year post-intervention period. The number of patients with a VL test performed 6 and 12 months after the intervention was calculated as a proportion of VL tests due at those time points (VL completion rate).

Results: The pre-implementation VL completion rate at the three sites was respectively 68% (140/205 patients), 54% (84/155 patients) and 64% (323/504 patients), and the 6-month post-implementation completion rate increased to 83% (995/1194 patients), 90% (793/878 patients) and 99% (3101/3124 patients) (P < 0.0001 for each site). VL completion rates remained significantly higher at 12 months post-implementation, with an average cumulative VL completion rate of >90% across all facilities.

Conclusion: We demonstrate a successful, multifaceted, quality-improvement intervention centered on a clinic-level VLC which, taken to scale, has important implications for attaining the third UNAIDS 90-90-90 target.

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STUDY POPULATION, DESIGN AND METHODS

Program setting

In 2017, 621411 persons living with HIV (PLHIV) were registered in eThekwini, of whom 390784 (62%) were receiving ART at 124 clinical sites. Between November 2016 and November 2017, we conducted a cross-sectional comparative analysis using primary data at three pilot government ART clinics. A total of 9184 active PLHIV were enrolled in the clinics, had been receiving ART since 2006 for varying periods of time and were due for VL testing. Site 1 was a mid-volume clinic with 40 ART initiations monthly and 1628 active ART patients at baseline; Site 2 was a low-volume clinic with 20 ART initiations monthly and 961 active ART patients at baseline; and Site 3 was a high-volume clinic with 75 ART initiations monthly and 6595 active ART patients at baseline.

In South Africa, the National Health Laboratory Services (NHLS) perform VL testing using plasma and 26% of adult patients underwent VL testing 6 months, 1 year and 2 years after ART initiation.

Improvement of VL testing coverage rates by addressing bottlenecks in the cascade has been the subject of multiple studies. A public ART clinic in Limpopo, South Africa, successfully used a quality improvement framework using a sticker-based system that flagged the month when a repeat VL blood draw was required. A multi-country Médecins Sans Frontières project evaluated key implementation strategies within the VL cascade aimed at making VL monitoring routine. One recommendation from this project was to implement a VL focal person specifically assigned to respond to high VL results.

We implemented a VL champion (VLC) model aimed to enhance VL monitoring, and assessed pre-vs. post-intervention whether VL testing rates had improved in three publicly operated clinics in eThekwini, Kwa-Zulu Natal. A system of clinical care champions introduced to improve quality and adherence to clinical protocols in chronic medical conditions, such as diabetes, has previously been extended to the management of HIV infection, although not for this specific purpose. We hypothesized that a VLC, typically a nurse from the facility trained in quality improvement, would enhance suboptimal VL monitoring through 1) identification of those in need of routine and repeat VL monitoring, and 2) triaging patients for appropriate management such as adherence counselling or switching to second-line ARVs.
The viral load champion: improving routine viral load monitoring

A VL strategic operational plan (SOP) was developed and implemented in the study clinics (Figure 1). A VLC at each clinic was assigned to optimize VL monitoring through oversight of the VL SOP in each study clinic. The VLC supervised two work streams: 1) a baseline pre-intervention catch-up phase of VL data clean-up and triangulation, where laboratory results were entered into clinical charts and the clinic’s ART program database, and 2) ongoing coordination and management of the multifaceted VL SOP to ensure routine VL monitoring, accurate reporting, and expedient follow-up on test results (Table 1).

For the VLCs, we sought registered nurses who had completed government certification through the Nurse Initiated Management of ART (NIMART) curriculum and were permanent clinic staff members. The nurses were chosen from within the clinic after expressing an interest in the position. The role of VLC (Table 1) was expected to replace 10 of the current 40 h weekly clinical duties. The VLC required staff support and the ability to maintain accurate paper-based and electronic records. The VLC coordinated VL monitoring and management work streams through daily interaction with the clinic doctor, pharmacist, data capturers and lay counsellors, each of whom had specific job descriptions (Table 2).

Implementation phase

The initial pilot implementation period focused on complete audits of clinic charts, using a baseline audit tool (Appendix Figure A.1), staff orientation, and VL cascade education. Weekly quality improvement meetings were held during the implementation periods. On baseline ART chart audits, clinical files of patients who had completed government certification through the Nurse Initiated Management of ART (NIMART) curriculum and were permanent clinic staff members. The nurses were chosen from within the clinic after expressing an interest in the position. The role of VLC (Table 1) was expected to replace 10 of the current 40 h weekly clinical duties. The VLC required staff support and the ability to maintain accurate paper-based and electronic records. The VLC coordinated VL monitoring and management work streams through daily interaction with the clinic doctor, pharmacist, data capturers and lay counsellors, each of whom had specific job descriptions (Table 2).

FIGURE 1 High VL standard operating procedure. *See Appendix for sample and/or links to the tools used. VL = viral load (copies/ml); EAC = enhanced adherence counselling; FL ART = first-line ART; ART = antiretroviral therapy; m = month; SL ART = second-line ART; VLC = VL Champion; LTU = lost to follow-up; NHLS = National Health Laboratory Services; DOH = Department of Health; QA = quality assurance.

KEY WORDS
HIV; South Africa; AIDS; clinical champion

ACKNOWLEDGEMENTS
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Preparation / monitoring

Visit 1: EAC, Month 0 (VL > 1000)

Visit 2: EAC, Month 1

Visit 3: EAC, Repeat bloods, Month 2

Visit 4: Management, Month 2

* Pregnant women (VL > 1000) repeat VL at visit 2 (month 1) management decision at visit 3 (month 2)

FL ART = continue ART for 6 m, flagged VL at later review at m 8, SL ART = continue ART to m 12, Repeat VL at m 11 m and review at m 12

VL CChampion: Sea month of VL anniversary and assess notes to ensure that VL sample was collected

VL < 400 Continue with monthly repeat script and annual VL, review gleeo data on appointment card for month 11 VL sample collection and month 12 clinic monitoring. Offer differentiated care

VL > 400 Continue with bi-monthly repeat script and annual VL, review gleeo data on appointment card for month 11 VL sample collection and month 12 clinic monitoring. Offer differentiated care

Preparatory team

- Importance of VL monitoring, VL anniversary and adherence to clinic appointment issues.
- Completes ART adherence initiation checklist and adherence worksheet for clinical failure.
- Follow-up of missed appointments and accurate return to clinical workshopping parties per referral order.
- Lay counselor to manage high VL regular.

Drug dispensing unit

- Do not allow more than 1 month of ART if VL is not available upon renewal.
- Collect all patient files and handover to VLC for TIER-net entry

Viral load champion

- Integrate VL results daily, 3 times in patient files and alerts all lines with high VL (VL > 1000).
- Ensure that results are entered in high VL regular during EAC visits by the counsellor.
- Monthly audit of missed appointments and contact tracing.
- Identify those LTU after 3 months, reconcile with high VL regular and manage per protocol

Clinical management: clinic doctor

- Submit weekly list of high VL from NHLS dashboard to VLC.
- Manage team to implement referral pathway, appointments and maintenance database of SL ART

Data team

- Provide monthly report on high VL to VLC to identify early missed appointments by lay counsellor
- Provide weekly/monthly VL due list for follow-up per DOH recommendations
- Provide monthly report of all high VL patients to VLC for review with GA team
- Obtain file daily for data entry
- Return file with incomplete data to VLC

Group A VL < 400

Group B VL 400–1000

Group C VL > 1000

VL CChampion: Sea month of VL anniversary and assess notes to ensure that VL sample was collected

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TABLE 1  VL management activities led by VLC

<table>
<thead>
<tr>
<th>Pre-intervention chart audit</th>
<th>Implementation period</th>
<th>Post-implementation period</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Organize and supervise baseline audit of all clinical charts</td>
<td>1. Maintain VL due list</td>
<td>• Monthly review audit of a sample of clinical files for quality assurance</td>
</tr>
<tr>
<td>• Reconciliation of NHLS database, clinic chart and TIER.net</td>
<td>• Identify patients with VL due through monthly laboratory and database reports</td>
<td>• Oversee PDSA cycle audits with clinic team</td>
</tr>
<tr>
<td>• Creation of VL due register and high VL register</td>
<td>• Supervise designated team to contact patients with missed appointments</td>
<td>• Record and update patient demographic details and intention to change service provider</td>
</tr>
<tr>
<td>• Creation of a LTFU register</td>
<td>• Identify patients &gt;3 months after missed appointment and add to LTFU list for contact tracing by community health worker</td>
<td>* Lay counsellor, psychosocial service, clinician doctor or nurse.</td>
</tr>
<tr>
<td>• Develop QI plan to address clinical and process impediments in VL testing</td>
<td>2. Maintain high VL register</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Update high VL register (VL &gt; 1000 copies/ml) every month</td>
<td>• Monthly review audit of a sample of clinical files for quality assurance</td>
</tr>
<tr>
<td></td>
<td>• Supervise completion of appropriate follow-up for patients with high VL, including:</td>
<td>• Oversee PDSA cycle audits with clinic team</td>
</tr>
<tr>
<td></td>
<td>1. EAC*</td>
<td>• Assign a VL anniversary month to patient chart and appointment card</td>
</tr>
<tr>
<td></td>
<td>2. Clinic chart VL entry with alerts to clinical provider for follow-up</td>
<td>• Provide appointment dates for VL blood draws</td>
</tr>
<tr>
<td></td>
<td>3. Patient receipt of follow-up visit dates and repeat VL testing</td>
<td>• Train and orient all staff to protocols and follow up on key indicators</td>
</tr>
<tr>
<td></td>
<td>• Allocate a team member to maintain a call log register for patients with missed appointments in the high VL register</td>
<td></td>
</tr>
<tr>
<td></td>
<td>3. Multidisciplinary coordination</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Ensure all patients failing first-line ART are reviewed by EAC* team</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Refer patients requiring second-line ART or failing second-line ART to VL priority clinic</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Oversee ART prescription duration based on evidence of VL testing and result</td>
<td></td>
</tr>
<tr>
<td></td>
<td>4. Patient education and accountability</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Assign a VL anniversary month to patient chart and appointment card</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Provide appointment dates for VL blood draws</td>
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<tr>
<td></td>
<td>• Train and orient all staff to protocols and follow up on key indicators</td>
<td></td>
</tr>
</tbody>
</table>

* Lay counsellor, psychosocial service, clinician doctor or nurse.

Study data management and analysis

The following routine clinical data were accessed from TIER.net: total patients remaining on ART, VL test date, VL result, CD4 cell count, ARV regimen, patient visit date, and VL due. The District Health Information System was used to validate the total number of patients remaining on ART, and sample clinical charts were audited for VL result and VL test date. The pre-implementation period, which encompassed initial chart auditing, assigning clinic roles, and roll-out of the SOP, averaged 2 months for each clinic. From November 2016 to November 2017, during the post-implementation period, a descriptive analysis of 6- and 12-month VL follow-up tests results, defined as any VL test conducted within a 60-day window of the ex-
Outcomes following the VLC intervention were assessed by cohort analysis at 6 and 12 months (Figure 2). The pre-implementation VL completion rate at the pilot sites was 68% (140/205 patients), 54% (84/155 patients) and 64% (323/504 patients) at Sites 1, 2, and 3, respectively. Six months after implementation, the VL completion rate had increased to 83% (995/1194 patients), 90% (793/878 patients) and 99% (3101/3124 patients), respectively. This improvement was maintained at 12 months, with an average cumulative VL completion rate of >90% across all facilities and improved accuracy of VL suppression rates (Cochran-Armitage trend test for VL tests performed per site at Site One: $P < 0.0001$; Site Two: $P < 0.0001$, Site Three: $P < 0.0001$; cumulative: $P < 0.0001$). No significant trend of improvement was reported for VL suppression rates at baseline, 6 and 12 months all of which remained at >80%.

During the team feedback sessions, it was concluded that successful application of the extensive job requirements required to implement VL monitoring required a VLC who could dedicate 10 hours per week to the role.
DISCUSSION

We implemented a quality improvement project based on prevailing South African national guidelines at three pilot sites, directed by an assigned clinical champion—the VLC—that emphasized VL monitoring focused on timely requests, well-documented results, and reliable follow-up. Cascades of care have become an established mechanism to illustrate the effectiveness of coverage of care in HIV programs. The third pillar of viral suppression within the cascade reflects the cumulative effectiveness of HIV treatment programs at an individual and public health level for the prevention of viral transmission and an increase in acquired immune-deficiency syndrome (AIDS) free survival.

Our study shows the impact of strengthening targeted health systems to ensure appropriate levels of coverage of services to enhance program effectiveness. The VL completion rate improved to >80% within 6 months, and to a combined average of >90% over 12 months. This multifaceted clinic-centered intervention is replicable in both low-and high-volume ART clinics, which, if taken to scale, has important implications for achieving the UNAIDS third 90 target.

Our results also demonstrate the importance of improved VL monitoring in accurately reporting viral suppression to achieve the UNAIDS goals for epidemic control. Before the implementation of the project, the overall average virological suppression rate of the pilot sites was reported to be 91%, but was based on a VL completion rate of <50%. This result could easily be misinterpreted as a valid result for the third ‘90’ of the HIV cascade (90% of those receiving ART will achieve VL suppression). In addition to the negative effects at the individual and public health levels, without accurate reporting, local and global efforts at evaluating the implementation project are handicapped, and further, it may dissuade decisions to fund the third ‘90’ of the HIV care cascade.

Limitations of our multifaceted quality improvement project include delineating the effects of individual components, specifically, an inability to directly attribute the improvement of VL completion rates to the VLC. However, the outcomes demonstrate that the bundled approach for VL monitoring was potentially effective in South Africa’s clinic model in facilities with both low and high patient volumes. An additional limitation of our data is the lack of external validity. In this setting of three pilot sites that received outside support and attention, it can be expected that a clinical research setting may outperform a real world clinical setting. However, the key factor in the initial root cause analysis of the poor VL monitoring was the lack of ownership of the problems of missed VL monitoring and treatment failure. Our data demonstrate that the addition of a dedicated, experienced person to this role is a necessary aspect of the multifaceted quality improvement project.

This initiative suggests that substantial improvements in VL completion rates can be achieved quickly in programmatic settings. Implemented more widely, the intervention has the potential to substantially improve both individual ART outcomes and, through identification of viremic patients, have downstream impact on reduced transmission, possibly preventing disease progression, and reducing the emergence of ARV resistance in the community.

References


APPENDIX

Adherence worksheet/EAC worksheet
A combined tool for clinical follow-up visits and enhanced adherence counselling for clients identified as Risk of Treatment Failure Client for the VL priority clinic. This worksheet was adapted from the Médecins Sans Frontières (MSF) Risk of Treatment Failure programme. Both the adherence worksheet and the adherence initiation checklist were attached to all patients’ clinical chart on initiation. Reference 1 will link to an example of the original MSF tool.1 The project-modified tool is available on request from the authors and, in future, the KZN Department of Health.

Adherence Initiation Checklist
This tool was placed on all patient charts at initiation of ART. The tool was adapted from sections 4, 5 and 7 of the KZN Department of Health Clinical Chart (or HAST [HIV/AIDS, STIs and TB] clinical chart). The official DoH stationery is not currently available online. Please contact the KZN Department of Health or local district health offices for availability.

Reference

<table>
<thead>
<tr>
<th>Clinic file No.</th>
<th>Name</th>
<th>ID Number</th>
<th>Date of initiation</th>
<th>Regimen</th>
<th>Last VL</th>
<th>Last VL date</th>
<th>Next VL</th>
</tr>
</thead>
</table>

FIGURE A.1 Baseline chart audit register.

<table>
<thead>
<tr>
<th>Date</th>
<th>Name and ID</th>
<th>Barcodes/unique patient identifier</th>
<th>Results and dates</th>
<th>Comments</th>
</tr>
</thead>
</table>

FIGURE A.2 Viral load sample register.
Objectif : Dans le but de se rapprocher de l’atteinte de la troisième cible des objectifs 90-90-90 du Programme commun des Nations Unies sur le VIH/Sida (ONUSIDA), nous avons prospectivement mis en œuvre un programme « champion de la charge virale » (VLC) visant à améliorer le suivi de la charge virale (VL) et la reconnaissance de l’échec du traitement.

Schéma : Trois centres à eThekwini, Kwa-Zulu Natal (volume faible, moyen et élevé, soit 9184 patients au total), ont été chacun affectés au VLC. Nous employons une analyse descriptive (audit de dossiers) afin de comparer la période avant l’intervention à la période d’un an qui a suivi l’intervention. Le nombre de patients ayant eu un test VL 6 et 12 mois après l’intervention a été calculé comme une proportion de test VL exigibles à ces dates respectivement (taux d’achèvement du VL).

Résultats : Le taux d’achèvement du VL avant la mise en route dans trois sites a été de 68% (140/205 patients), 54% (84/155 patients) et 64% (323/504 patients), respectivement, et le taux d’achèvement à 6 mois après la mise en œuvre a augmenté à 83% (995/1194 patients), 90% (793/878 patients) et 99% (3101/3124 patients), respectivement ($P < 0,0001$ pour chaque site). Les taux d’achèvement du VL sont restés significativement plus élevés à 12 mois après la mise en œuvre, avec un taux cumulé moyen du VL >90% dans toutes les structures.

Conclusion : Nous avons montré la qualité d’une intervention d’amélioration réussie à multiples facettes, centrée sur le VLC au niveau des centres qui—à plus grande échelle—a des implications majeures pour l’atteinte de la troisième cible 90-90-90 de l’ONUSIDA.