

Targeting the third '90': Introducing the viral load champion

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Targeting the third '90': introducing the viral load champion

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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 eThekweni, 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.

Human immunodeficiency virus (HIV) viral load (VL) suppression prevents disease progression,¹ reduces transmission² and minimizes the acquisition of resistance to antiretrovirals (ARVs).³⁻⁵ Optimized implementation of VL monitoring, especially in disease-endemic, resource-limited settings, is key to achieving the Joint United Nations Programme on HIV and AIDS (UNAIDS) 90-90-90 targets, whereby by 2020, 90% of people living with HIV will know their status, 90% of those diagnosed will be receiving sustained antiretroviral treatment (ART), and 90% of those receiving ART will achieve VL suppression.⁶

Among the estimated 7 200 000 people living with HIV in South Africa in 2017, 61% were receiving ART and only 47% were virologically suppressed.⁷ Laboratory-based VL monitoring remains vastly underutilized in South Africa, despite being widely accessible.^{8,9} In the KwaZulu-Natal eThekweni health district, an audit of files of ART patients from 11 clinics in 2016 demonstrated that respectively only 42%, 32%

and 26% of adult patients underwent VL testing 6 months, 1 year and 2 years after ART initiation.¹⁰

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.¹¹ 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.¹²

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 eThekweni, 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,¹³ 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.

STUDY POPULATION, DESIGN AND METHODS

Program setting

In 2017, 621 411 persons living with HIV (PLHIV) were registered in eThekweni, of whom 390 784 (62%) were receiving ART at 124 clinical sites.¹⁴ 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

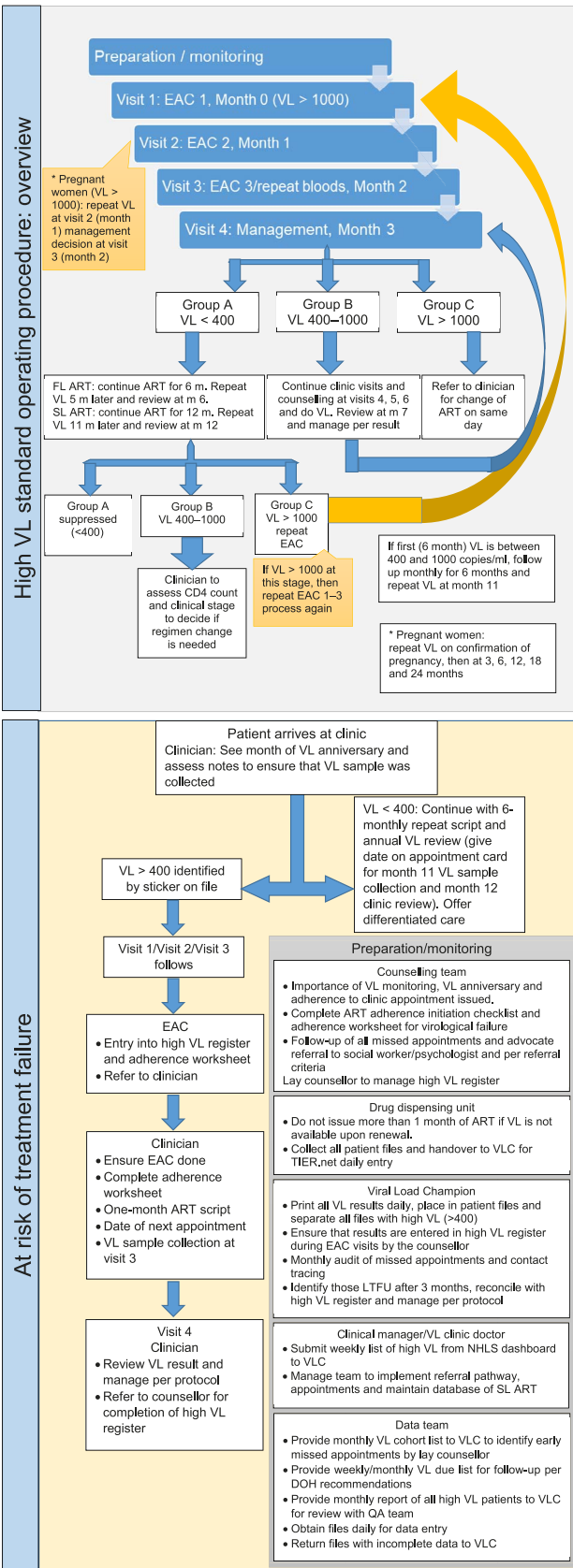
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blood samples, and compile weekly reports of elevated VL results that are accessible to clinicians via an online dashboard. However, manual entry is required for reconciliation, as the dashboard does not interface directly with the clinic electronic medical record, the Three-Tier Interlinked Electronic Register (TIER.net). National public health surveillance on VL completion rates is monitored through TIER.net, and there are significant inaccuracies resulting from incomplete data entry, inadequate monthly clinical documentation and delayed uploading due to staff shortages and equipment failure.

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, the clinical files of patients who

KEY WORDS

HIV; South Africa; AIDS; clinical champion

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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; LTFU = lost to follow-up; NHLS = National Health Laboratory Services; DOH = Department of Health; QA = quality assurance.

TABLE 1 VL management activities led by VLC

Pre-intervention chart audit

- Organize and supervise baseline audit of all clinical charts
- Reconciliation of NHLS database, clinic chart and TIER.net
- Creation of VL due register and high VL register
- Creation of a LTFU register
- Develop QI plan to address clinical and process impediments in VL testing

Implementation period

1. Maintain VL due list

- Identify patients with VL due through monthly laboratory and database reports
- Supervise designated team to contact patients with missed appointments
- Identify patients >3 months after missed appointment and add to LTFU list for contact tracing by community health worker

2. Maintain high VL register

- Update high VL register (VL > 1000 copies/ml) every month
- Supervise completion of appropriate follow-up for patients with high VL, including:
 1. EAC*
 2. Clinic chart VL entry with alerts to clinical provider for follow-up
 3. Patient receipt of follow-up visit dates and repeat VL testing
- Allocate a team member to maintain a call log register for patients with missed appointments in the high VL register

3. Multidisciplinary coordination

- Ensure all patients failing first-line ART are reviewed by EAC* team
- Refer patients requiring second-line ART or failing second-line ART to VL priority clinic
- Oversee ART prescription duration based on evidence of VL testing and result

4. Patient education and accountability

- Assign a VL anniversary month to patient chart and appointment card
- Provide appointment dates for VL blood draws
- Train and orient all staff to protocols and follow up on key indicators

Post-implementation period

- Monthly review audit of a sample of clinical files for quality assurance
- Oversee PDSA cycle audits with clinic team
- Record and update patient demographic details and intention to change service provider

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

†Month of ART initiation for annual VL testing.

VL = viral load; VLC = VL Champion; NHLS = National Health Laboratory Services; LTFU = lost to follow-up; QI = quality improvement; EAC = enhanced adherence counselling; ART = antiretroviral treatment; PDSA = plan-do-study-act.

were active and suppressed on ART, had a recent unsuppressed VL, were lost to follow-up (LTFU), or had no record of VL testing were identified and separated into different work streams (Figure 1). VL data were entered into clinical charts and updated in TIER.net. Lay counsellors contacted the patients and scheduled repeat appointments for those who were LTFU or required a repeat VL test. This cycle was repeated monthly, and was accompanied by close inspection of monthly data management performance, including assessment of the rate of blood sample rejection, delayed result access, inclusion of VL results in clinical charts, and clinical management of unsuppressed VL in accordance with South African national guidelines.¹⁵ In addition, qualitative feedback sessions, led by the VLC, were included during the quality improvement meetings to address work flow outcomes and the roles of the team members.

All patients received nurse-directed education at every clinic visit, with an emphasis on the importance of VL monitoring and maintaining optimal ART adherence, and a VL 'anniversary' was established for each patient. Patients were incentivized by the possibility of less frequent clinic visits (6-month instead of 3-month refills) if VL was suppressed at the time of consultation.

Monitoring outcomes

The purpose of the VL monitoring SOP was to enhance VL data management. All samples collected were recorded in a VL sample register (Appendix Figure A.2), which was used to ensure that VL

results were obtained from the laboratory, and that these results were recorded and/or placed in clinical charts daily. Rejected samples were flagged, and patients were contacted by lay counsellors for repeat blood draws.

Clinical managers and senior nurses were trained to generate weekly high VL reports from the laboratory intranet and identify patients who required tracking and follow-up clinical management. This list was merged with the high VL register (Appendix Figure A.3) and the list of missed appointments to be managed by the lay counsellors, who then contacted the patients. Patients with an undetectable VL were triaged for less frequent dispensing with repeat prescriptions.

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-

TABLE 2 Team member roles for improved VL monitoring

Team member roles

Program manager-clinical manager/medical manager/senior ART doctor

- Ensure that all key staff are appointed and inducted and provide leadership to facility team
- Maintain a second-line ART database
- Analyze the weekly NHLS dashboard for the lay counsellor to enter into the high VL register
- Identify facility VLC and QA team to meet for monthly QA meetings to monitor indicators
- Identify lead clinicians by PHC facility that refer patients to the site from the drainage area
- Audit clinical notes regularly to ensure that all clinicians are entering the VL result and follow-up details into the patient file longitudinal chart

VL sample log phlebotomist and data entry into log

- Use approved VL sample log register with barcodes for all VL blood draws daily
- Ensure that VL results are entered into the sample log: duty may be delegated to another nursing staff member who will work as the VL sample log data person
- VL sample log may be used as data source for the high VL register if needed

Data capturer

- Reconcile database from completed file audit with Tier so that final numbers of active patients and LTFU are determined
- Ensure that data entry is done daily
- Provide baseline audit of VLP and VLS for first- and second-line cohorts and thereafter monthly so that Tier becomes the final, complete and most reliable source of data
- Identify charts that do not have VL entries and report to VLC daily to follow up on correct entry
- Generate reports for LTFU and at risk of LTFU. Report on all at risk patients with a high VL
- Create a list of weekly patient appointments and VL due list

EAC counsellor

- Manage all patients referred to clinic per protocol
- Liaise with other nursing, paraclinical and pharmacy staff to facilitate patient management
- Update high VL register daily
- Education on abnormal result and common causes of treatment failure
- Assess and address barriers to adherence, review adherence plan and set new treatment goals, encourage adherence to influence next result
- Keep the high VL register for each month separately and continue to follow up these pts for three months. At the end of that time, put them on a LTFU list.
- Enter all calls onto a call log daily and hand over to VLC weekly
- All pts who miss a VL due (from the VL due register) for that month need to be called

Drug dispensing team

- Maintain prospective second-line ART database
- Gatekeeping to ensure that no repeat script is issued till a VL result is entered onto the script
- Work with the ART team to access and manage access to third-line ART

Quality assurance manager and IPC team with M&E manager

- Lead the QIP for VL and DR at the facility
- Work with QA manager from the district office and quality staff from district partners
- Document and report progress on an ongoing basis

ART = antiretroviral treatment; NHLS = National Health Laboratory Services; VLC = viral load champion; QA = quality assurance; PHC = public health care; LTFU = lost to follow-up; VLP = VL performed; VLS = VL suppressed; EAC = enhanced adherence counselling; IPC = infection prevention and control; M&E = monitoring and evaluation; QIP = quality improvement project.

pected date, was conducted. Patients with VL test performed outside the 60-day window were censored from the VL performed (VLP) denominator used for the VL suppression calculation, as <5% of patients had VL testing outside this window. The number of patients with VL testing performed at 6 and 12 months was calculated as a proportion of VL tests due at those time points. Statistical testing for association was assessed using the Cochran-Armitage test for trend.

The study protocol was approved by the KwaZulu-Natal Provincial Health Research Committee and the Biomedical Research Ethics Committee of the University of KwaZulu-Natal (BFC 377/16).

RESULTS

Outcomes following the VLC intervention were assessed by cohort analysis at 6 and 12 months (Figure 2). The pre-implemen-

tion 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.

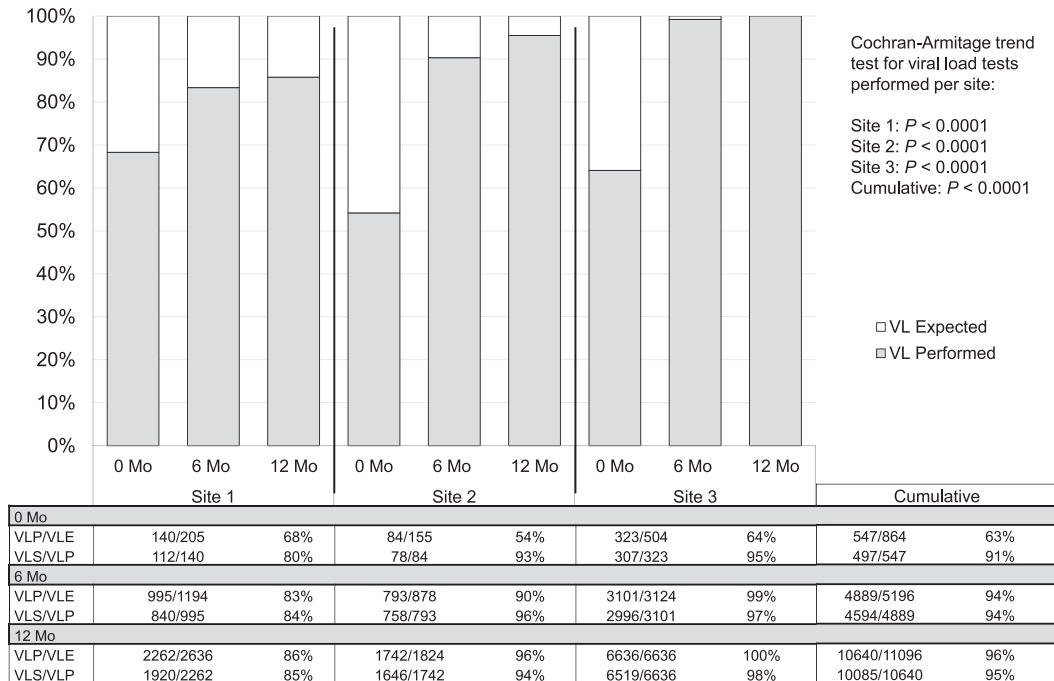


FIGURE 2 VL completion rates at 0, 6 and 12 months. Individual pilot site and cumulative data for the number of total VL performed (VLP), VL expected (VLE), and VL suppressed (VLS) at the time of project implementation, at 6 months and at 12 months. The month 0 denominator represents a snapshot of patients for whom VL was 'due' at month 0. VL = viral load; VLP/VLE = VL completion rate. VLS/VLP = VL suppression rate; Mo = month.

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.¹⁶ Cascades of care have become an established mechanism to illustrate the effectiveness of coverage of care in HIV programs.⁶ 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 transmission¹⁷ and an increase in acquired immune-deficiency syndrome (AIDS) free survival.¹⁸

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 $\geq 80\%$ 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.

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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.

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Clinic file No	Name	ID Number	Date of initiation	Regimen	Last VL	Last VL date	Next VL

FIGURE A.1 Baseline chart audit register.

Date	Name and ID	Barcodes/unique patient identifier	Results and dates	Comments

FIGURE A.2 Viral load sample register.

Clinic File No.	Patient name	ID No	Age	Contact No 1	Contact No 2	Contact No 3	HIV VL result	HIV VL date	Action	Action date
									Patient called	
									Patient booked	
									Patient came in	
									Patient did not come in	

Date follow-up visit EAC 1	Date follow-up visit EAC 2	Repeat VL	Date repeat VL	Date check VL result and manage	Date continue first-line ART	Date COR

FIGURE A.3 High VL 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 eThekweni, 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.

Objetivo: Con el propósito de avanzar hacia el cumplimiento del tercer elemento del objetivo «90-90-90» del Programa Conjunto de las Naciones Unidas sobre el VIH/SIDA (ONUSIDA), se introdujo un programa con un promotor del seguimiento de la viremia, encaminado a reforzar la vigilancia de la concentración vírica y el reconocimiento del fracaso terapéutico.

Método: En cada uno de tres consultorios de eThekweni, en Kwa-Zulu Natal (con una carga asistencial baja, intermedia y alta, que cubrían un total de 9184 pacientes) se nombró un promotor del seguimiento de la viremia. Mediante un análisis descriptivo, se comparó el período preintervención con un período posintervención de un año. El número de pacientes en quienes se practicó la viremia a los 6 y 12 meses después de la intervención se calculó como la proporción de las viremias previstas en estos puntos temporales (tasa de completación de la viremia).

Resultados: La tasa de completación de la viremia en los tres centros fue como sigue: 68% (140/205 pacientes), 54% (84/155 pacientes) y 64% (323/504 pacientes) y a los 6 meses posintervención, esta tasa aumentó respectivamente a 83% (995/1194 pacientes), 90% (793/878 pacientes) y 99% (3101/3124 pacientes) ($P < 0,0001$ para cada centro). Las tasas de completación de la viremia permanecieron significativamente más altas a los 12 meses posintervención con una tasa acumulada superior al 90% en todos los establecimientos.

Conclusión: Se puso en evidencia una intervención polifacética eficaz de mejoramiento de la calidad centrada en un promotor clínico del seguimiento de la viremia en cada consultorio, cuya aplicación en una escala más amplia, tendría importantes repercusiones en favor del cumplimiento del tercer elemento del objetivo «90-90-90» del ONUSIDA.