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HIV Viral Load Assessment in the South African Public Health Landscape: Navigating Changing ART Guidelines and Technological Progression, 2013-2022

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Abstract

HIV Viral Load (VL) assessment serves as a pivotal tool in HIV clinical management, offering insights into adherence and antiretroviral effectiveness. Over time, both national and global antiretroviral treatment guidelines have evolved to recommend regular VL testing. South Africa (SA) has advocated for routine VL testing since 2004. The centralized HIV VL program, overseen by the National Health Laboratory Service (NHLS), has experienced substantial expansion. An analysis of de-identified retrospective VL data spanning from 2013 to 2022 was conducted to assess program performance. The volume of tests performed exhibited remarkable growth, surging from 1,961,720 tests in 2013 to an impressive 45,334,864 tests in 2022. Median total in-laboratory Turn Around Times (TAT) fluctuated, ranging from 94 hours in 2015 to 51 hours in 2022. The introduction of two novel assays contributed to enhanced median TATs across all laboratories. The occurrence of VL levels exceeding 1000 copies/mL exhibited a steady decline. While experiencing initial growth, instances of VL counts below 50 copies/mL plateaued at around 70% starting in 2019, gradually decreasing to 68% by 2022. Some discrepancies among assays were noted. In summation, South Africa's VL program has achieved significant success. Remarkably, the program stands as the world's largest of its kind, offering valuable insights for future public health initiatives reliant on laboratory support for patient outcomes and program performance assessment.

Keywords: HIV viral load • National program • Advances technology

Introduction

South Africa (SA) stands at the forefront of the global HIV pandemic, housing a staggering 8.45 million individuals living with HIV as of 2022. Consequently, the SA National Department of Health (NDoH) administers the world's largest antiretroviral initiative, serving an estimated 5.5 million individuals under treatment. Integral to optimal patient care, laboratory tests have become increasingly crucial within antiretroviral treatment (ART) programs. Central to this endeavor is the HIV Viral Load (VL), an indispensable tool in managing PLWHIV's clinical outcomes. Dating back to 1996, VL emerged as a surrogate gauge of ART response, with sustained positive outcomes correlating to improved morbidity and mortality rates [1]. Moreover, VL thresholds differentiate virologically suppressed (VS) patients from those experiencing ART failure (VF); guidelines suggest more frequent testing in cases of non-suppression and failure, with variations according to recommendations.

The landscape of ARV guidelines directly shapes laboratory testing practices. World Health Organization (WHO) guidelines are either adopted or adapted for use in resource-constrained settings. These clinical directives guide testing algorithms, subsequently influencing test volume and assay selection. WHO's progressive recommendations led to broader ART eligibility criteria, evolving from a CD4 count <200 cells/μL and/or WHO clinical stage 4 in 2003, to <350 cells/μL and <500 cells/μL with WHO stage 3/4 in 2010 and 2013, respectively, driven by accumulating evidence for early treatment and improved ART safety [2]. By 2016, all PLWHIV became eligible for treatment, regardless of CD4 count, with VL monitoring advised at six-to-twelve-month intervals. The WHO VF threshold, established in 2013 at a confirmed VL exceeding 1000 copies/mL on two occasions, remained unchanged, having been reduced from 5000 copies/mL in 2010. The introduction of the VS threshold of ≤50 copies/mL occurred in 2021.

Remarkably, South Africa's ARV Guidelines, unique in their routine recommendation of VL testing every six months, were established as early as 2004. This initial version set VF criteria at 5000 copies/mL. Subsequent updates triggered implications for the VL testing program. In 2010, pregnant women and individuals co-infected with tuberculosis (TB), presenting with CD4 ≤ 350 cells/μL, gained ARV eligibility; however, CD4 ≤ 200 cells/μL criteria remained for others. VL failure diagnosis now demanded two consecutive VL readings ≥1000 copies/mL, three months apart. The universal CD4 ≤ 350 cells/μL criterion came into effect in 2013, subsequently increased to ≤500 cells/μL in 2014. 2016 marked the introduction of universal treatment, while 2019 witnessed the inclusion of suppression criteria (<50 copies/mL), with VL >50 copies/mL necessitating a test three months after enhanced adherence counseling [3].

Description

The advent of the Joint United Nations Programme on HIV/AIDS (UNAIDS) '90-90-90' targets, focusing on 90% awareness of HIV status, 90% treatment coverage, and 90% viral suppression, alongside the 'Undetectable=Untransmittable' campaign, emphasized the need to scale up testing services and provide precise VL quantification at clinically relevant thresholds [4]. Local, national, and global monitoring of virological suppression rates serves as a gauge for advancing toward the third UNAIDS target. The quality of reported VL data relies on laboratory and assay performance.

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Advancements in VL assays have transcended the initial less-sensitive, labor-intensive, and technologically complex commercial HIV-1 quantitative assays approved by the FDA. Clinical evidence prompted assay improvements, swiftly reaching a lower detection limit of <20 copies/mL. Subsequent enhancements focused on specificity and result precision. Current platforms offer increased sophistication, incorporating automation with primary tube sampling, heightened throughput, reduced test completion time, lower sample input volumes, alternative sample types, and software upgrades for integration with laboratory information systems (LIS) [5].

Public sector laboratory services for over 80% of the SA population are provided by the National Health Laboratory Service (NHLS). The NHLS's National Priority Programme (NPP) oversees HIV VL program operations, aligning laboratory and clinical activities with health priorities set by the NDoH. VL testing, conducted in centrally located laboratories using medium- to high-throughput molecular assays, relies on plasma samples. Assay selection stems from a national supply chain management tender process, tailored to meet program and laboratory needs. Since its inception, the VL program has undergone three tender awards. The approximately six million plasma VL tests performed in 2022 signify substantial program growth from the initial 34,000 tests conducted in 2004 [6].

This study's objectives encompass illustrating the molecular VL testing expansion, highlighting the influence of shifting ARV guidelines and assay changes on virological failure, suppression, and turnaround-time performance. The SA HIV VL program serves as an apt backdrop for this analysis.

Conclusion

The centralized model for HIV viral load testing, embraced in South Africa, has yielded commendable outcomes. Notable achievements encompass the early establishment of routine VL testing, swift expansion of testing capabilities, enhanced turnaround times, and more streamlined tender implementation strategies. These achievements stem from the adoption of advanced automated, high-throughput VL assays, leveraging insights from prior experiences, and vigilant oversight of laboratory operations. Nevertheless, persistent challenges entail refining turnaround times and heightening the identification of low-level viremia instances, while contending with assay performance variability near the lower detection thresholds. To enhance turnaround times, targeted interventions should be explored. Deeper investigations are necessary to comprehend the factors behind the decline in samples with VL counts below 50 copies/mL and the consequential impact of assay performance on this trend.

Acknowledgment

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Conflict of Interest

None.

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