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Commentary

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Factors affecting viral load testing turnaround time in Malawi

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Abstract

Viral Load Testing (VLT) remains key in monitoring of HIV treatment. Despite being the gold standard test in disease monitoring, the tests face lengthy turnaround times in Malawi. With more people on ART, the demand for VLT has exponentially increased. Malawi faces a plethora of factors that enhance or hinder viral load testing. Some of the enlisted determinants and challenges include lack of molecular testing facilities, underutilization of GeneXpert machines for use in viral load testing, inconsistent specimen transport networks, procurement and supply chain management, and instrument downtime and functionality. These challenges have opened avenues for introduction of modifications to minimize turnaround times as would be desirable and eventually to reduce turnaround times and improve timely clinical management. This paper examines the status quo of viral loading testing in Malawi, highlights key areas affected by lengthy turnaround time in HIV management and presents recommendations on improving VLT turnaround time.

Commentary

Globally, over 37.9 million people are living with Human Immuno-deficiency Virus (HIV), which more than half (20.6 million) are in Eastern and Southern Africa. Approximately 24.5 million of people living with HIV (PLHIV) have access to antiretroviral therapy (ART) [1]. As a way of showing solidarity in supporting country and regional efforts to end the epidemic, the United Nations Program of HIV/AIDS (UNAIDS) launched the 90-90-90 treatment strategy in 2014 with the aim of ensuring that 90% of PLHIV know their status; 90% of all people diagnosed with HIV are on ART; 90% of all people receiving ART achieve viral suppression [2]. To achieve this goal set by UNAIDS, most low- and middle-income countries (LMCs) including Malawi massively scaled up the number of individuals receiving ART. This exponential administering of ART to HIV patients requires constant monitoring of treatment. The World Health Organization (WHO) recognises VLT as the gold standard in HIV treatment monitoring. Viral Load Testing (VLT) has been used by the developed countries as a better way of treatment monitoring and a guide to the switching of second line treatment [3]. Viral Load Testing (VLT) has also provided a good platform to monitor treatment compliance and diagnosing HIV infection in children aged less than 18 months. The expensive equipment, dedicated laboratory space and need for trained laboratory technicians however limits the accessibility to VLT in most HIV patients from LMCs [3].

Status of viral load testing in Malawi: Malawi, a country in sub-Saharan Africa (SSA), has close to 1.1 million (10.6% prevalence) of PLHIV of which 962,782 are in need of ART and over 805,232 are on ART. The demand for VL testing for the country cannot be over emphasized. Unfortunately for Malawi, setting up a molecular laboratory is a challenge due to limited resources and extreme poverty levels. With 28 districts, Malawi, has 10 districts only spread within the three regions having molecular laboratories. Almost all (99.8 percent) of VL testing is done at these 10 molecular laboratories. Currently, the average Turn Around Time (TAT) for VL testing from specimen collection to result dispatch by the laboratories is at 25 days. Districts without molecular lab testing facilities have longer pre-test turnaround time than those with testing facilities [4]. Viral Load Testing (VLT) in Malawi has largely been centralized with the use of dry blood spots (DBS) required in Polymerase Chain Reaction (PCR). The challenge with centralized testing with DBS has, however, been lengthy TAT to get the results [5]. Point of care (POC) VL testing has been proven ideal in reducing the TAT in remote, hard to reach, resource limited clinics. In 2013, the Medicins Sans Frontiers (MSF) through the Ministry of Health rolled out the first POC VL testing. The sample amplification based assay (SAMBA) was used in Chiradzulu district as a decentralized HIV program which was later evaluated [6]. Point of Care (POC) VL testing has demonstrated a good impact for the viremic patients [7]. The POC VL testing proved to lessen the TAT needed from

sample collection to processing. Even though done at a small scale, the main issue with the POC VL testing has been quality. Another strategic decision by the Ministry of Health (MoH) to scale up the capacity within the 10 molecular laboratories, has been implementing VL testing using GeneXpert machine. GeneXpert machines were primarily used for Tuberculosis (TB) and now are integrating TB, Early Infant Diagnosis (EID) and VL. This paper will explore some of the factors affecting VL testing that contributes to longer TAT.

Factors affecting viral load testing

Lack of molecular testing facilities: only 7 districts of the 28 in Malawi, have HIV molecular testing laboratories for doing VLT. This stipulates that the remaining 21 districts send specimens to the 7 districts, hence increasing the TAT for the associated 21 districts. Logical factors in getting samples to the testing centers, limited capacity in the testing sites and bulky sample load contributes to the TAT of all the VLT samples [4].

Under-utilization of GeneXpert in viral load test platform: Malawi incorporated the use of GeneXpert for Tuberculosis (TB) screening of patients in its bid to scale up efficiency of TB diagnosis particularly amidst the pre-existing burden of HIV. A national scale-up plan involved to deployment of GeneXpert machines to various government and private hospitals including health centres. The same machines can be programed to be used for VLT, leveraging the already existing machines for use in VLT. The availability of cartilages for use in VLT platform on these machines is however a challenge, with many machines not being used routinely for VLT despite their availability in many health centers and hospitals.

Inconsistent specimen transport networks: transportation of specimens from the collection sites to the testing facilities remains a challenge in Malawi. A number of districts in Malawi do not have dedicated resources to sample transports and referrals, samples remain in storage boxes for quite some time before they are transported to the testing facilities for processing. The existing transportation systems are mostly not consistent with many facilities still experiencing interrupted specimen transportation services at the hands of hired transporters.

Procurement and supply chain management: laboratory consumables are controlled by the pharmacy department both at district and national level. Lack of diagnostic network optimisation in the supply chain management tends to frustrate reagents and consumables supply to the centres with instruments that are not donor funded or disease specific hence increasing the TAT. This approach has greatly contributed to inconsistency in supply of reagents and consumables due to delays in procurement, limited funding and frail laboratory workforce in the system [8].

Instrument downtime and functionality: adequate maintenance, service contracts and preventive maintenance coverage is one of the main challenges contributing to longer instruments down times. Lack of dedicated resources and monitoring and evaluations on vendors with service contracts to closely monitor their performance in regards to instruments performances on tier service contracts has increased lack of adherence to monitor performance difficulty hence increased turnaround time [8].

Recommendations: rolling out wider coverage of point of Care Viral-Load-Testing (POCV) is ideal. Point of care viral-load-testing takes short time to run and is therefore a promising platform to achieve desirable VL TAT. The complexity of centralized testing platforms lengthens VL TAT; increase efficiencies in specimen collection, transportation and handling have been linked to reducing TAT [8]. Familiarity with the workflow reduces TAT [8]. Efficiencies in specimen collection will ensure that there is no unnecessary delay in obtaining specimens, rejections and recollections leading to reduced TAT; conduct data driven investigations in laboratory quality management to ensure Malawi reaches 90,90,90; making use of the

new technological advancements like drones to ferry samples from hard-to-reach areas to testing centers, has shown much improvement in transport logistics and costs than motorcycles and vehicles [8]; improving quality improvement strategies of facility by appointing a designated staff to coordinate viral load activities to ensure adherence to standard operating procedures and efficient documentation would reduce inefficiencies and minimize data loss. It is important to increase provider training to improve confidence and knowledge about VL monitoring as well as delivering better patient care; provision of patient based educational materials improve the demand for viral load tests and visits; the President's Emergency Plan For AIDS Relief (PEPFAR) guidance recommends prioritizing viral load monitoring particularly in the COVID-19 pandemic for Early Infant Diagnosis (EID) for children, pregnant and breastfeeding women, adults with viral non-suppression. It is suggested that priority in viral load monitoring should be for those with treatment failure, initial VL assessment before initiation of ART. This has been one of the ways of decongesting ART clinics [9].

Conclusion

Malawi has over the years improved provision of VLT. However, due to centralized mode of testing has contributed to poor TAT and other technical logistics. Decentralized VLT amalgamated with POCV covers a wide coverage of testing. Efforts to roll out wider coverage and improved management of quality systems would improve TAT and save the many lives of PLHIV.

Competing interests

The authors declare no competing interests.

Authors' contributions

All the authors have read and agreed to the final manuscript.

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