EpiC Spotlight on Scale-Up of Viral Load Monitoring

Why is viral load (VL) monitoring important to efforts to achieve and maintain epidemic control?

For people living with HIV, achieving an undetectable VL is essential to eliminate continued HIV transmission. Once on antiretroviral therapy (ART), knowing one's VL result should be as universal as knowing one's HIV status. An undetectable VL indicates effective treatment, adherence to that treatment, and retention in care. Moreover, a suppressed VL is a pre-condition to enrolling patients in some differentiated models of care, such as multimonth dispensing, which reduce the burden on health care facilities and allow patients to access their treatment in convenient and client-centered ways. As the number of patients on treatment increases, the capacity to monitor treatment outcomes through VL suppression must keep pace.

WHAT ARE THE CHALLENGES?

Many challenges exist to completing the steps in the VL continuum of care (see Figure 1). Currently, the proportion of patients accessing VL testing (VL coverage) is limited in a number of countries. In addition, VL turnaround times (TATs) are extended beyond the average 14-day target TAT in most developing counties. With an interrupted value chain and extended TATs to receive results, both providers and patients may undervalue the need for consistently checking VLs. This, in turn, leads to inappropriate treatment and patients with unsuppressed VLs that may fall out of care and remain infectious.

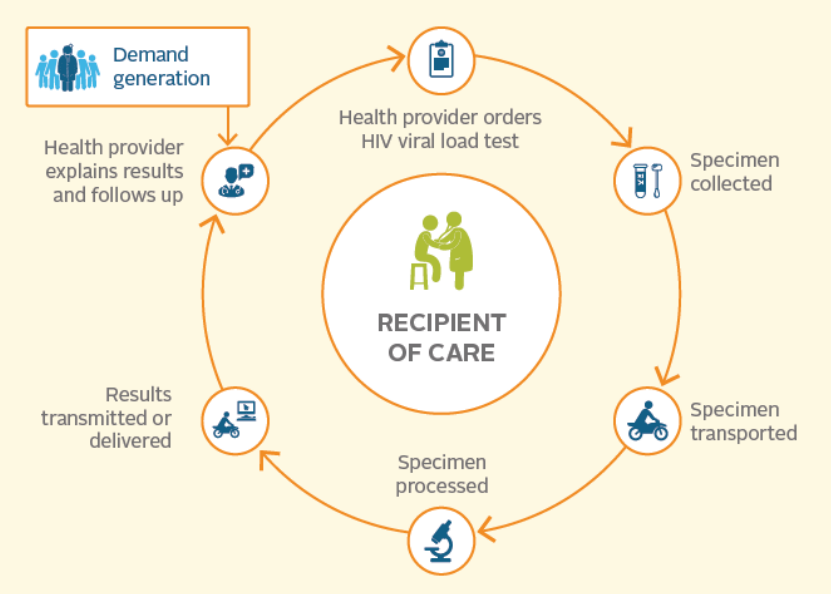


Figure 1. Viral load continuum of care

EpiC is a global cooperative agreement dedicated to achieving and maintaining HIV epidemic control. It is led by FHI 360 with core partners Right to Care, Palladium International, Population Services International (PSI), and Gobee Group. For more information about EpiC, including the areas in which we offer technical assistance, click here.

Several challenges are associated with the HIV VL value chain spanning the pre-analytic, analytic, and post-analytic phases. Pre-analytic challenges at the facility, including commodity shortages and limited ancillary equipment, can degrade sample integrity. Limited reliable and efficient sample transportation can also affect sample integrity, requiring facilities to align sample collection with transportation schedules and available human resources into “blood draw” days resulting in reduced VL coverage. Sample collection needs to be available at the patients’ convenience with a result TAT within the stipulated time to ensure results are available for action and the next clinic visit. Other pre-analytic phase challenges include limited demand for VL testing among both patients and providers, and lack of widespread implementation of differentiated models for VL sample collections especially at the community level.

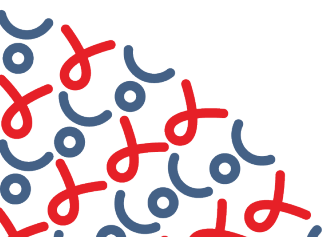
TAT is affected by challenges during the analytic phase including inadequate analyzer capacity, shortage of trained lab staff in the area of commodity management, shortage of reagents and commodities, prolonged analyzer downtime, and cumbersome technical processes. Another contributing factor is limited advocacy at the national level to include VL supplies in national quantification efforts. A quality management process must be in place for a laboratory to confidently process samples and produce good quality results. Lack of laboratory information systems (LISs) prolongs sample processing time and quality of intra-lab process indicators. Any of these challenges can result in backlogs and extended TATs if bottlenecks in the value chain are not identified and mitigated.

Post-analytic phase challenges are concentrated on efficient communication and documentation of VL results back to facilities. Integrated national LIS and ART EMR systems are rare, requiring manual delivery and processing of VL results, documentation in the clinical record, and action on unsuppressed results. Additionally, testing laboratories need to have an equitable distribution of processing capacity and be linked with an appropriate number of clinics in their network to optimize sample transportation and the clinical/lab interface (CLI). Point-of-care testing should be considered for last-mile access to patients where a reliable transportation network is unavailable.

EpiC brings proven and innovative solutions to common VL monitoring challenges

The Meeting Targets and Maintaining Epidemic Control (EpiC) consortium brings extensive experience improving the VL continuum of care, including patient and provider demand, VL transportation networks and sample tracking, optimized clinical and laboratory operations, and scale-up of new innovations that improve CLIs and reduce TATs. Additionally, the consortium provides expertise in working with private pharmacies, community ART groups, and peripheral ART pick-up points to ensure patients receive the correct treatment at their convenience and remain in care with a suppressed VL.

VL Challenges	EpiC Solutions and Technical Assistance Offerings
Insufficient demand for VL testing and limited patient and provider literacy on VL benefits	EpiC can drive patient and provider literacy through targeted promotions for the undetectable = untransmittable (U=U) campaign, focusing on subpopulations with lower VL testing coverage and increased risk of treatment failure, such as young people and men. Job aids and provider mentorship can be introduced in the clinic to improve provider-initiated VL testing and patient sample quality, as well as file management strategies to flag files of patients due for VL testing. We can also provide specialized technical assistance (TA) to existing direct service delivery partners to improve clinical workflows and increase VL demand creation to ensure providers are ordering VL tests when due and at appropriate intervals.
Challenges with plasma sample collection, storage, and transport, especially at the community level	EpiC can assist countries with evaluating the need to include alternative VL sampling techniques such as dried blood spots and plasma separation cards to allow samples to stay longer at room temperature without compromising the integrity. These techniques can improve VL coverage and sample stability, storage and transport, especially in more rural and harder-to-reach locations.
Limited capacity to utilize VL testing results to quickly identify treatment failure and the need to switch ART regimens	EpiC provides TA to programs to ensure patients with suppressed VLs are offered enrollment in available differentiated models of care, such as multimonth dispensing and fast-track pharmacy collection. Patients with unsuppressed VLs are enrolled in enhanced adherence counselling or switched to a new ART regimen as needed.
Lengthy TAT for VL testing results	EpiC is prepared to scale new VL technologies. This includes mHealth solutions for VL sample tracking from order to results delivery to help managers easily identify the bottlenecks in the value chain and respond in real time. Additionally, support to national laboratories to use data from LIS to obtain relevant VL cascade information and training of lab managers on data utilization will help address and improve their program VL cascade. The same innovations can prompt clinical staff to take action on abnormal results quickly as notifications are sent from the laboratory for all unsuppressed patients and rejected specimens. Successful implementation of this approach by EpiC consortium members has led to decreases in TAT from more than a month (in some cases, three months) to less than 10 days. In fact, electronic receipt of the result at the facility with clinical decision support to identify high VL results allows facility staff to immediately take action on a high VL result and bring a patient back to care for enhanced adherence counselling or treatment optimization.



Lack of cost-efficient sample transportation plans	EpiC can develop optimized cost-efficient, country-specific sample transportation plans. These plans utilize GIS mapping and economic modeling to maximize the capacity of testing laboratories, decreasing travel time and distance by eliminating district borders, and have been shown to reduce the cost of per sample testing by more than 50%. These models can also be used to place Point of Care GeneXpert machines in appropriate facilities to increase coverage to 100% of the treatment cohort.
Issues with the quality of VL testing, especially in the analytical phase	Intra-laboratory optimization TA is available from EpiC consortium partners to maximize efficiency and instill continuous quality improvement (CQI) in VL testing laboratories. EpiC partners use standardized rapid lab assessment tools to identify areas for improvement in sample handling, machine capacity, and human resource optimization, and create standard operating procedures (SOPs) that help improve laboratory throughput and minimize backlogs. EpiC also specializes in re-engineering workflows leading to leaner processes and increased operational efficiency. By improving quality management systems in the laboratories with approved methods such as SLIMTA and standardized scorecards, the TA teams facilitate laboratories to eventually gain accreditation by approved bodies to ISO 15189 standards.
Poor management of supply chain processes, sometimes resulting in stock-outs and waste	EpiC can build the capacity of laboratories in efficient management of supply chain processes to ensure adequate reagents and commodity supply and avoid wastage due to expiration. Supply chain management principles, such as first in first out (FIFO), are provided through standardized training. TA partners also assist countries to negotiate fair prices for reagents and commodities based on bulk purchase and economies of scale. EpiC can support training of laboratory staff on commodity management (including quantification and forecasting) and/or advocacy at a higher level to include VL supplies/reagents in national quantification efforts. We can also ensure laboratory testing is used for other priority programs including MDR-TB and prevention of mother-to-child transmission (PMTCT). GeneXpert machines can be optimized to ensure efficient multidrug-resistant tuberculosis (MDR-TB) diagnosis and EID VL processing. This integrated testing approach enables appropriate TB treatment initiation, improving patient treatment outcomes.

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