MEETING TARGETS AND MAINTAINING EPIDEMIC CONTROL (EPIC) PROJECT

COOPERATIVE AGREEMENT NO. 7200AA19CA00002

White paper on private sector engagement to improve outcomes across the HIV viral load value chain

OPPORTUNITIES AND EVIDENCE FOR SUSTAINABILITY AND EQUITY

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Executive Summary

HIV viral load (VL) testing is the most reliable indicator of treatment success for people living with HIV (PLHIV). However, the anticipated benefits of VL monitoring depend on regular testing and how quickly providers use the VL test results for clinical decision-making. Increasing access to VL testing and using its results in a timely manner for clinical interventions can improve both individual and population-level clinical outcomes and can be cost-effective. Despite this, many countries face low VL testing coverage due to systemic bottlenecks across the value chain. Public health facilities often rely on public systems, including laboratories, to provide VL testing, and they often experience persistent bottlenecks that further exacerbate barriers to access for many PLHIV. One potential solution is strengthening national VL testing capacity through transformative partnerships with the private sector. Partnerships with private laboratories have contributed to increased VL coverage and reduced turnaround time for VL test results. Some have also improved access to VL testing services for those who may not otherwise have been able to obtain these services. Partnerships offer a viable opportunity to leverage private sector expertise to augment public diagnostic systems sustainably. However, it is critical to evaluate the design of the partnerships and models to ensure efficiency and improved client clinical outcomes, as these have important implications for the cost-effectiveness and sustainability of such solutions. With funding from PEPFAR and USAID, the Meeting Targets and Maintaining Epidemic Control (EpiC) project engaged private sector laboratories to improve VL coverage. Experiences from and costing analyses conducted on private sector partnerships established in Nigeria, Botswana, and Indonesia shed light on strategies that could be employed and on areas of the agreements with the private sector and the model design that could be adjusted to improve the cost-effectiveness of these partnerships. The solutions to address VL testing coverage will vary from country to country, and no one solution may sufficiently address all gaps. Nonetheless, the contribution of the private sector in health care services in low-and-middle-income (LMIC) countries is growing and evolving, and the solutions these opportunities offer should be considered as potentially cost-effective and sustainable strategies to close the gaps in VL testing coverage among people living with HIV (PLHIV) and progress towards epidemic control.

Background

HIV viral load (VL) testing for PLHIV who are receiving antiretroviral therapy (ART) is the best predictor of individual treatment success and a measure of population-level progress toward HIV epidemic control. The third goal of the UNAIDS' 95-95-95 goals calls for 95% of people on HIV treatment to be virally suppressed (the proportion of PLHIV who have received an HIV VL test result that is suppressed), a measure that cannot be monitored without high levels of HIV VL testing coverage (the proportion of PLHIV on treatment eligible for VL testing who have received their VL testing result). The anticipated benefits of VL monitoring depend on regular testing per the World Health Organization (WHO) standards and the timeliness with which providers use the VL test results for clinical decision-making. For example, obtaining VL test results quickly can allow for timely detection of first-line ARV regimen failure or treatment non-adherence, which would allow clinicians to make prompt decisions, including providing enhanced ART adherence counseling or switching to a second-line regimen without delay to prevent amplification of resistance and treatment failure.

Therefore, increasing coverage of VL testing with rapid turnaround time (TAT) of results (time taken from VL sample collection to clients receiving their test results) can potentially improve PLHIV clinical outcomes. Studies have found that increasing coverage of VL testing among PLHIV on treatment reduced HIV infections by 4.5% and HIV-related deaths by 3.9%.[1] Other studies have also found that faster turnaround time of results improved viral suppression (83% vs. 93%) and treatment continuity (85% vs. 92%) facilitated by same-day adherence counseling for those unsuppressed and faster identification of viral failure and a subsequent switch to second-line ART compared to standard centralized testing.[2] Faster turnaround time has also been found to increase clinically indicated ART regimen switches (86% vs. 67%) and to reduce the time to switching (6.8 months vs. 9.7 months).[3]

Same-day testing has also allowed rapid referral of suppressed clients into differentiated care through community-based ART delivery programs.[2] A suppressed VL test result is frequently a requirement for enrollment into many differentiated service delivery (DSD) models for PLHIV who are established on treatment. Enrollment into DSD models can help to improve the convenience of accessing services and, therefore, support treatment continuation for PLHIV. A study conducted in Mozambique found that DSD models improved client clinical outcomes

[1] Sharma M, Mudimu E, Simeon K, Bershteyn A, Dorward J, Violette LR, et al. Cost-effectiveness of point-of-care testing with task-shifting for HIV care in South Africa: a modelling study. Lancet HIV. 2021;8(4):e216-e224. doi:10.1016/S2352-3018(20)30279-4

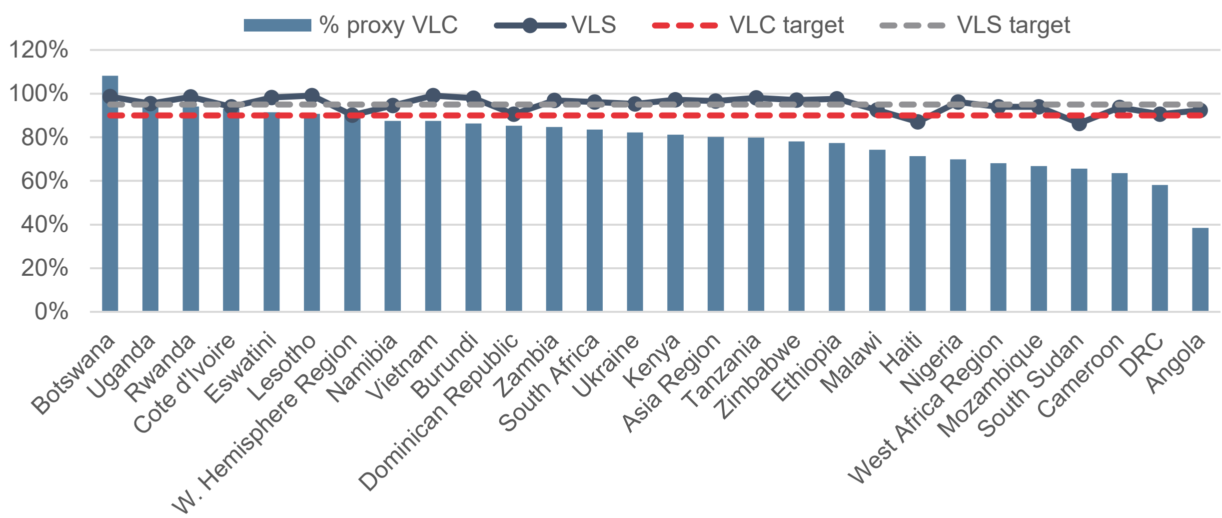
[2] Drain PK, Dorward J, Violette LR, Quame-Amaglo J, Thomas KK, Samsunder N, et al. Point-of-care HIV viral load testing combined with task shifting to improve treatment outcomes (STREAM): findings from an open-label, non-inferiority, randomised controlled trial. Lancet HIV. 2020;7(4):e229-e237. doi:10.1016/S2352-3018(19)30402-3

[3] Nicholas S, Poulet E, Wolters L, Wapling J, Rakesh A, Amoros I, et al. Point-of-care viral load monitoring: outcomes from a decentralized HIV programme in Malawi. J Int AIDS Soc. 2019;22(8):e25387. doi:10.1002/jia2.25387

and were more cost-effective than conventional care from the health system and the societal perspectives.[4]

However, low coverage of HIV VL testing is an enduring challenge across many countries due to various bottlenecks across the entire value chain. As of December 2023, while most PEPFAR countries are reaching the 95% target for VL suppression among those tested for VL, most countries do not meet the 90% target for HIV VL coverage (Figure 1).

Figure 1. Viral Load Coverage (VLC) and Viral Load Suppression (VLS) in PEPFAR-Supported Countries (January – March 2024)



Data source: PEPFAR Panorama, Fiscal Year 2024 Quarter One VL Global Dashboard

Many public health facilities currently rely on public systems, including laboratories, to provide VL testing, but systemic bottlenecks, such as weak supply chain systems leading to frequent reagent stockout, unreliable specimen referral and transportation, and equipment breakdown, are common. Additionally, many PLHIV live far from health facilities that conduct specimen collection or from central laboratories, adding to the layers of access barriers.

As a result of these challenges, PLHIV miss having their blood samples taken or when they do, results are received weeks to months after their blood sample collection. Especially as the number of PLHIV on treatment continues to grow, public laboratory systems can be further overwhelmed.[5]

[4] Moiana Uetela DA, Zimmermann M, Chicumbe S, Gudo ES, Barnabas R, Uetela OA, et al. Cost-Effectiveness and Budget Impact Analysis of the Implementation of Differentiated Service Delivery Models for HIV Treatment in Mozambique: a Modelling Study. *J Int AIDS Soc.* 2024;27(5):e26275. doi:10.1002/jia2.26275

[5] Justman JE, Koblavi-Deme S, Tanuri A, Goldberg A, Gonzalez LF, Gwynn CR. Developing laboratory systems and infrastructure for HIV scale-up: A tool for health systems strengthening in resource-limited settings. J Acquir Immune Defic Syndr. 2009;52 Suppl 1:S30-S33. doi:10.1097/QAI.0b013e3181bbc9f5

Diagnostic network optimization and multiplexing have also been found to help improve the efficiency and sustainability of diagnostic testing.[6,7,8] For example, expanding and optimizing the national sample transportation network can be a viable solution, but countries have found that reaching the last mile with only this solution can be cost-prohibitive.[9] Other studies have also demonstrated that while targeted POC VL testing at high-volume health facilities can be cost-effective, placing POC VL testing in all health facilities may not be cost-effective nor affordable and, therefore, may not be appropriate for all health facilities.[10] Other strategies that share the same benefits of expanding the sample transportation network and POC VL testing – reaching the last mile, faster turnaround time of test results, and faster clinical interventions – should be explored to complement the existing diagnostic systems.

One potential solution is strengthening national VL testing capacity through transformative partnerships with the private sector. Especially as HIV programs transition from donor-funding to country-led programs, innovations and investments must consider the sustainability of interventions. Engaging the private sector for HIV service delivery to complement public sector efforts provides an opportunity for sustainable and equitable solutions and impact.

Introduction: Private Sector Engagement for National Diagnostic Optimization

Solutions for optimizing national diagnostic networks will be unique to every country, and no one solution may apply to all nor be sufficient to resolve all bottlenecks. Figure 2 below shows the various bottlenecks in the viral load testing value chain that might cause long TAT or low VL testing coverage and the solutions the private sector could provide.[11] One literature review of public-private partnerships focused on laboratory system strengthening found that public-private partnerships have helped address challenges in scaling up national viral load programs in reaching clients in remote communities, improving sample referral networks, reducing the cost of reagents, increasing the number of tests conducted, reducing the TAT of reporting results,

[6] Albert H, Rupani S, Masini E, Ogoro J, Kamene M, Geocaniga-Gaviola D, et al. Optimizing diagnostic networks to increase patient access to TB diagnostic services: Development of the diagnostic network optimization (DNO) approach and learnings from its application in Kenya, India and the Philippines. PLoS One. 2023;18(11):e0279677. Published 2023 Nov 30. doi:10.1371/journal.pone.0279677

[7] Eswatini DNOs bring steady improvements to HIV and TB testing: Diagnostic network optimization in 2018 and 2021 yields results. *USAID Global Health Supply Chain Program*. December 2, 2022. Available at: https://www.ghsupplychain.org/news/eswatini-dnos-bring-steady-improvements-hiv-and-tb-testing. Accessed November 11, 2024.

[8] Ghana's TB And HIV Diagnostic Networks For Improved Access, Efficiency, And Reduced Cost: Findings From A National Diagnostic Network Optimization Analysis. Presented at: African Society for Laboratory Medicine 2023; December 12-15, 2023; Cape Town, South Africa. Available at: https://www.ghsupplychain.org/sites/default/files/2023-12/00200_ASLM_Ghana_DNO_ConferencePoster_ForPRINT%203.pdf. Accessed November 11, 2024.

[9] Nichols BE, Girdwood SJ, Crompton T, Stewart-Isherwood L, Berrie L, Chimhamhiwa D, et al. Monitoring viral load for the last mile: what will it cost?. *J Int AIDS Soc*. 2019;22(9):e25337. doi:10.1002/jia2.25337

[10] Girdwood SJ, Crompton T, Sharma M, Dorward J, Garrett N, Drain PK, et al. Cost-effectiveness of adoption strategies for point of care HIV viral load monitoring in South Africa. EClinicalMedicine. 2020;28:100607. Published 2020 Nov 4. doi:10.1016/j.eclinm.2020.100607

[11] Shrivastava R, Fonjungo PN, Kebede Y, et al. Role of public-private partnerships in achieving UNAIDS HIV treatment targets. BMC Health Serv Res. 2019;19(1):46. Published 2019 Jan 18. doi:10.1186/s12913-018-3744-z

and some partnerships resulted in cost savings.[11] However, many of these examples were partnerships with international private-sector organizations.

Figure 2. Bottlenecks in the HIV VL Testing Value Chain and Potential Private Sector Solutions

Bottlenecks in VL testing	Potential private sector solutions
▪ Inadequate specimen transport system	▪ Transport systems dedicated to specimen transport from health facilities to labs
▪ Stockout of VL testing commodities	▪ Well-functioning supply chain system that could fill supply gaps as needed
▪ Inadequate PCR lab infrastructure	▪ Well-maintained lab facilities and machines that can also serve as backup up during equipment downtimes or support during periods of increased demand for testing
▪ Shortage of trained staff	▪ Dedicated and well-trained workforce
▪ Limited public lab working hours	▪ Longer working hours including weekends
▪ Inadequate client-centric decentralized options (all facility-based sample collection)	▪ Availability of home-based or other client-specified or decentralized location specimen collection options
▪ Manual error-prone sample documentation systems ▪ Delayed communication of results	▪ Electronic specimen and results documentation system for real-time reporting to health facilities

Leveraging Private Clinical Laboratories

The expanding role of the private sector in health care service delivery in LMIC countries is known,[12] and while their influence on the health care system is not well understood, there has been a steady accumulation of evidence on the importance of their role.[12] There is also variation in the contribution of the private sector in health care services across countries, regions, and health services,[13,14,15] but where they exist, they can carry strong capacity. For example, in Nigeria, under the EpiC project, a landscape assessment of private laboratory capacities found that, across 23 private laboratories assessed, 11 had the capacity for (in terms of human resources, equipment, supplies, etc.) and were actively conducting HIV VL testing. The assessment also found that while a wide variety of equipment and services were available through private laboratories, many did not possess the molecular diagnostics equipment

[12] Forsberg BC, Montagu D, Sundewall J. Moving towards in-depth knowledge on the private health sector in low- and middle-income countries. *Health Policy Plan*. 2011;26 Suppl 1:i1-i3. doi:10.1093/heapol/czr050

[13] Grépin KA. Private Sector An Important But Not Dominant Provider Of Key Health Services In Low- And Middle-Income Countries. Health Aff (Millwood). 2016;35(7):1214-1221. doi:10.1377/hlthaff.2015.0862

[14] Yadav H, Shah D, Sayed S, Horton S, Schroeder LF. Availability of essential diagnostics in ten low-income and middle-income countries: results from national health facility surveys. Lancet Glob Health. 2021;9(11):e1553-e1560. doi:10.1016/S2214-109X(21)00442-3

[15] Montagu D, Chakraborty N. Standard Survey Data: Insights Into Private Sector Utilization. Front Med (Lausanne). 2021;8:624285. Published 2021 Apr 12. doi:10.3389/fmed.2021.624285

platforms approved under the National Equipment Harmonization Policy, highlighting the need for greater coordination. It can grow and evolve even in countries where the private sector remains small or lacks capacity.[16]

Private sector laboratory engagement in national diagnostics systems leverages locally existing capacity for optimal and sustainable systems. Engagement of private sector laboratories should not replace public sector laboratories but rather complement, strengthen, and build on the existing public sector capacity and integrate with the national diagnostic systems to help close diagnostic testing gaps.

While the engagement of private sector laboratories mainly helps to alleviate the burden on the analytic phase of the value chain – testing the samples, producing and returning the results to health facilities – the intervention can also support the pre-analytic phase – sample collection from clients and sending the samples to the laboratory – and post-analytic phase – returning the results to clients, and clinical decision-making is based on the results (Figure 3).

Figure 3. Viral Load Testing Phases and Potential Private Laboratory Solutions

Pre-analytic Sample collection to delivery to lab	**Analytic** Receipt of sample at lab to results	**Post-analytic** Results returned to health facilities to results returned to the client and clinical decision making
▪ Decentralized sample collection outlets ▪ Weekend and afterhours sample collection ▪ Private laboratory supported transport for specimen delivery ▪ Provision of sample collection equipment during stock outs at health facilities (i.e., PPT tubes)	▪ Private laboratory testing to fill gaps during backlogs due to equipment down time, reagent or other commodity stock outs, or any other challenges that impedes the public laboratory from operating optimally	▪ Private laboratory supported transport for results return ▪ Private laboratory electronic data system for efficient results returns systems for providers and clients

Some private laboratories are internationally accredited, which should be a requirement for private sector engagement in the context of VL testing, have the capacity to lend support to cover the high volume of national diagnostic testing needs, and some may implement innovative solutions that can also be leveraged for national diagnostic system optimization. National gaps in diagnostic testing may extend beyond HIV VL into HIV CD4 cell count, sexually transmitted infection (STI), Hepatitis, and tuberculosis (TB) and human papillomavirus (HPV)

[16] World Health Organization (WHO). Engaging the private health service delivery sector through governance in mixed health systems: strategy report of the WHO Advisory Group on the Governance of the Private Sector for Universal Health Coverage. Geneva, Switzerland: WHO; 2020. Available at: https://iris.who.int/bitstream/handle/10665/341057/9789240018327-eng.pdf?sequence=2. Accessed November 13, 2024

among others, including through multiplexing. Private sector laboratories may also solve diagnostic gaps for other health areas beyond HIV VL testing.

The purpose of this White Paper is to highlight the feasibility, advantages, potential, and evidence for engaging private laboratories in national diagnostic network systems for HIV VL monitoring and its added value towards locally sustainable solutions through citing program case examples from the USAID-funded EpiC project activities in Nigeria, Indonesia, and Botswana.

Diversification of HIV VL testing Options and Decentralization of Sample Collection

Leveraging private sector investments and innovations to improve access to diagnostic testing, turnaround time of results, and viral load testing coverage

Private sector laboratories are local resources and capacities that can be leveraged to complement the public diagnostic system and help fill the gaps as needed. Private laboratories offer supplemental resources – human resources, equipment, supplies, network of branch labs, and time – to help avoid delays and allow for faster TAT of results. Establishing partnerships and contracts with private labs can ensure continued testing of samples even during equipment breakdowns, reagent stockouts resulting in a backlog of untested samples, or other bottlenecks that may emerge in the public system for more consistent and timely availability of VL results.

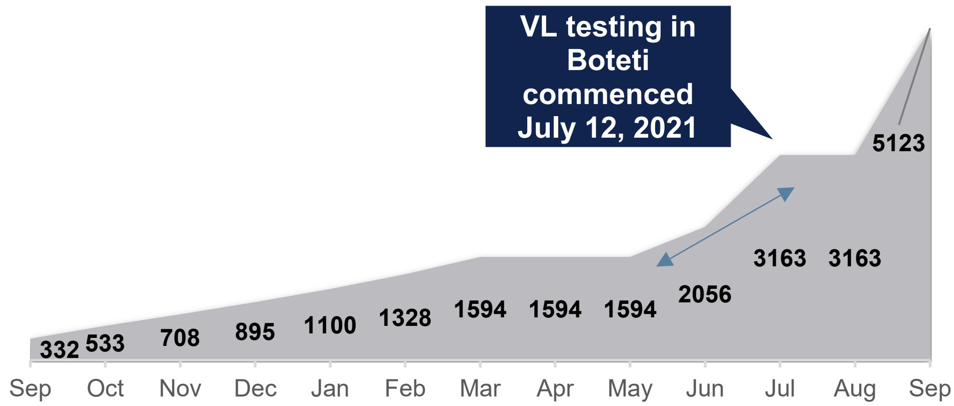
Under the EpiC project in Nigeria, the partnership with a private laboratory, Zankli Medical Centre Molecular Laboratory, was piloted in 25 health facilities in Adamawa State. This partnership contributed to 53% (3,480) of the VL coverage in the 25 health facilities during the pilot period between July – August 2023. During the partnership period, there was a 14.4% increase in VL coverage from 76.6% during the quarter before the intervention to 91.0% during the quarter in the same health facilities. Through the private lab, the average TAT from when the private lab received the samples to returning the results to the health facilities was 7 days. In the public laboratory, the average TAT over 9 months was 29 days. Before the intervention, the public sector laboratory supporting Adamawa State had experienced a fire, forcing a periodic halt in testing. While samples were transferred to other labs, this created a bottleneck and expanded the backlog of VL samples that had yet to be processed. The private laboratory had the capacity – the equipment, supplies, training, human resources, and time – to support the public sector in processing the backlog of VL samples and returning results in a timely manner, allowing clients with unsuppressed results to receive the necessary interventions faster. Laboratories can face bottlenecks from time to time due to accidents, equipment down times, or a sudden surge in other diagnostic testing needs diverting resources away from HIV VL testing, such as the surge of PCR testing needed during the COVID-19 pandemic. Diversifying the options available for testing HIV VL samples by leveraging private sector laboratories as backup systems can allow samples to be processed more consistently and with a reliable TAT.

Many private sector laboratories have also invested in and provided innovative services that improve convenience and flexibility for clients to access diagnostic testing, which may not be available in the public sector. Through partnerships, these private sector innovations can be leveraged by the public sector to improve access to and reduce barriers to HIV VL testing for people living with HIV, including for key and vulnerable populations as well as those who live in more remote areas. For example, private laboratories may provide options for decentralized HIV VL sample collection through their community lab outlets, which provides options for clients and may be in more convenient locations for those who may have challenges reaching health facilities to access VL sample collection, as demonstrated in the example from Botswana and Indonesia below.

In Botswana, routine public sector VL testing was drastically affected nationally by the COVID-19 pandemic response measures, exacerbating existing challenges. To address the growing gap, a partnership was established with a private laboratory based on their capacity to provide VL testing through 25 private laboratory-supported sample collection outlets and to return VL test results within 24 hours. Through this partnership, VL samples were collected at the health facilities and sent to the private laboratory's main facility. Clients were also referred and supported to schedule their VL sample collection appointments at one of the 25 lab outlets of the clients' choice at their convenience time, including on weekends. This model was implemented from October 2020 to September 2021 in 12 EpiC-supported clinics across the ten districts, which also provided services to key populations.

Between October 2020 and September 2021, 5,123 VL tests were conducted via private laboratories (Figure 4), 20% of which (1,042) were among KP individuals. At the 12 participating clinics, VL testing coverage increased from 83% to 90% among KPs and slightly among the general population (90% to 91%) during the implementation period. Service providers also benefited. The time saved from not having to collect VL samples incentivized them to refer more clients for testing and allowed them to focus on other service delivery areas.

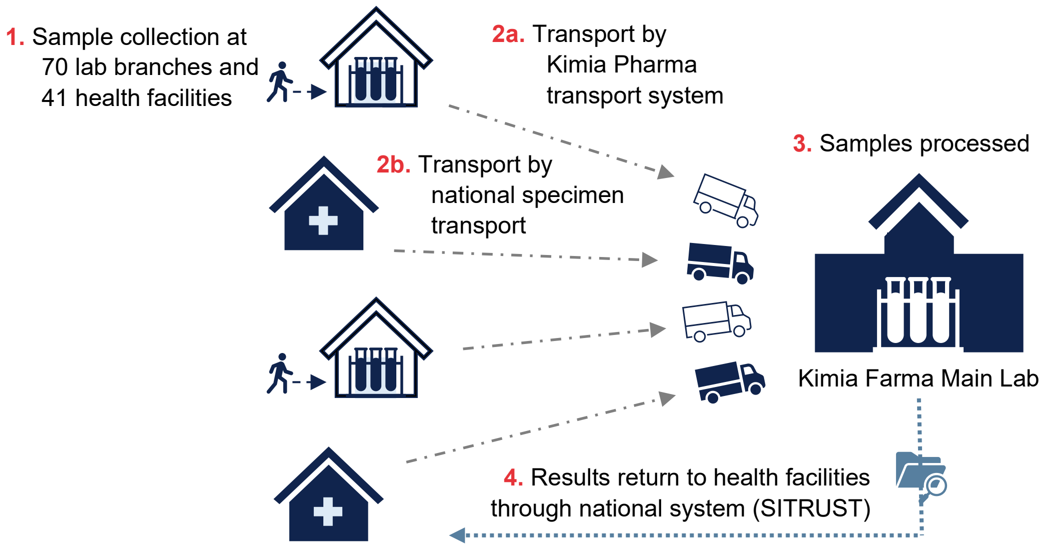
Figure 4. Monthly Private Sector Viral Load Testing in Botswana: September 2020 – September 2021



The Boteti district of Botswana was especially impacted by the COVID-19 response measures and faced disproportionate backlogs compared to other districts. Viral load testing through the private sector was leveraged in July 2021 to address the large VL testing backlog experienced since the onset of the COVID-19 pandemic. A review of routinely collected implementation data found 3,743 general population clients eligible for VL testing but had not yet received the service. Over three months, 2,243 were reached with the private laboratory intervention, and among those reached, 1,062 (47.3%) had never had a VL test since initiating ART.

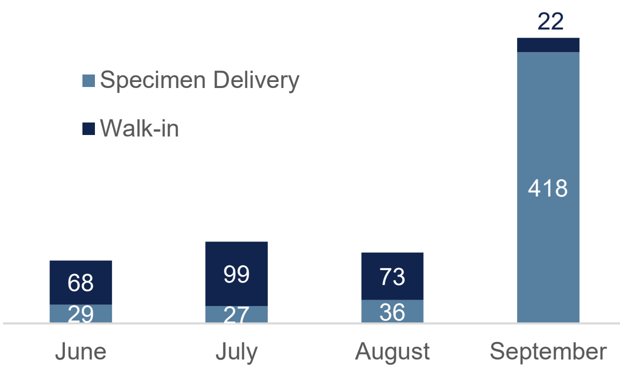
Similarly, in Jakarta and Greater Jakarta, Indonesia, a partnership was established with Kimia Farma, one of Indonesia's prominent private pharmaceutical companies, renowned for its extensive network of accredited laboratories nationwide. Specifically, this laboratory network included 70 decentralized lab outlets across Indonesia where clients could have their samples taken, allowing for greater flexibility and potentially shorter travel time and less travel costs. HIV VL samples could also be collected at health facilities and sent to the private laboratory's main facility for testing (Figure 5).

Figure 5. Kimia Farma Private Laboratory Partnership Model in Indonesia



As this partnership will roll out to support the public system, the private laboratory was initially leveraged only for clients who lived outside the catchment areas and may have longer distances to travel and other unique barriers to access VL sample collection at public health facilities.

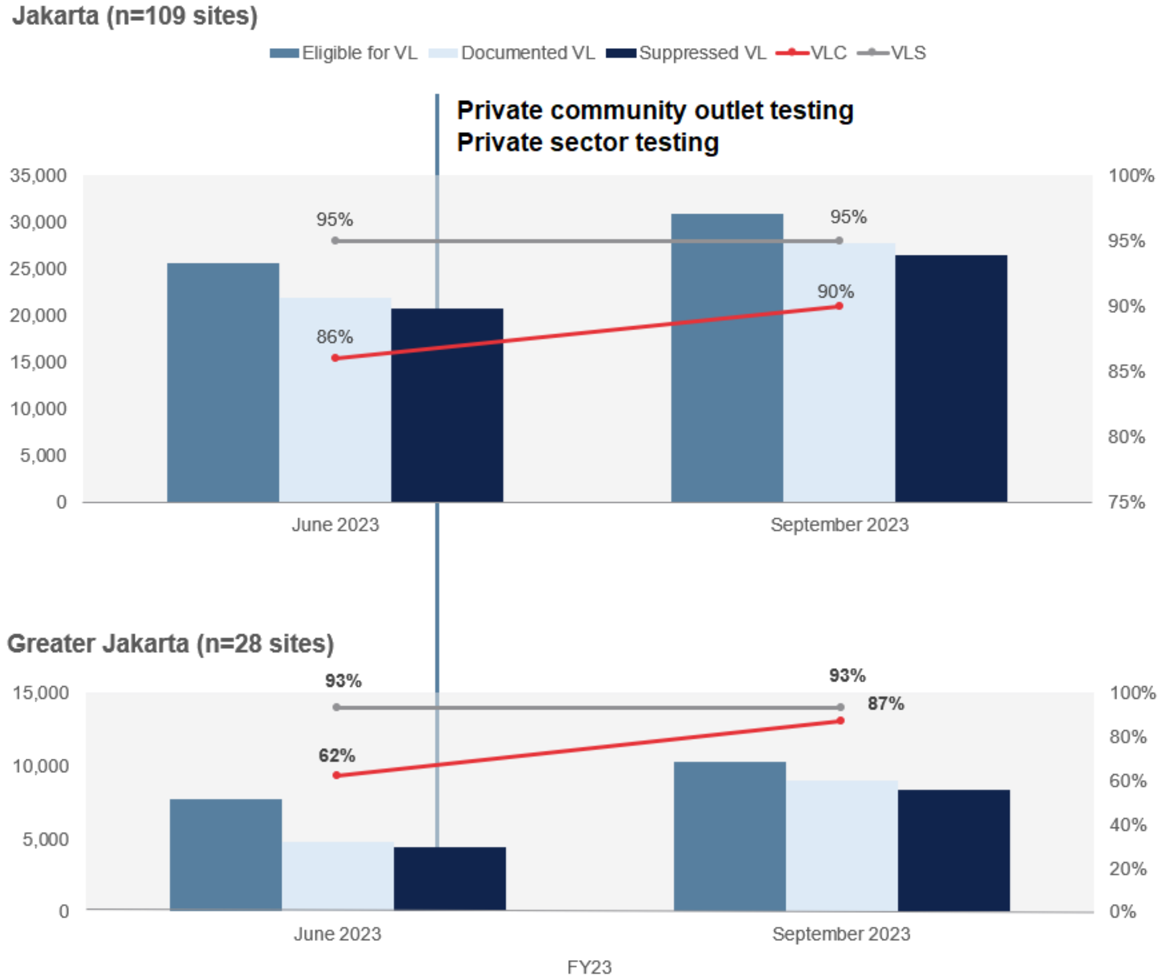
Figure 6. Sample Collection in Indonesia by Month and collection site (June – September 2023)



In the first few months of the partnership, most of the samples tested through the private laboratory were collected at one of the 70 private laboratory outlets for clients who may not have otherwise accessed VL sample collection services. In the final month of the pilot, the public laboratories faced shortages. To address the periodic gap, samples collected at public health facilities were sent to the private laboratory main facility, where commodities continued to be available (Figure 6).

As a result, the viral load coverage in Jakarta and Greater Jakarta increased from 86% and 62%, respectively, during the quarter before the partnership to 90% and 82%, respectively, by the final month of the partnership four months later (Figure 7). During the partnership, between June and September 2023, the private laboratory supported 20% of the total VL tests conducted by the participating facilities, including by reaching the clients who live outside of the health facility catchment area and may have more difficulty accessing a health facility for VL sample collection. Additionally, the TAT of test results through the private laboratory was around three to five days compared to seven to 30 days through public referral laboratories.

Figure 7. Viral load Coverage and Suppression in Jakarta and Greater Jakarta from June - September 2023



Partnerships with private laboratories in Nigeria, Botswana, and Indonesia have allowed the public sector to leverage the resources and innovations invested in by the private sector to alleviate bottlenecks experienced in the public system and reach clients who may not have otherwise received HIV VL sample collection services, and therefore, improve VL testing coverage. The partnerships improved the public system's capacity for flexibility in offering additional options for the health system and clients, facilitating improved quality of care.

"My viral load testing experience with Kimia Farma went smoothly. After waiting for 10-15 minutes, they called me, and I can do the viral load test for free. I received the result in three days from Angsamerah Clinic through a [private] WhatsApp Chat. On my previous test with a public lab, I received the result after 7-10 days."

- Walk-in client in Surabaya province

Costs of VL Testing through the Private Sector

The cost and cost-effectiveness of viral load monitoring for HIV vary by context and depend on a variety of factors, including agreements with equipment and supplies manufacturers, the volume of testing conducted, labor costs, and programmatic factors, such as VL testing approaches used, the establishment of pathways to health improvements for clients and responding to the VL test results, and the simplicity of HIV care and the use of differentiated care[17]. Local policies can also impact the cost-effectiveness of VL testing. For example, the rapid identification of PLHIV as virally suppressed and their enrollment into differentiated and simplified models of care is cost-effective.[4] However, in contexts that lack policies supporting differentiated services, the cost-effectiveness of identifying virally suppressed individuals may be undermined.

As such, the cost and cost-effectiveness of engaging private laboratories to improve VL coverage also depend on the same factors as well as other variables, including the price per test negotiated, the volume of VL tests contracted, and the effectiveness of the innovations offered by the private laboratory to improve access, TAT, and consistency of services. For example, although in Botswana, the price per test negotiated with the private laboratory was USD 20, the price per test negotiated in Indonesia was USD 52 and in Nigeria USD 40. Of note, while both Botswana and Nigeria benefit from the USAID Global Health Supply Chain Program for subsidized supply costs, Indonesia does not, which also largely impacts the cost per test. Therefore, the cost-effectiveness of private laboratory engagement in each country would be different.

Similarly, an activity-based costing exercise comparing the costs of HIV VL sample analysis on a per-sample basis between the private laboratory and public laboratory found that, in Indonesia, the resources required in the private sector lab for the full VL testing process (from sample collection to return of results) were estimated to be substantially lower than in the public laboratory ($31 vs $96 respectively). However, a similar exercise was conducted in Nigeria and found that the resources required for processing the VL sample (not the full VL testing process)

[17]Barnabas RV, Revill P, Tan N, Phillips A. Cost-effectiveness of routine viral load monitoring in low- and middle-income countries: a systematic review. J Int AIDS Soc. 2017;20 Suppl 7(Suppl 7):e25006. doi:10.1002/jia2.25006

in the private sector were substantially higher than in the public laboratory ($24 vs $13 respectively (using September 2023 conversation rates from Naira).

In both cases, the difference in cost was primarily due to the difference in the equipment manufacturer and reagents used in respective labs. Additionally, the difference in cost was also attributed to the equipment's utilization level. The exercise in Indonesia found that if the public laboratory could utilize the machine five days per week instead of two days per week, the cost per sample processed would decrease ($79). The exercise in Nigeria found that the larger volume of samples analyzed in the public sector helped to distribute the cost of the supplies across a higher volume of samples leading to lower costs per sample. However, in both countries, the key cost driver per test was the cost difference in equipment and supplies.

As such, the cost-effectiveness of engaging private laboratories for VL monitoring hinges on a variety of variables, and careful consideration should be taken into the design of the partnership and model. For example, private laboratories may be open to price negotiation by volume of tests. In Botswana, the private laboratory agreed to a cost per volume, which led to a negotiated cost of VL testing at USD 20 per test—comparable to public laboratory testing and less than half the usual cost in private laboratories based on the larger number of VL tests ordered. By increasing the volume of VL tests conducted by private laboratories and possibly by leveraging the partnership for additional types of tests such as for TB, STIs, or even NCDs, the cost per test may be reduced, improving cost-efficiencies and sustainability. Additionally, the contract with the private laboratory in Botswana was 12 months compared to four months in Indonesia and 45 days in Nigeria. Increasing the volume of tests and the length of time of the contract may improve negotiations for price per test.

Strategies to support improvements in efficiency in the private laboratory could also be considered. In Nigeria, the cost of supplies encompassed 98.7% of the total cost to process a VL sample through the private sector, representing a significant proportion. The public sector may have negotiated a lower cost of equipment and supplies with the manufacturer. Allowing the private laboratory to access the same price point could help improve the cost per test and improve the efficiency of the innovation.

Finally, other strategies have also been evaluated to improve viral load coverage, especially for populations whose services remain inaccessible due to distance, stigma, or other barriers. For example, in Zambia, the incremental cost of optimizing the sample transport network to reach the most remote 20% of clients to improve VL coverage was assessed, and it found that the cost per test increased as the model expanded the sample transportation network, making this option possibly cost-prohibitive.[9] The proportion of clients for whom services remain inaccessible can be relatively small, and the innovations and investments needed to reach these populations may not be cost-effective for the current public systems. Yet, strategies are needed to improve the equity of services, and the most cost-efficient option to ensure equity should be employed. Leveraging the innovations and systems invested in by the private sector can be another option to explore.

Recommendations

Engagement of private sector laboratories is one viable option for addressing the persistent gaps in HIV viral load testing coverage, including increasing access, especially for those who face additional barriers, and providing options and facilitating the provision of differentiated care for PLHIV. Private laboratories may have innovations that can allow countries to improve punctuality, increase reach, and maintain the reliability of their services, allowing for the VL results to be used most effectively. As countries move from donor-funded to self-reliant funding for HIV services and as the number of PLHIV grows, sustainable strategies to increase local diagnostic capacities, especially through leveraging the private sector, are increasingly urgent.

Private laboratories can effectively be engaged in national diagnostic networks to fill both persistent and temporary gaps. They should be included in national practices and institutions, including diagnostic network optimization and assessment exercises and national certification and accreditation and quality monitoring mechanisms, ensuring standardization of equipment and supplies utilized and managed through the private sector. Documentation and mapping of private sector laboratories and their capacities can allow countries to pull their support as needed. As such, ensuring standards and procedures for private sector engagement in the national guidelines are necessary for the rapid engagement of the private sector. Preemptively establishing agreements, terms, and partnerships with private laboratories can facilitate their rapid engagement and improve the reliability of and access to the national diagnostic network.

Private sector partnerships through strong systems for engagement and accountability

A successful and sustaining partnership between the public and private sector must have strong systems in place for engagement and accountability. In Indonesia, through close collaboration with national and subnational health authorities, EpiC streamlined the VL test process documentation and results reporting pathways between Indonesia's national HIV information systems (SIHA 2.1, ARK 6.0 and SITRUST) and Kimia Farma allowing for secure, electronic and real-time communication and updates on progress and return of results.

Strategic model designs, terms of partnerships, and competitive partner selection based on their offer price, services, and available innovations that effectively fill the identified gaps in the current diagnostic network are critical to improving the cost-efficiencies of the private laboratory engagement strategy. Negotiated prices for bulk sample transportation and testing can be explored. Establishing longer-term contracts across larger geographic areas may also improve leverage in price negotiations. To increase efficiencies, private labs should be considered in multiplex testing.

Ensuring the rapid use of viral load test results, regardless of whether it is unsuppressed or not, for clinical decisions for clients is crucial for both population health and cost-effectiveness gains. Harmonized electronic reporting systems will facilitate reductions in the TOT for results and enable clinicians to make necessary clinical decisions faster, hence allowing VL monitoring to optimally benefit the clients.

Additionally, private laboratories may have capacities beyond diagnostic testing, such as innovations for decentralizing other health and HIV-related commodities, which can contribute to expanding community-based services, reinforcing differentiated service delivery, and facilitating quick actions to be taken by both clients and healthcare providers once the VL results are made available without delays. In addition to VL and other diagnostic testing, other health gain opportunities and possibilities for partnerships should be explored and considered.

Yet, engaging private laboratories may also have its drawbacks. Misalignment of public and private sector priorities, high costs per test even after negotiations, and lack of transparency and complete data visibility between sectors may create barriers to establishing effective partnerships and scaling up. To address the hurdles, establishing a strong platform for well-represented stakeholder engagement and discussions from the inception of the activity is critical. Further, identifying champions from among key stakeholders to facilitate negotiations may also prove valuable.

Overall, considerations should be made to engage and establish an enabling environment for the rapid engagement and leveraging of private laboratories and their innovations to support and complement the existing public laboratories. Opportunities to operationalize and optimize these strategies should be explored.