



CASE STUDY

CHAI supports South Africa and global partners to achieve landmark HIV Viral Load access program

HIV VIRAL LOAD TESTING IMPROVES THE QUALITY OF CARE FOR PATIENTS ON ANTIRETROVIRAL THERAPY. CHAI PARTNERED WITH THE GOVERNMENT OF SOUTH AFRICA, UNAIDS, PEPFAR, GLOBAL FUND, AND ROCHE TO NEGOTIATE A GLOBAL ACCESS PRICE FOR VIRAL LOAD OF US\$9.40 PER TEST, WHICH WILL SAVE MORE THAN US\$150 MILLION BETWEEN 2015 AND 2019 AND DRAMATICALLY IMPROVE TREATMENT MONITORING IN LOW- AND MIDDLE-INCOME COUNTRIES.

OVERVIEW

The case for regular viral load (VL) testing for patients on antiretroviral therapy (ART) is well established and has been the standard of care in high-income settings for over 15 years.^{1,2,3,4} Use of VL testing confirms patients are responding to their medications, and that their virus has been suppressed such that they are no longer contagious. The test also enables early and accurate diagnosis of treatment failure and the need to switch to second-line drugs, thereby improving the quality of care that HIV patients receive.

However, in low- and middle-income countries (LMICs), less than 20 percent of patients have access to VL testing. In these countries, CD4 testing is the primary method used to monitor treatment, yet it has poor predictive power for treatment failure. As a result, roughly 30-50 percent of patients diagnosed with treatment failure have not yet developed resistance to specific antiretroviral (ARV) drugs.⁵ This contributes to many unnecessary switches to second-line drugs, subjecting patients to more expensive and more toxic ARV regimens and limiting future treatment options.^{6,7} Furthermore, for those patients that are failing first-line treatment, CD4 testing often does not detect failure early enough to enable initiation of adherence interventions and, if necessary, a prompt switch to a second-line regimen.⁸

Until 2014, price was the main barrier to access in LMICs, with VL costing up to US\$60 per test. Complicated technology that required rigorous training for high-level technologists also contributed to slow uptake, as did the widespread belief that existing infrastructure for VL testing was not in place.

APPROACH

Recognizing the significant patient care and public health benefits that VL testing could provide to LMICs, CHAI began advocating for increased uptake and use in 2010. These efforts were augmented in anticipation of the 2013 update to the World Health Organization (WHO)

THEORY OF CHANGE

Using VL testing to monitor ART in LMICs can significantly improve patient outcomes. Access can be increased if prices are reduced and sample transport challenges addressed.

IMPACT

Price negotiations resulted in a global access price from Roche of US\$9.40 per test, reducing the average price by more than 40 percent in LMICs. The agreement is expected to save more than US\$150M between 2015 and 2019 and enable scale up of VL testing in LMICs.

KEY PARTNERS

- DFID
- NHLS
- Roche
- Diagnostic Access Initiative: UNAIDS, UNITAID, GFATM, and PEPFAR

guidelines for ART, which provided an opportunity to incorporate VL as the preferred approach to monitoring and facilitate widespread use for the first time, thus enabling CHAI to leverage economies of scale.

In parallel with advocacy efforts for the inclusion of VL testing as the preferred method for monitoring ART in the WHO guidelines, CHAI intensified engagement with key partners to overcome supply- and demand-side barriers and facilitate broader access to VL testing.

On the demand side, CHAI's approach to addressing key barriers to VL testing included the following activities:

- **Supporting scale-up planning in high volume and high HIV burden countries** using existing laboratory infrastructure, sample transport capabilities, and equipment. These activities allowed countries to include scale-up funding requests in their Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM) New Funding Model applications as well as Country Operational Plan requests to the President's Emergency Plan for AIDS Relief (PEPFAR);



- **Communicating the programmatic benefits of VL testing** in terms of value for money and quality of care; and
- **Continuing advocacy for changing national ARV program guidance** on the use of VL testing, promoting alignment at the policy level.

On the supply side, CHAI conducted activities to better understand the market landscape and factors contributing to pricing:

- **Analyzed the cost of goods sold (COGS)** for VL tests. This included a supplementary analysis of the impact on price per test of instrument capital costs, service, and maintenance;
- **Collected data on pricing and contract terms**, which varied widely throughout LMICs. This confirmed that current pricing was a function of the relative volumes and negotiating power of the buyer rather than the COGS; and
- **Prepared forecasts of future demand** for VL testing under different pricing scenarios.

CHAI engaged all of the major suppliers (Cepheid, Abbott, Roche, Hologic, and BioMerieux) to discuss potential scale-up scenarios and the subsequent impact on future pricing. Suppliers were generally willing to consider volume-related discounts and working with programs to support increased capacity utilization of existing instruments.

In June 2013, the WHO officially recommended VL as the preferred method for treatment monitoring. This change to the guidelines reinforced CHAI's advocacy on the benefits of VL testing and encouraged countries to adopt VL into their national programs. CHAI proceeded to establish programs in 12 countries¹ with funding from DFID and UNITAID. CHAI helped these countries update their national guidelines to reflect the 2013 WHO recommendations, and develop implementation plans for scale-up.

Substantial testing capacity and political will were already in place in Kenya, Ethiopia, Malawi, and Uganda, allowing for rapid expansion of testing once price reductions and funding were secured. CHAI also demonstrated that VL testing could be implemented in additional countries without significant investments by utilizing the existing instrument-base, human resources capital, sample transportation, and results delivery infrastructure in place for early infant diagnosis (EID) testing.

¹ Countries included Zimbabwe, Zambia, Nigeria, Ethiopia, Uganda, Kenya, Tanzania, Swaziland, Lesotho, South Africa, India, and Malawi.

A critical component to negotiating the global access price came from partnering with South Africa. CHAI identified South Africa's National Health Laboratory Service (NHLS) as the largest purchaser of VL tests in the world, accounting for over 50 percent of the volume in LMICs. CHAI's market analysis suggested that combining NHLS purchases with expected VL scale-up funding from PEPFAR and GFATM could lead to improved pricing for all parties. The NHLS took a leadership role in the initiation of what would become a landmark access program.

CHAI, NHLS, and partners developed a strategy to negotiate a global access price agreement alongside the NHLS tender by requesting that bidders for the tender provide a "voluntary global access price." The global access price would offer a voluntary access price for VL tests that could be accessible to all countries supported by PEPFAR and GFATM.

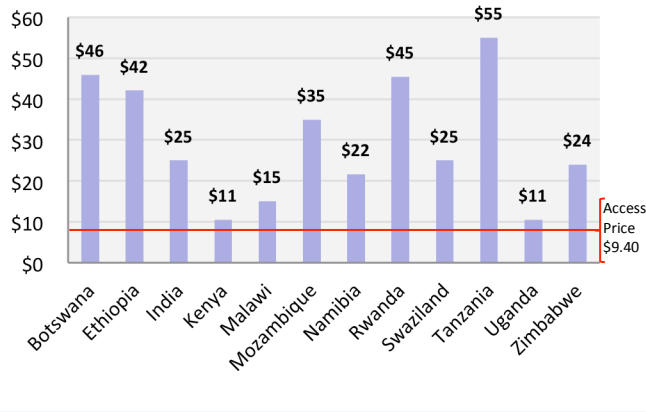
Partners supported the process by providing assurances that funding for VL would be available to support increased volumes. During the tender negotiations, PEPFAR leadership indicated that they would support funding for VL testing for the four million patients on ART that are supported by PEPFAR, enabling them to receive at least one VL test per year. In addition, the Diagnostic Access Initiative (DAI), led by UNAIDS, provided a forum for generating political will to support funding to scale up VL testing. Paired with the South African Government's leadership and willingness to leverage their market influence for global benefit, suppliers saw an opportunity to expand volumes if they reduced prices and submitted favorable bids for the NHLS tender and for the voluntary Global Access Program.

IMPACT

In September 2014, after several rounds of negotiations, Roche emerged as the lowest bidder for the NHLS tender, producing savings in dollar terms of over 25 percent. Roche offered NHLS a full-service contract including shipping, instrument leasing, service, training, and all reagents.

CHAI concurrently worked closely with key partners to negotiate a US\$9.40 access price per test for the Global Access Program (Figure I), which will reduce Roche's average price by over 40 percent in LMICs. When fully implemented, the agreement is expected to save more than US\$150 million between 2015 and 2019.

Figure I. NEGOTIATED VL ACCESS PRICE IN RELATION TO PRE-AGREEMENT PRICING



FUTURE OUTLOOK

As a result of this work, more countries will be able to afford VL testing, allowing for increased procurement with existing funding levels. The price reductions will also allow Ministries of Health (MOHs) to make the case for increased investment in additional tests, given the added value for money. To support adoption and scale-up, CHAI will continue to work closely with key countries to ensure that revised national guidelines are in place, human resources are being appropriately trained, and systems are ready for higher volumes of tests.

Measures will also be taken to address key barriers to implementation through programmatic interventions for VL testing. These interventions may include training additional human resources, developing systems to expedite results delivery, improving monitoring and evaluation, and increasing efforts to educate patients on the value of VL.

Addressing barriers to implementation will be critical over the coming years. In light of this, CHAI, in collaboration with other DAI members, formed the viral load implementation task force (VLITF) to coordinate the implementation of VL scale-up globally. The following activities will be executed by the VLITF:

- Track and address implementation challenges of VL scale-up in countries;
- Integrate global EID and VL programs; and
- Disseminate best practices to countries.

CHAI and other DAI members plan to roll out these activities in all LMICs affected by HIV. Preliminary success has already been observed through the increased pace of adopting the WHO 2013 guidelines, drafting of VL

implementation plans, and increased inclusion of VL commodities and programmatic funding requests in GFATM concept notes. Effective and sustainable programs in country will provide an increasing proportion of patients with access to VL tests, contributing to the global goal of achieving viral suppression for 90 percent of all people receiving ART by 2020.⁹

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About the Clinton Health Access Initiative, Inc.

The Clinton Health Access Initiative, Inc. (CHAI) is a global health organization committed to strengthening integrated health systems and expanding access to care and treatment in the developing world. CHAI's solution-oriented approach focuses on improving market dynamics for medicines and diagnostics; lowering prices for treatment; accelerating access to lifesaving technologies; and helping governments build the capacity required for high-quality care and treatment programs. Though CHAI remains committed to its initial focus on HIV/AIDS, CHAI has also expanded its scope to work in the following program areas: HIV/AIDS and Tuberculosis (TB), Improving the Efficiency and Effectiveness of Healthcare Systems, Malaria, Human Resources for Health, Vaccines, and Maternal, Child, and Newborn Health. For more information, please visit: www.clintonhealthaccess.org

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