Project scope

This joint initiative between Clinton Health Access Initiative (CHAI) and UNICEF, funded by UNITAID, aims to support the Point of Care (POC) HIV diagnostics market for accelerated scale up in seven focus countries: Ethiopia, Kenya, Malawi, Mozambique, Tanzania, Uganda and Zimbabwe. The project will be implemented together with Ministries of Health and existing partnerships and initiatives, within the context of strengthening laboratory systems and treatment guidelines within countries.

Unmet need for CD4, Early Infant Diagnosis, and Viral Load Testing

There are 34 million people living with HIV/AIDS in the world today. About 8 million of them are on antiretroviral treatment (ART), yet there are still millions of people who need treatment but are not receiving it. Children in need of treatment are even less likely to have access than adults. Diagnostic testing is critical for determining eligibility to start ART and monitoring responses to treatment.

Access to rapid testing of HIV status has increased greatly in the past few years, providing a gateway to treatment and bringing important prevention benefits. However, the current global diagnostic market for CD4 count, Early Infant Diagnosis (EID) and Viral Load (VL) does not meet the needs of the millions of people living with HIV/AIDS in resource limited settings. The complex technologies that dominate the market are expensive, and require sophisticated laboratory infrastructure, stable electricity supply and highly trained technicians. As a result, they have limited geographical reach. Although HIV treatment programs are scaling up rapidly, coverage of essential diagnostic testing remains low: 61% for CD4, 26% for EID and 25% for VL.¹

With conventional diagnostic testing, HIV positive clients can wait for weeks to months to receive results for CD4, EID and VL tests. They sometimes make multiple clinic visits before the test results are available. These test results are critical for health care providers to make decisions about when to start treatment and whether any changes in medication are needed.

¹ Unpublished CHAI data
Consequences of limited access to CD4, EID and VL testing

<table>
<thead>
<tr>
<th>Test</th>
<th>Clinical Significance</th>
<th>Consequence of Limited Access</th>
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<tbody>
<tr>
<td>CD4 test</td>
<td>Failing immune system: ART eligibility for adults and children over 5</td>
<td>Delayed treatment: greater morbidity and mortality from HIV/AIDS</td>
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<tr>
<td>EID test</td>
<td>HIV positive status of infants: immediate treatment</td>
<td>Delayed treatment for infants living with HIV: without treatment, 50% of HIV infected infants die by age 2 years</td>
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<tr>
<td>VL test</td>
<td>Treatment failure: switch to second line antiretroviral drug regimen</td>
<td>Late switching to second line treatment: greater morbidity and mortality from HIV/AIDS</td>
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Filling the gap: Point of Care technologies

A new generation of POC HIV diagnostic technologies is under development. Unlike conventional diagnostics, POC diagnostics do not require sophisticated laboratory infrastructure and can typically be operated by lower cadre health care workers. This enables the provision of diagnostic services in more remote areas, which improves equity. POC diagnostics enable same day test results, reducing loss-to-follow-up and facilitating timely life-saving clinical decisions closer to patients, which strengthens the effectiveness of treatment. Same day test results also reduce wastage from results never being received by patients, which contributes to efficiency.

There is potential for POC tests to revolutionize access to CD4, EID and VL testing, and significantly impact HIV treatment outcomes. New POC diagnostic products will likely be available for evaluation and use in 2013 and 2014, as detailed in the UNITAID landscape analysis of HIV diagnostics.²

Expected outcomes and impact

The initial phase of the project focuses on preparing the POC diagnostics market for accelerated scale up. The subsequent phase will focus on scale up and implementation in alignment with the new 2013 World Health Organization (WHO) HIV Treatment Guidelines.

At the market level, this project will help to foster a healthy, competitive market, with multiple competing products in each product class (CD4, EID, and VL), improved information on the demand for these products, and encouragement for new suppliers to invest in the development and production of POC diagnostics that meet the need in resource limited settings.

At the country level, project outcomes will include timely regulatory and policy approvals for a range of new products in focus countries, development of a decision making process for rational deployment, research to support appropriate implementation, development of in-country systems to rapidly scale up POC testing, and overall strengthening of laboratory systems. The lessons learned will also be incorporated within international normative guidance on HIV laboratory and treatment services.

At the public health level, the introduction of POC HIV diagnostic technologies will result in a significant reduction of morbidity and mortality in countries with a high burden of HIV/AIDS (due to earlier treatment initiation and switching to second line treatment). This has the potential to improve long-term population level prevention. The technologies will also create long-term savings within health systems.

Finally, at the individual level, improved access to HIV diagnostics will reduce time and costs for clients seeking HIV services. This has the potential to improve the health and lives of millions of those living with HIV/AIDS.
For further information, please see:

http://www.clintonhealthaccess.org

http://www.unicef.org/aids/index.html

http://www.unitaid.org