

## **New rapid CD4 test could be game-changer for people with advanced HIV disease**

While many rich countries struggle to cope with COVID-19, the global health community is racing against time to help contain the potentially devastating impact of the virus in resource-limited countries with weak health systems. The biggest fear is that over-stretched health facilities in the poorest countries could implode if COVID-19 spreads uncontrollably, putting at risk patients receiving treatment and care for other diseases such as HIV and tuberculosis. Unitaid and its partners are ramping up efforts to introduce solutions with potential to take pressure off over-burdened health systems. The latest is a rapid CD4 test, that holds out the promise to improve care for patients with advanced HIV disease. We talked to Robert Matiru, Director of Programme Management at Unitaid, about the initiative.

### **Why does Unitaid seek wider access to rapid test kits for CD4 cell counts?**

An easy-to-use portable test is now available that can quickly determine whether a person's CD4 cell count – which measures the resilience of the immune system – has dropped to a critical level. Effective and widely available CD4 testing is vital for countries to be able offer the best possible treatment and outcomes to patients with advanced HIV disease. These are people whose immune system is dangerously weakened by the time they start antiretroviral therapy, or resume it after a break in treatment. We want to get many more of these tests carried out as close as possible to the point of care, including in villages and small

towns, where more complex diagnostic tools are harder to access.

### **Will the new test make it easier to manage advanced HIV disease?**

Yes, it will. The new test, known as the VISITECT CD4 Advanced Disease test, is more affordable than existing laboratory-based tests; requires no additional equipment; and can be used in all kinds of health facilities. It has the potential to identify more people with advanced HIV disease more rapidly so that they can receive the right treatment before they fall seriously ill.

### **What kind of CD4 testing has been on offer until now?**

Conventional and point-of-care equipment-based tests are run on platforms, requiring investment in equipment and maintenance. Blood samples are taken from the patient at a health clinic and are then sent to a laboratory, which is sometimes outside the facility. This may require patients to return a week or two later to the clinic to get their results before follow-up treatment can begin. Omega's CD4 diagnostic can test individual blood samples instantly, which will speed up case management and also alleviate the burden on healthcare systems.

### **Why is advanced HIV disease so dangerous?**

About one third of all people with HIV who start antiretroviral therapy have advanced HIV, previously known as AIDS,

and are therefore at risk of opportunistic disease and death. Around 10 percent of these patients die within three months of beginning therapy. This is because the weaker the immunity of an infected person, the less able they are to fight off opportunistic infections, such as pneumonia and cryptococcus, that can prove fatal. The WHO recommends that all patients starting or restarting HIV therapy should first be given a CD4 test. If their CD4 count is below 200, they are deemed to have advanced HIV disease and may have to take drugs to prevent or treat opportunistic infections. Such patients are also very exposed to the spread across the globe of COVID-19, which is particularly dangerous for people with pre-existing health conditions.

### **What else is Unitaid doing to fight advanced HIV disease?**

Our investment in rapid CD4 testing is part of a wider initiative, in partnership with the Clinton Health Access Initiative (CHAI), to bring treatments and diagnostics to low and middle-income countries so they can manage advanced HIV more effectively. The \$20 million CHAI grant aims to expand access to a package of care for advanced HIV disease that can then be scaled up by countries and funding partners.

### **How will Unitaid go about introducing the new rapid CD4 tests?**

We aim to kickstart the creation of a market for affordable tests by funding up to 500,000 tests for each country that

meets the selection criteria. Unitaid, CHAI and Omega Diagnostics, which at the moment is the only company to make a disposable test, have agreed a price deal to help deliver CD4 tests at US\$3.98 in more than 130 low-and middle-income countries. This would be the lowest price for such a test anywhere in the world. By comparison other tests cost from US\$5.50 to US\$9.0. In order to accelerate introduction of the new diagnostic, Unitaid has set up an Early Market Access Vehicle, to be managed by CHAI, to facilitate market introduction and establish a body of evidence for the product's use which can help countries plan how to scale up point-of-care use of the device in decentralized facilities.

Beginning on 28 April, [CHAI and Unitaid](#) have been accepting Expressions of Interest and admitting selected partners on a rolling basis until September 30, 2021 – or when maximum volume commitment of 500,000 tests is delivered ([hyperlink to CHAI website](#)). Selected implementing partners can qualify for Unitaid-funded procurement of the testing device.

### **Which countries are most likely to be early adopters of the test?**

Malawi, Nigeria and Uganda are among potential first movers and we hope that if the rapid tests are successfully introduced, governments will then scale up their use with support from funding partners such as the Global Fund and PEPFAR.

[www.unitaid.org](http://www.unitaid.org)