

MIT OpenCourseWare
<http://ocw.mit.edu>

HST.939 Designing and Sustaining Technology Innovation for Global Health Practice
Spring 2008

For information about citing these materials or our Terms of Use, visit: <http://ocw.mit.edu/terms>.

Deploying Rapid CD-4 Tests for HIV/AIDS

Background

More than 35 million HIV-infected people live in the developing world, where resources are scarce. In 2002, the U.S. National Intelligence Council (NIC) predicted that the number of HIV-infected individuals in the developing world would rise to 80 million by 2010. Effective antiretroviral therapy (ART) for HIV has been available in developed countries for more than a decade. Worldwide, 1.3 million people are currently receiving treatment. To increase access to HIV care and improve treatment outcomes, there is an urgent need for low-cost diagnostic tools that could be implemented in developing countries.

The absolute number of CD4+ T lymphocytes in blood is vital for evaluating HIV-infected patients and has important prognostic and therapeutic implications. The CD4 count is used to initiate treatment and to monitor the response to treatment. Guidelines recommend that patients be monitored routinely for CD4 counts. In high-income settings, CD4 counts rely on flow cytometry. Available flow cytometers cost from \$30,000 to \$150,000, and a single CD4 count can cost upwards of \$50 per result, including labor costs and maintenance expenses. While lower prices are available in some resource-limited countries, the cost remains unaffordable as well as inaccessible due to geography for many patients since the test must be performed at a central laboratory.

Challenge

A new point-of-care, low-cost (<\$1), disposable, microfluidic device, which uses a finger stick blood sample (<10 μ l) and produces a CD4 count rapidly (<1 min) with on-chip sample handling has been created. It is thought that this new invention will greatly accelerate CD4 counting in resource-limited settings. To date the inventors of this new device have contacted several leading research units within the US and Europe specializing in global health research in resource poor settings. Each time the investigators have been told that funding is not available for development of such devices. However they can apply for an NIH innovations grant which might take upwards of 2 years to secure, with only a 20% likelihood of actual success. Furthermore diagnostic companies have created controversial advertising campaigns to potential donors and ministries of health raising questions regarding the efficacy of the device even though studies have demonstrated the sensitivity and specificity of the rapid test is identical to existing technologies. Furthermore representatives of USAID and PEPFAR have raised concerns over absorptive capacity of health workers to change from existing methods and the amount of in-service training required ensuring a successful product adoption rate.

Thought questions

- What key questions should the inventors of the rapid CD4 test address specific to adoption? (HINT: distinguish between users versus payers.)
- What alternative sources of funding should the inventors seek above and beyond traditional federal and donor grants? What are the advantages and disadvantages to these new sources of funding?
- What technologies might be available to support in-service training to reduce both cost and time associated to new product adoption?