New HIV test for infants seen as possible breakthrough for sub-Saharan Africa

October 26 2012, by Peter Frost And Melissa Harris, Chicago Tribune

In HIV-plagued sub-Saharan Africa, it can take up to three months for mothers to learn whether their babies have been infected by the deadly virus, delaying what could be life-sustaining treatment.

Many of the far-flung and rudimentary public health clinics aren't equipped with basic services such as reliable electricity and refrigeration, let alone the sophisticated laboratories required to process HIV tests for infants.

As a result, tests must be sent off to a lab. Because of that delay, even among women willing to walk miles to get their infants tested, more than half never receive the results.

A team at Northwestern University say they are on the verge of addressing the problem. On Friday, they planned to unveil a new HIV test for infants of mothers who have tested positive for the virus, which promises to produce a result in less than an hour at a palatable cost.

The researchers say the product could be a breakthrough for early diagnosis and treatment of HIV in sub-Saharan Africa, where an estimated 22.5 million live with the virus, representing more than two thirds of the global total, according to 2009 figures from UNAIDS, the Joint United Nations Program on HIV/AIDS.

Infants diagnosed early can be placed on anti-retroviral drugs that help them manage the disease for decades. More than half of those who aren't

treated die within two years, according to the U.N. data.

Designed by David Kelso, a Northwestern biomedical engineering professor, with the help of Abbott Laboratories, Quidel Corp. and others, the new medical device is targeted specifically for testing infants in rural Africa.

The effort, funded largely through a $5 million grant from the Bill & Melinda Gates Foundation, has been a decade in the making and underscores the gap in delivering much-needed medical care in developing nations in the absence of a guaranteed corporate profit.

Snap tests for HIV in adults are widely available in Africa because there's a huge market for them. But they don't work on infants because they measure antibodies, a protein the body produces in response to infection. Because the vast majority of infants in Africa are breastfed, nearly all of them receive the antibodies from their mothers and test positive for HIV.

But that doesn't mean they have the virus itself.

Existing tests for infants in the developed world rely on expensive and sophisticated equipment.

Kelso's device is about the size of a single-slice toaster and runs on battery power. It was designed to be used by lightly trained nurses or community health workers and is estimated to cost less than $500.

His team aims to drive the cost of performing each test below $10 and get the equipment in as many rural public health clinics as possible. The plan is for mothers of infants who test positive to leave the clinic with at least a month's supply of anti-retroviral drugs.

Dr. Elaine Abrams, a leading HIV researcher and professor of pediatrics and epidemiology at Columbia University in New York, said the device is a welcome innovation, but said it is "a big leap" to think it will result in significantly more HIV-positive infants receiving treatment.

The Northwestern researchers intend to tackle that question in a clinical trial scheduled to begin in early 2013 in Mozambique.

The device will first be evaluated in five clinics in the capital city of Maputo and eventually be expanded to rural settings, where researchers will measure the accuracy of the test, how its availability affects the number of infants tested and how many of those found to be HIV positive are treated.

Results from a first round of trials conducted in South Africa earlier this year were promising. In a sample of 634 infants, researchers found the device was 99.4 percent specific - meaning there's less than a 1 percent chance that the test would produce a false positive - and 95 percent sensitive, meaning there's a 5 percent chance they'll miss an infected baby.

"It may sound as though a 5 percent error (is) really large," Kelso said. "But it's better than the current methods available in some countries ... where less than half of those results ever get reported to the mothers. With those procedures, there's a 50 percent chance a positive baby isn't going to get detected."

The effort to develop the device began about a decade ago, and involved Kelso teaming up with Kara Palamountain, a health care consultant who was pursuing an MBA at Northwestern and had an interest in Africa.

After they won the Gates Foundation award, Kelso turned to North Chicago-based Abbott Laboratories, his former employer and a major

international player in the HIV test-device market, for help developing the device.

The company agreed to lend two proprietary antibodies to Kelso for use in his research and provided lab space and scientists.

As part of their agreement, Abbott had first right of refusal on marketing and distributing the product with the caveat that it must provide the equipment for humanitarian missions at cost.

John Robinson, senior director of collaborative research management in Abbott's diagnostics division, said the company declined the option because it no longer has the expertise nor manufacturing facilities to produce the devices or the test strips they use.

"This is not a business we're really in, and we had no intention to ever make (or distribute) this product, because it's not what we do," Robinson said. "But we felt it's a very important program and we wanted to really support David."

To manufacture and distribute the test, Northwestern created a nonprofit foundation.

"It's always nice if you can utilize the capabilities of a commercial partner - in some sense, that may have been easier," said Daniel Diermeier, a Kellogg School of Management professor and the chairman of the Northwestern Global Health Foundation. "On the other hand, you can really design it the way you want to do it."

The nonprofit foundation will act in much the same way as a commercial medical device company: It will outsource manufacturing, set up distribution channels and manage sales and inventory.

Some wonder whether the test can be adopted widely.

"Things like this are wonderful and can save some lives," said Daniel Halperin, a public health expert at the University of North Carolina. "But it's not going to have an earth-shattering impact on the AIDS epidemic in Africa."