Rapid Diagnostic Tests Could Benefit Millions In The Developing World

University of Cambridge

Chlamydia trachomatis is an enormous global public health problem—infecting more than 90 million annually in both the developed and developing world.

As the most prevalent bacterial pathogen causing sexually transmitted disease (STD), chlamydia frequently causes Pelvic Inflammatory Disease (PID) and its long-term consequences, which include chronic pain, ectopic pregnancy and infertility. It also can cause sterility in woman and it is the main cause of blindness in babies in the developing world. The World Health Organization (WHO) recognizes it as a major cause of disability in affected communities in Africa, the Middle East, Central and Southeast Asia.

The infection is difficult to diagnose, with around 70 percent of female carriers and 50 percent of male carriers showing no symptoms. But if detected early, the disease is very easy to treat with one antibiotic pill.

Can chlamydia be detected early and thus treated? Researchers at the University of Cambridge in the United Kingdom and various funding partners— Wellcome Trust, WHO and National Institutes of Health—believe that it can through rapid diagnostic tests for the chlamydia infection.

Almost 10 years ago a group of industry scientists who worked at a multinational diagnostic company set up the Diagnostics Development Unit at the University of Cambridge. Led by Helen Lee, Ph.D., Associate Professor of Medical Biotechnology, the team's goal was to develop innovative, simple, rapid and inexpensive but high performance tests for the detection of infectious agents in developing countries.

The company "Diagnostics for the Real World" was established in 2002, acquiring rights to the founding technology from Cambridge Enterprise, the University's technology transfer office. The first product to emerge from their research is called FirstBurst, a "dipstick" test that gives results in half an hour.

> *The speed of the diagnostic test enables health care providers to treat patients immediately instead of having them return to a clinic after two or three weeks.*

It is ideal for use in the developing world as well as in clinical settings in the developed world. FirstBurst received the CE mark from European Union authorities and is scheduled to be presented to the U.S. Food and Drug Administration for approval.

The antibody-based dipstick relies on a patented sensitive visual amplification detection technology platform called the Signal Amplified System (SAS), which provides a strong visual signal that chlamydia is present. Inexpensive, robust and stable, the device is easy to use and non-invasive because it uses selfcollected vaginal swabs for women and the first few milliliters of urine for men. Field development work and trials in the Philippines and the United Kingdom proved it to be a more effective than any of the rapid tests currently available when compared to the "gold standard" nucleic acid-based test.

Lee and her colleagues still hold true to their altruistic goal: to develop innovative, simple, rapid and inexpensive tests for the detection of infectious agents in developing countries. They are exploring ways to develop tests that use their patented technology platforms for the detection of hepatitis B virus (HBV), human immunodeficiency virus (HIV) and hepatitis C virus (HCV). Today, the team also runs Diagnostics for the Real World, a California-based spin-out company that provides a business structure to deliver the much needed diagnostic tests to resource-limited settings in both the developed and developing world. The company is on sound footing because Cambridge Enterprise, the University of Cambridge technology transfer company, and Wellcome Trust, the United Kingdom's largest non-governmental source of funds for biomedical research, collaborated to establish the intellectual property ownership that led to the formation of the spinout in 2002.

"As our corporate shareholders, they have supported us throughout the years, from the development of our platform technologies, to the launch of our first product and on through the design of our business model," said Lee. "Now, we would like to successfully implement a two-tiered pricing policy to provide the tests to the developing world at near to manufacturing cost, and work with distributors as well as non-government organizations so the FirstBurst test is applied in settings where the more than 90 million people annually infected by chlamydia can be diagnosed and treated early."

This story was originally published in 2009.

To see available technologies from research institutions, click here to visit the AUTM Innovation Marketplace.