

Advancing a New Diagnostic Test for Onchocerciasis in Africa

Health need

Onchocerciasis, or river blindness, is a major cause of preventable blindness around the world. Caused by parasitic worms transmitted to humans through the bite of the blackfly, onchocerciasis typically affects poor, rural communities near fast-flowing streams and rivers. An estimated 180 million people are at risk for the disease, and 37 million people are infected. Most of the disease burden is in Africa, where affected individuals experience intense itching, severe skin disfiguration, and—with years of repeated exposure—permanent blindness. In addition to its health effects, the disease leads to massive economic losses when productive agricultural lands are abandoned for fear of infection.

Programs to control blackflies with insecticides and mass treatment of affected communities with Ivermectin have succeeded in reducing the disease burden. As efforts move from disease control to elimination, better diagnostic tools will be needed, especially for monitoring post-control areas for signs of reinfection and for detecting cases in low-prevalence areas. PATH is developing a new diagnostic test that can be used to support programs as they move to the disease elimination phase.

Technology solution

PATH is developing a rapid test for onchocerciasis that is based on the detection of antibodies to the parasite antigen Ov16. The new test will address limitations of existing diagnostic tools in use. Anticipated advantages over current methods include point-of-care use, low cost, rapid results, minimal training requirements, the need for only a finger prick to collect blood samples for analysis, and the ability to detect early infections.

Current status and results

The Ov16 rapid test will be used in the context of post-elimination monitoring of communities that have been treated with ivermectin for many years. The test will be used to monitor the communities to detect any possible reemergence of the infection so that immediate action can be taken.

We have successfully developed test prototypes that were evaluated for performance at the National Institutes of Health in April 2012. The results of the alpha prototype evaluation were excellent; the prototype met all performance benchmarks. Additionally, we completed a usability study to understand how users interact with the test and are incorporating the user feedback into the design of the next prototype. We are partnering with the African Programme for Onchocerciasis Control and other researchers for the field-based evaluations of the beta prototypes, which began in June 2013.

In 2011, we completed on-site manufacturing assessments of six companies located in India, South Africa, and South Korea and identified three potential manufacturers to commercialize the test. In 2012 we selected Standard Diagnostics as our manufacturing partner. A technology transfer process has begun, and verification of their first article Ov16 tests is expected later this year.



PATH/Allison Golden

Ov16 rapid test prototypes.

“During these past 15 years, most of the efforts have been geared towards the control of onchocerciasis as a major public health problem affecting millions of persons among the poorest. Now, scientific evidence has demonstrated the feasibility of onchocerciasis elimination, thus opening a window of hope for the future.”

Dr. Paul-Samson Lusamba-Dikassa, Director, African Programme for Onchocerciasis Control (APOC), from “15 Years of APOC, Unique Global Public-Private Partnership”

Availability

For more information regarding this project, contact Tala V. de los Santos at tdeossantos@path.org.

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