Onchocerciasis Point-of-Care Rapid Test

Funded by the Bill & Melinda Gates Foundation

NEED

River blindness—also known as onchocerciasis—is a parasitic infection transmitted to humans through the bite of the blackfly. It causes itching, skin disfiguration, and, with chronic exposure, permanent blindness. It also leads affected communities to abandon productive agricultural fields for fear of infection. Worldwide, approximately 26 million people suffer from the disease, and an estimated 123 million are at risk, mostly in poor, rural communities near streams and rivers in Africa.

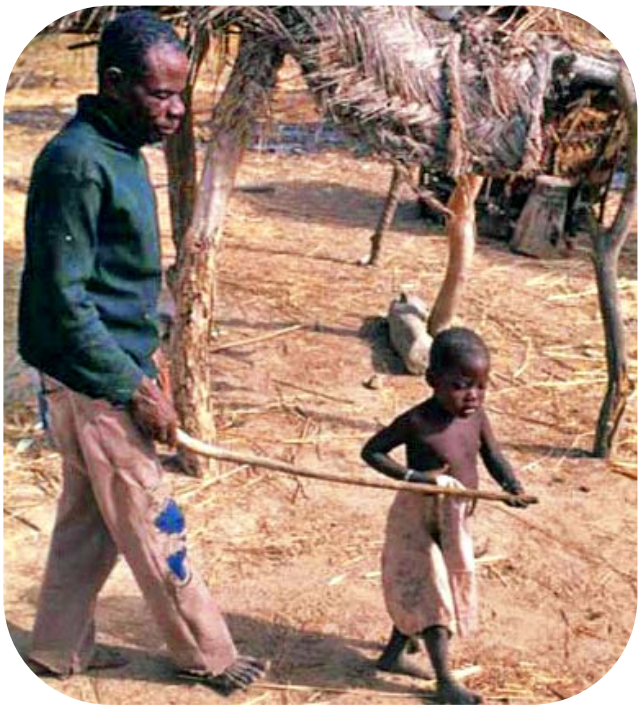
Onchocerciasis and other neglected tropical diseases (NTDs) exact a devastating toll on vulnerable communities in sub-Saharan Africa, Asia, and Central and South America. Through illness, disability, pain, and suffering, they are damaging to health and economic development and perpetuate cycles of poverty and inequity. Recognizing this threat, the World Health Organization (WHO) has targeted 17 NTDs, including river blindness, for control, elimination, or eradication by 2020. Developing new diagnostics is one key priority to meet these goals.

International partnerships have helped reduce the burden of onchocerciasis by ensuring that affected communities can access the only effective treatment, a drug called ivermectin. In many regions, a combination of mass drug treatment and blackfly control has decreased disease prevalence, paving the way for elimination. In the past two years, WHO declared two countries in the Americas, Colombia and Ecuador, free of the disease.

Moving toward elimination relies on continuous, community-wide testing, which allows control programs to target efforts and monitor disease recurrence. Until now, the best available test was an invasive, labor-intensive procedure called a skin snip. Achieving the WHO elimination goals in African countries requires better diagnostic tools.

GOAL

The goal of this project was to develop an affordable rapid test that is easy to use with minimal training requirements, requires less invasive sampling methods, and provides faster results. Its design features make the test practical and convenient for use in the field.



An old man, blinded by onchocerciasis (river blindness), grasps the thin wooden stick that he uses to help him walk around his village. Children are often called upon to act as guides, leading the blind on the end of their wooden sticks. Photo: WHO/TDR/Ward

In combination with other strategies, a simple, field-friendly, and affordable rapid test could be a powerful tool for use in Africa as onchocerciasis programs move from control to elimination. One target application is the use of the rapid test in post-control areas. In these places, the test can be used to screen children for exposure and recent infection, indicating recent or ongoing transmission. Together with epidemiological and entomological data, results from the rapid test could allow for timely actions to suppress possible reintroduction of infection into a given area.

APPROACH

PATH has collaborated with the US National Institutes of Health (NIH), a South Korean manufacturer, and others to bring a new rapid test for river blindness to market. The simple, affordable test will support efforts to accelerate elimination of the disease and prevent the recurrence of river blindness in endemic areas.

SD BIOLINE Onchocerciasis IgG4 pre-production prototype. Photo: PATH/Dunia Faulx

The new point-of-care test developed by PATH is based on the detection of antibodies to a parasite antigen called Ov16, which was identified by scientists at the National Institute of Allergy and Infectious Diseases (NIAID), part of NIH. The test detects exposure to *Onchocerca volvulus*, the parasite that causes onchocerciasis, by checking for Ov16 antibodies in a single drop of blood from a finger prick. It is fast, accurate, easy to use, and less painful for patients than the skin-snip test.

In 2012, the NIAID evaluated test prototypes and found excellent performance. In addition, PATH studied how users interacted with the test and used their feedback to refine the test's design.

PATH partnered with two organizations in the endemic country of Togo to conduct field-based evaluations in early 2013. The goal of this work was to evaluate the performance of the test in field conditions. PATH compared the Ov16 antibody test to the two proven methods of diagnosis, the skin-snip and the ELISA test, evaluating dried blood spots in the laboratory, collected during field work. Using the valuable data provided by the field study, PATH further refined the test.

To bring the test to market, PATH sought a manufacturing partner that could meet regulatory and process requirements to create and effectively distribute the product at an affordable price. After onsite assessments of several candidates, PATH selected Standard Diagnostics, Inc. (SD), based in South Korea.

In early 2013, PATH transferred the technology for the test to SD, which pursued regulatory approval and prepared for manufacturing.

PATH also began follow-up laboratory- and field-based evaluations of the test in the first half of 2014 with its previous partners in Togo. The results of this work informed the final iterations of the test prototypes.

STATUS

PATH and SD launched the SD BIOLINE Onchocerciasis IgG4 rapid test in November 2014. The test is available through SD, which is handling all ordering, manufacturing, and distribution. The test is the first in a suite of diagnostic innovations by PATH intended to support the elimination of NTDs.

NEXT STEPS

PATH is providing forecasting and production planning support to SD during the initial launch year. Furthermore, PATH is actively engaging key stakeholder and country programs to support the inclusion of the new tool in ongoing surveillance efforts alongside existing methods. PATH is working with implementation partners to offer technical assistance, training materials, access to positive control, and more.

The new test, together with mass drug treatment, has the potential to help vulnerable communities finally end the suffering caused by onchocerciasis.

FOR MORE INFORMATION

For more information or to talk with PATH about collaborating, please contact Tala de los Santos, project leader, at dxinfo@path.org or visit PATH online at http://sites.path.org/dx/ntd/oncho.

PATH

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PATH is the leader in global health innovation. An international nonprofit organization, we save lives and improve health, especially among women and children. We accelerate innovation across five platforms—vaccines, drugs, diagnostics, devices, and system and service innovations—that harness our entrepreneurial insight, scientific and public health expertise, and passion for health equity. By mobilizing partners around the world, we take innovation to scale, working alongside countries primarily in Africa and Asia to tackle their greatest health needs. Together, we deliver measurable results that disrupt the cycle of poor health. Learn more at www.path.org.

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