Dual-detection, point-of-care test for lymphatic filariasis and onchocerciasis

NEED

Neglected tropical diseases (NTDs), such as lymphatic filariasis (LF) and onchocerciasis, are a group of 17 infectious diseases that affect some of the poorest people in the world. These diseases cause disability, stigmatization, pain, and suffering for up to 1.4 billion people around the world. Women and children are especially vulnerable to the effects of NTDs—which can last a lifetime—on their health and development. Finally, NTDs contribute to a cycle of poverty as people become too ill or disabled to work or attend school.

In the past few years, significant progress has been made possible through commitments from donors and private-sector partners to accelerate efforts to achieve the World Health Organization’s (WHO) goals for controlling or eliminating ten NTDs through the London Declaration. Elimination is increasingly envisioned as a feasible target for many diseases, including onchocerciasis and LF.

As global NTD disease burdens decrease and efforts shift from purely control tactics to an elimination strategy, program implementers need affordable, efficient, and user-friendly diagnostic tools with the required sensitivity and specificity to monitor progress and to continue surveillance to prevent the reemergence of disease.

LF, also known as elephantiasis, is a painful and profoundly disfiguring NTD. More than 1.3 billion people in 73 of the poorest countries in the world are at risk, with approximately 95 percent living in Africa and Southeast Asia. LF afflicts more than 25 million men with genital disease and more than 15 million people with lymphedema (swelling of the arms and legs).

LF is caused by three types of parasitic worms transmitted to humans through mosquito bites. Approximately one-third of all LF cases are in Africa and are caused solely by the Wuchereria bancrofti (Wb) parasite. The adult worms live and replicate in the victim’s lymphatic system, compromising the immune system and resulting in a variety of complications.

Onchocerciasis, also known as river blindness, is spread by the bite of a blackfly carrying the Onchocerca volvulus (Ov) parasite. This disease causes itching, skin disfiguration, and, with chronic exposure, permanent blindness. Onchocerciasis typically affects poor, rural communities near streams and rivers. Worldwide, an estimated 123 million are at risk, and 26 million people suffer from the disease, 99 percent of whom live in sub-Saharan Africa.

A woman and child in Burkina Faso, where lymphatic filariasis is endemic.

Most of the countries endemic for onchocerciasis are also endemic for LF. In these areas, control and elimination programs have cooperated for several years to deliver ivermectin for mass drug administration (MDA) efforts. Additionally, in some countries, NTD control programs share resources and staff. For these reasons, there is a growing interest in the global NTD control community to coordinate surveillance efforts between the programs.
The current lack of available combined tools, as well as the overlap in diseases and desire to be more effective in delivering treatments, has led to the need for a single diagnostic tool for the surveillance stage of combined programs in co-endemic areas.

GOAL

The goal of this project is to make an effective onchocerciasis and LF dual-detection—or “biplex”—test accessible to the NTD control and elimination community, and to facilitate its adoption into integrated control and elimination programs. The tool needs to be sufficiently sensitive, specific, and convenient to be appropriate in the mostly rural and low-resource areas where the two diseases overlap.

APPROACH

PATH is collaborating with the National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC), and the Task Force for Global Health to develop the biplex test, ultimately in support of the WHO goals for eliminating both diseases by 2020.

The new point-of-care test PATH is developing simultaneously detects antibodies generated in response to both the Wb123 antigen from *W. bancrofti* and the Ov16 antigen from *O. volvulus*. These antigens were identified by scientists at the National Institute of Allergy and Infectious Diseases (NIAID), part of the NIH. The test will detect exposure to both parasites by checking for antibodies in a single drop of blood from a finger prick. Test results for serum antibody responses to both diseases will be available in the same display window.

The anticipated primary use case for this test will be in co-endemic areas where MDA for both diseases has been ongoing for several years. In these now low-prevalence areas, antibody-detection tests in children under the age of ten years give important information about recent transmission rates. Data from these surveillance studies may then be used to make critical decisions about whether to continue, halt, or reinitiate MDA efforts.

STATUS

PATH and its manufacturing partner, Standard Diagnostics (SD), are working with NIAID to advance the biplex test.

In the fall of 2014, PATH and SD launched the SD BIOLINE Onchocerciasis IgG4 rapid test, a point-of-care test for exposure to onchocerciasis, manufactured and sold by SD. Development of this test established the partnership with SD, facilitating the technology transfer and communications needed to move efficiently through the biplex development.

NEXT STEPS

PATH is currently planning field evaluations of the test, as well as continuing laboratory evaluations, to better characterize its performance and stability.

PROJECT PARTNERS

African Programme for Onchocerciasis Control
AbD Serotec, a Bio-Rad company
Centers for Disease Control
National Institute of Allergy and Infectious Diseases
Standard Diagnostics, Inc./Alere
The Task Force for Global Health
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