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USAID Health-Related Research and Development Progress Report

An Update on the 2011–2015
Health Research Strategy





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NEGLECTED TROPICAL DISEASES

Neglected tropical diseases (NTDs) affect more than 1 billion people worldwide and disproportionately impact poor and rural populations. NTDs not only cause severe sickness and disability, but also compromise mental and physical development, contribute to childhood malnutrition, reduce school enrollment, and hinder economic productivity.

The U.S. Agency for International Development's (USAID's) NTD Program targets seven of the most prevalent NTDs, including: lymphatic filariasis (LF), blinding trachoma, schistosomiasis, onchocerciasis, and three soil-transmitted helminthiasis. Since its launch in 2006, USAID's NTD program has supported country-led efforts to introduce and scale up delivery of preventive drug treatments for these diseases. This approach, known as mass drug administration, is safe, effective, cost efficient (~30 cents/person/year), and endorsed by the World Health Organization (WHO).

Despite great progress, new tools and strategies are needed to overcome emerging challenges and guide both programmatic decision-making and post-intervention disease surveillance. In 2014, USAID and the Bill & Melinda Gates Foundation jointly created the Coalition

on Operations Research in Neglected Tropical Diseases. This coalition enables a broader reach of research partners and input from country programs, improves global coordination across the research spectrum, and aims to remove barriers and accelerate progress toward the WHO 2020 NTD goals.

To this end, USAID is committed to supporting the following five operations research goals:

Goal 1: Support innovative approaches in disease mapping

Information about the geographic distribution of individual NTDs is limited, particularly in areas of sub-Saharan Africa where NTDs such as Loa loa infection (a disease of the skin and eye) may be co-endemic, and better programmatic approaches to eliminating LF and onchocerciasis are urgently needed. Additionally, the mapping strategy utilized in the past for LF is not sufficiently robust to support programmatic decision-making in very low prevalence settings. A new protocol based on cluster sampling and endorsed by WHO has been developed to re-evaluate LF in these settings.

Recent research validated a new survey protocol for LF re-mapping in areas where initial mapping data were insuf-

A mother is holding her infant for a blood sample to measure trachoma antibody levels in the high lands of the People's Democratic Republic of Lao; courtesy of a USAID-funded partner and the Lao PDR Ministry of Health.

HEALTH RESEARCH GOALS

- 1. Support innovative approaches in disease mapping**
- 2. Develop new laboratory diagnostics and tools**
- 3. Support best practices for monitoring and documenting progress toward elimination**
- 4. Develop tools to manage morbidity**
- 5. Deliver a macrofilaricide for onchocerciasis and lymphatic filariasis**

PRIORITY COUNTRIES

- Bangladesh
- Benin
- Burkina Faso
- Cambodia
- Cameroon
- Cote d'Ivoire
- Democratic Republic of Congo
- Ethiopia
- Ghana
- Guinea
- Haiti
- Indonesia
- Laos
- Mali
- Mozambique
- Nepal
- Niger
- Nigeria
- Philippines
- Senegal
- Sierra Leone
- Tanzania
- Togo
- Uganda
- Vietnam



Field laboratory technicians perform rapid diagnostic tests to measure filaria antigen levels in Tanzania; courtesy of a USAID-funded project and the Tanzania Ministry of Health.

efficient for programmatic decision-making. The protocol was field-tested in areas where the LF disease prevalence was uncertain to determine if LF transmission is ongoing and mass drug administration is necessary. The study was conducted in areas found to have antigen prevalence of greater than 1 percent but where treatment had not yet been initiated to validate the protocol. The new protocol was used to re-map 63 districts in the north and west of the country, and all districts were found not to require treatment (prevalence < 1 percent). The study allowed Tanzania to “shrink the map” of where drug treatment was needed, thus providing considerable cost savings. Tanzania has now initiated LF treatment in all endemic districts and is beginning to scale down mass drug administration. The country is likely to eliminate LF by 2020, as planned.

Goal 2: Develop new laboratory diagnostics and tools

Diagnostic tools used for disease surveillance must be capable of detecting incident infections in children with great sensitivity and specificity. Programmatic decisions on when to stop mass drug administration are based on surveys that document that the infection levels have been reduced below a given threshold, using clinical, parasitologic or serologic measures. As new tools become available, USAID will validate and work with

the Coalition on Operations Research in Neglected Tropical Diseases and others to make validated tools more widely available to support research activities.

Capacity building efforts will be focused heavily on building operational research expertise to support: 1) NTD country program manager’s challenges; and 2) post-mass drug administration program evaluation and surveillance efforts. Regional consultants will be engaged to act as trainers in the regions and provide technical support when needed for surveillance, WHO validation dossiers, and use of new diagnostics tools and survey methods among others.

Goal 3: Support best practices for monitoring and documenting progress toward elimination

An ongoing collaboration with WHO through the Coalition on Operations Research in Neglected Tropical Diseases is focused on validating new recommendations for incorporating soil-transmitted helminthiasis assessments in the LF transmission assessment survey. USAID will complement this by supporting the testing and utility of these new tools for evaluating program impact at scale as they become available.

USAID is also focused on determining when to stop drug treatment of populations using a scientifically rigorous, patient safety-centered coordinated effort. These efforts increase program efficiency and reduce costs by decreasing both training requirements and costs of conducting surveys. USAID is comparing tools for antibody, antigen, or DNA detection with the older techniques for NTDs in USAID-supported countries assessing stopping-mass drug administration programs.

In areas of LF/onchocerciasis overlap, the success of both programs is inextricably linked because of the necessity to coordinate the decision to stop mass drug administration and initiate post-mass drug administration surveillance. With the emerging interest on elimination of onchocerciasis in Africa, operational research is urgently needed to determine how best to coordinate program decision-making. With the development of the new laboratory tools to detect antibodies to both LF

and onchocerciasis with one test, USAID will seize new opportunities to test and validate these integrated surveys.

USAID uses operational research to improve programmatic efficiency and is currently focused on integrated approaches to transmission assessment and post-mass drug administration surveillance efficiencies. For example, USAID is exploring integrated surveillance for onchocerciasis and LF in post-mass drug administration surveillance. Re-establishing verification of elimination of LF as a WHO target is an important operational research objective that provides a stronger measure of success for U.S. Government-funded programs.

Goal 4: Develop tools to manage morbidity

Although mass drug administration programs will reduce the development of new morbidity from LF and trachoma, the approach does not address morbidities among those suffering from existing disease. Thus, the NTD office will support operations research to country programs to assess the disease burden and how to address it.

USAID, through the Coalition on Operations Research in Neglected Tropical Diseases, will launch a multi-center clinical trial of doxycycline. This trial will help confirm earlier research results that the antibiotic may be an effective treatment for the debilitating limb-swelling caused by LF.

Goal 5: Deliver a macrofilaricide for onchocerciasis and lymphatic filariasis

The USAID NTD Program is developing a macrofilaricide for use in individual case management and as an alternative preventive treatment in mass drug administration programs. A macrofilaricidal drug could reduce the number of mass drug administration cycles needed for onchocerciasis and LF, thereby easing program implementation and enhancing chances of disease elimination. Ongoing investments aim to measure efficacy using imaging/nano technologies and in-vivo cattle model testing.

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