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## **U.S. Agency for International Development (USAID) Report to Congress On Health-Related Research and Development for Fiscal Year (FY) 2017**

The U.S. Agency for International Development (USAID) submits this report, and associated five-year Strategy on Health-Related Research and Development, pursuant to Section 7019(e) of Division K of Public Law 115-141, the Department of State, Foreign Operations, and Related Programs Appropriations Act, 2018, which incorporates by reference the requirements of Senate Report 115-152, which directed that:

*The USAID Administrator shall develop a new, 5-year strategy on health-related research and development, and submit an annual report to the appropriate congressional committees on the new strategy, which shall also be posted on the USAID Web site not later than 180 days after enactment of the act. The new strategy shall detail coordination with the Centers for Disease Control and Prevention and other relevant Federal departments and agencies, nongovernmental organizations [NGOs], and other private sector partners, in support of innovative global health product development to address critical gaps.*

USAID's support for global health research and development (R&D) focuses on advancing new technologies and innovative implementation approaches to increase efficiencies, address critical unmet needs, and improve the impact of health programs. USAID's *Strategy for Global Health R&D for 2017-2022* is available on USAID's webpage, as directed by Public Law 115-141.<sup>1</sup> The *Strategy* identifies three priority goals, which relate to the development of health technologies, implementation science, and the building of local research capacity. The sections below provide priority updates on activities in Fiscal Year (FY) 2017 under each of these goals:

### **I. Health Technologies, Tools, and Approaches (Goal 1)**

#### **To accelerate the development, introduction, scale-up, and sustained use of health technologies, tools, and approaches to address critical unmet needs and emerging challenges**

*Tuberculosis (TB):* USAID funds clinical research to improve the treatment of multi-drug - resistant (MDR) TB. The STREAM Stage 1 trial is evaluating the efficacy and safety of a shorter regimen for the treatment of MDR-TB; the study has released preliminary data publicly, and the World Health Organization (WHO) will use the final data, expected at the end of 2018, to inform future treatment guidelines. The STREAM Stage 2 trial is enrolling patients to evaluate a shorter MDR-TB treatment regimen with a relatively new drug, bedaquiline, with the goal of improving treatment outcomes and reducing toxicities. USAID is also financing a trial to evaluate bedaquiline, pretomanid, and linezolid in patients with extensively drug-resistant TB, as well as a study of periodic treatment for latent TB infection in people who are living with HIV.

*Global Health Security:* USAID generates surveillance data on microbes that are circulating in wildlife populations, which feed into a publically available global database and help to identify high-risk settings in which humans and animals interact. Since 2014, USAID partners have sampled over 61,000 animals and 7,000 people in 28 countries, which has led to the discovery of over 1,000 novel viruses. Our partners have produced new high-resolution maps that identify the

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<sup>1</sup> [https://www.usaid.gov/sites/default/files/documents/1864/USAIDGlobalHealthRDStrategy\\_2017-2022.pdf](https://www.usaid.gov/sites/default/files/documents/1864/USAIDGlobalHealthRDStrategy_2017-2022.pdf).

areas of highest risk for the emergence of new diseases. Surveillance data in Asia on influenza viruses circulating in farm animals continue to shed light on the distribution, diversity, seasonality, and evolution of a virus family that has caused four pandemics in the past century.

*Malaria:* USAID's Malaria Vaccine Development Program funded a clinical trial to evaluate a new malaria vaccine candidate, and is preparing for a clinical trial of a vaccine to target the liver-stage of the parasite's life-cycle, as well as several pre-clinical studies to improve upon existing malaria vaccine candidates, identify novel ones, and evaluate potential vaccine-delivery systems. USAID continues to finance the development of anti-malarial drugs through the Medicines for Malaria Venture, and insecticides through the Innovative Vector Control Consortium. Progress includes late-stage clinical trials for three novel classes of malaria drugs in combination with partner drugs. USAID also funded the submission of tafenoquine—the first new medicine for relapsing malaria in over 60 years—to the U.S. Food and Drug Administration (FDA) within the U.S. Department of Health and Human Services (HHS), and the submission of rectal artesunate—the pre-referral treatment for severe malaria in children—for WHO prequalification.

*Neglected Tropical Diseases:* USAID has financed the development, field-testing, and policy change for a remapping protocol for lymphatic filariasis, which allows countries to identify non-endemic regions. Initial research in the Federal Democratic Republic of Ethiopia and the United Republic of Tanzania prevented many unnecessary treatments, which saved tens of millions of dollars. The tool has received the WHO's endorsement, and has been implemented in the Republic of Cameroon, the People's Republic of Bangladesh, and the Socialist Republic of Vietnam. To date, over 27.5 million people globally will not require treatment because of the new endemicity classification. USAID is also supporting a multi-country trial to test the efficacy of a six-week course of doxycycline in improving the clinical outcomes and quality of life of patients with filarial lymphedema (sometimes called elephantiasis). Results from this study have the potential to redefine global strategies for treatment of patients with more-advanced disease.

*HIV/AIDS:* USAID continues to fund the testing of the 30-day dapivirine vaginal ring, the first topical microbicide for HIV-prevention in women that has shown evidence of efficacy in multiple randomized clinical trials, including through an ongoing open-label trial in which all participating women are receiving it (IPM032). Interim data from IPM032 and a companion study supported by the HHS National Institutes of Health (NIH) suggest that women's knowledge that the product is safe and effective increases their consistent use of it. The dapivirine ring is now under regulatory review. USAID is also investing in other long-acting microbicides including biodegradable implants, patches, and a 90-day multipurpose dapivirine ring. Activities to support the introduction of oral pre-exposure prophylaxis and the dapivirine ring are underway and essential to ensuring access to these products for the women who need them. In addition, USAID continues to fund the International AIDS Vaccine Initiative (IAVI) to conduct epidemiological studies, characterize targets for immunity in African populations, and build capacity at clinical research sites that serve as go-to-centers for vaccine trials. Lastly, USAID is financing studies to optimize HIV-treatment regimens, including the ADVANCE trial in the Republic of South Africa, a comparison of three first-line regimens that include newer agents that might have lower manufacturing costs and less risk of resistance.

*Voluntary Family Planning/Reproductive Health:* USAID is funding R&D aimed at increasing safe, acceptable, and well-informed options for voluntary family planning. USAID is currently one of several donors that finance the Evidence for Contraceptive Options and HIV Outcomes Study, which will evaluate whether or not three widely used contraceptives influence the risk of acquiring HIV. USAID is also funding a trial to assess the effectiveness, safety, and acceptability of extending the duration of use of subcutaneous depo-medroxyprogesterone acetate, which could reduce costs and barriers to access. In addition, USAID is paying for the pilot introduction of the levonorgestrel intrauterine system to build an evidence base to inform future scale-up. USAID also continues to underwrite the development of the Nesterone/Ethinyl Estradiol one-year contraceptive vaginal ring, for which HHS/FDA has accepted a review.

*Maternal and Child Health:* The Saving Lives at Birth (SL@B) partnership, managed by USAID's Center for Innovation and Impact, is funding the development, introduction, and scale up of innovations to reduce maternal and newborn deaths. One of the SL@B supported innovators, Rice University, was one of four finalists in the MacArthur Foundation's 100&Change for its NEST 360° package of life-saving technologies, which includes innovations such as bubble continuous positive-airway-pressure device for neonatal resuscitation. The partnership has provided funding for planning to facilitate the evaluation and scale up of the package in Republic of Malawi and to look at approaches to introducing it into other markets.

*Nutrition:* USAID is collaborating with the HHS Centers for Disease Control and Prevention (CDC), the WHO, the United Nation Children's Fund (UNICEF), and universities to improve indicators that measure nutritional status through anthropometry and that detect the prevalence of anemia and deficiencies in vitamin A and iodine. USAID is funding field tests of a device that determines anthropometric indicators through computer calculations of body dimensions based upon inputs from photography.

## **II Implementation Science (Goal 2)**

### **To identify, generate, and apply evidence to influence the adoption, implementation, and health impact at scale of priority life-saving health and development interventions**

*TB:* USAID finances supports the study of the transmission of MDR-TB through combining analysis of whole genome sequencing data with spatial, epidemiological, demographic, and laboratory information. This enables improved understanding of the relative proportions of MDR-TB cases that result from hospital-acquired and transmitted resistance, and contributes to active case-finding and outbreak-surveillance for transmission at the community level.

*Malaria:* Through the President's Malaria Initiative, USAID funds operational research to improve the delivery of interventions. Studies completed in FY 2017 include testing a simplified algorithm for the management of fevers in children by community workers, and research to assess the magnitude and determinants of residual malaria transmission that current vector-control methods might not affect. Ongoing studies include research on extending seasonal malaria chemoprevention to children from ages five to ten in the Republic of Mali, the testing of targeting strategies for indoor residual spraying in the Republic of Zambia, and the evaluation of anti-malarials for the prevention of malaria in pregnancy in the Republic of Malawi.

*Global Health Security:* USAID funds in-depth research to locate high-risk populations and identify social preferences and practices linked to risky contact between humans and animals. USAID projects leverage prior characterization of the trade in wild-animal meat and analyses of biosecurity infrastructure in markets in the Democratic Republic of Congo, the Republic of Indonesia, the Lao People’s Democratic Republic, and the Socialist Republic of Vietnam. This information provides an understanding of the amount and types of wild-animal meat that moves through markets, and the value-chain, and how that meat is handled.

*HIV/AIDS:* USAID, through the U.S. President’s Emergency Plan for AIDS Relief, finances implementation-science activities focused on the prevention, care, and treatment of HIV. Activities include assisting Ministries of Health and countries with planning to achieve higher coverage of voluntary medical male circumcision, the scale-up of HIV treatment, leveraging community platforms more effectively, and reducing barriers to accessing HIV services.

*Voluntary Family Planning/Reproductive Health:* USAID is funding research to address social norms, including a study with results expected in 2018 that evaluates whether an intervention to promote gender equality and positive masculinities within faith communities increases the uptake of voluntary family planning and decreases intimate-partner violence. USAID is also financing activities to assess the role of pharmacies and drug shops in voluntary family planning.

*Maternal and Child Health:* To improve child survival, USAID funds implementation research to improve the care of small and sick newborns and young children. Newborn deaths account for nearly half of under-five mortality. USAID is underwriting the introduction of management guidelines for infants with possible serious bacterial infection, which will make it faster and cheaper to provide care and, therefore, easier to save lives. USAID is also financing studies to strengthen the understanding and engagement of the private sector in the treatment of childhood illness. USAID-funded research has shown that, in some countries, the largest proportion of caregivers of children seek care from the private sector. Better understanding the capacity and role of private providers will improve the quality of care, and reduce the burden on public facilities. To improve maternal health, USAID funds the “Global Maternal Sepsis Study and Awareness Campaign” to better understand the true burden of disease and how health workers identify and treat women with infection during pregnancy, childbirth or post-partum, or post-abortion. USAID is applying behavioral economics to providers’ behaviors, with the goal of improving the administration of magnesium sulfate for eclampsia, which accounts for 80 percent of maternal deaths, and to increase the proper recognition of and referral for, severe eclampsia.

*Nutrition:* USAID is funding an assessment of the nutritional and health needs of large urban centers in East Africa to provide insight for nutrition programs. USAID also financed technical assistance to help Ministers of Health in the Republic of Ghana, the Federal Democratic Republic of Nepal, the Republic of Sierra Leone, and the Republic of Uganda to use research findings to develop multi-sectoral anemia-reduction strategies and policies. USAID funded an evaluation of programmatic implications and recommendations on the use of nutritional products to reduce child stunting and improve physiological outcomes. Results showed that physical and mental development depends on by more than just their nutrient supply and health status at birth.

*Health Systems:* Through the “Marshalling the Evidence Initiative,” USAID has synthesized the body of literature that link improvements in the quality, governance, and financing of service-delivery to health outcomes and institutional performance. USAID also funded a study in the United Republic of Tanzania to identify the factors that influence the engagement of health workers and its impact on service delivery, which found four key characteristics: 1) being a change agent; 2) job satisfaction; 3) accountability; and 4) equitable and client-centered care. USAID plans to incorporate training of health workers in these characteristics within programs.

### **III. R&D Systems (Goal 3)**

#### **To strengthen the capability and resilience of people, institutions, and partnerships to conduct research and utilize results to improve health outcomes**

In FY 2017, USAID continued to fund the development of clinical research capacity in sub-Saharan Africa. For example, USAID partnered with IAVI to co-finance the Vaccine Immunology Science and Technology for Africa program, which pairs leading global institutions with U.S. and Africa-based clinical research centers to transfer next-generation technologies to areas most affected by the HIV/AIDS epidemic. Currently, the program is developing critical data-sharing capacity, which will ultimately make valuable immunological data available worldwide. To combat malaria, USAID continues to provide targeted funding to build and maintain the capacity of research institutes in sub-Saharan Africa for the field testing of the new insecticides as they move along the product-development pathway. In addition, USAID is working with the Republic of South Africa’s Ministry of Health to identify new sites for trials for the treatment of MDR-TB, which will strengthen research capacity in this country.

USAID also has provided leadership to strengthen institutions and partnerships to conduct implementation research to improve programs. Across maternal, neonatal, and child health, USAID has strengthened collaborative networks and communities of practice to accelerate the transfer of knowledge to implementers and policy-makers. For example, through the Respectful Maternity Care Council, and now also through the Quality Equity Dignity Network, respectful maternity care has become accepted as part of the standards of care for tracking the experience of care for women in many countries. USAID also continues to provide leadership to the High-Impact Practices (HIPs) partnership; HIPs are a set of evidence-based practices documented in an easy-to-use format to facilitate use in decision-making around effective practices in voluntary family planning. USAID Bureaus are working collaboratively to create innovations for improving nutrition in complex environments that face drought, conflict, and instability, such as supplements based on blends of native cereals, grains (legumes), and local lipid-rich ingredients that have produced similar results as the peanut-base lipid supplements.

USAID has also been working with partners to strengthen organizations that will provide data for public health programs. For example, USAID and HHS/CDC’s International Micronutrient Malnutrition Prevention and Control Project is working in the Republics of Guatemala and Uganda to provide technical assistance to local institutions to establish low-cost, permanent surveillance systems to help determine the effectiveness of each country’s nutrition-specific programs, follow the evolution of the populations’ nutritional situation, and gain insight into potential future nutritional problems. USAID also funded the development of a new maternal health care module for surveys to gather improved and nuanced information on maternal health care to estimate mortality causes more accurately, which will inform programming.