



U.S. Agency for International Development Report to Congress Global Health Innovations for Fiscal Year 2023

The U.S. Agency for International Development (USAID) submits this report pursuant to Public Law 115-411, the Global Health Innovation Act of 2017, which directs that:

Not later than 180 days after the date of the enactment of this Act, and annually thereafter for a period of 4 years, the Administrator of USAID shall submit to Congress a report on the development and use of global health innovations in the programs, projects, and activities of the Agency.

Introduction

For decades, innovation has been a critical component of USAID’s work in global health. Striking reductions in maternal and child deaths; a vast expansion of access to life-saving drugs for HIV, tuberculosis, and malaria; measured improvements in treatments for neglected tropical diseases; and many other successes in global health have come about through innovation, including efforts to address the global COVID-19 pandemic. By sourcing novel ideas and approaches, enhancing existing solutions, and engaging new partners, USAID is committed to the continued use of innovation to overcome health challenges.

Innovation at USAID

USAID defines “innovation” as the pursuit of novel approaches that lead to substantial improvements in addressing development challenges. Over the last year, USAID/Global Health transformative innovations reached new communities with new models and incremental innovations enabled expanded uptake or enhanced approaches. These iterative and dynamic pursuits result in four types of innovation described below.

1) Offerings include new products, drugs, diagnostics, vaccines, systems, and services. For example, USAID is supporting the introduction of Truenat, a battery-powered instrumentation that can be used at high ambient temperatures, as a point-of-care rapid molecular test for tuberculosis (TB). The instrumentation can also be provided in an optional suitcase to allow for portability and be used for active case finding in remote settings. In conjunction, USAID is supporting the use of a digital chest X-ray coupled with computer-aided detection (CAD) to detect TB to combat a lack of skilled radiologists in these settings. By utilizing Artificial Intelligence (AI) and Machine Learning (ML) to read the X-rays, patients can be referred for confirmatory testing when an abnormal score is generated. This technology is already scaling up in seven countries, supporting increases in diagnosis of TB and provision of treatment, and generating evidence that will inform future scale up of the new technologies.

USAID offerings include continued deployment of the model it developed to estimate the economic and health cost of substandard and falsified (SF) medicines—specifically looking at oxytocin in Kenya and amoxiclav in Pakistan. The model estimated the burden from one year’s

use of SF oxytocin as: more than 5,000 additional cases of postpartum hemorrhage; 275 additional deaths; \$4.8 million in costs to the healthcare system; and \$9.4 million in productivity losses for a total societal cost exceeding \$14 million. Results from this pilot are providing a mechanism to advocate for strengthening quality assurance systems to reduce SF medicines in Kenya.

2) Delivery Approaches include means of reaching end-users through new channels or customer-engagement approaches and business models. For example, Good Manufacturing Practices (GMP) are critical to ensuring a medical product is quality assured and fit for its intended use. USAID supported the development of a free online GMP eLearning course. Medical product manufacturers and medicine regulators in a low- or middle-income country (LMIC) can take the course to increase their understanding of GMP and, thereby, improve the quality of medicines in their markets. In Zimbabwe, USAID's Development Innovation Ventures (DIV) program is making mental health care accessible by supporting Friendship Bench, which has developed an evidence-based, scalable model that allows government nurses and staff from non-governmental organizations (NGO) to train community health workers as lay counselors to provide cognitive behavioral therapy. Community health workers screen people seeking support, provide up to six sessions of therapy, and connect individuals to a peer support group. The U.S. President's Malaria Initiative (PMI), is marking the first introduction of a smartphone-based rapid diagnostic test reader into current malaria case management workflows across four pilot countries: Benin, Côte d'Ivoire, Nigeria, and Uganda. If proven useful, this deployment could prove broader use of this technology, or similar technologies, in improving malaria surveillance data across sub-Saharan Africa.

3) Process/Ecosystem Innovations focus on novel enabling approaches and the development of a culture in which innovation can flourish. In Mali, USAID and partners developed and institutionalized a new surgical diploma that will allow for expanded and improved training on safe surgery for healthcare workers in family planning and obstetrics. To promote local capacity-building efforts, USAID developed the Quantification and Analytics Tool (QAT), a modernized solution for country-led forecasting and supply planning of health commodities, including those funded by USAID. This tool enables forecasters and supply planners to easily build and compare multiple forecasts, optimize commodity procurement and delivery schedules, monitor the stock status of products, and share data with external platforms and key stakeholders. USAID also continues to prioritize investments focused on ensuring youth are actively engaged in shaping health interventions.

4) Finance Innovations relate to business models and partnerships. The private sector's increasing interest in investing in the health sector creates new opportunities for USAID and partner country governments to mobilize more sustainable and efficient resources to improve health outcomes. For example, the Policy, Advocacy, and Communication Enhanced for Population and Reproductive Health (PACE) Fellows Project supported youth leaders to equitably participate in national health policy and budget discussions and enhance family planning impact in policies, service delivery commitments, and funding across sub-Saharan Africa. In Zambia, advocacy from youth leaders successfully increased the Ministry of Health's family planning funding by 17 percent (a \$22 million increase over the previous

year).

USAID provided \$1 million in catalytic grant capital to establish the Transform Health Fund (“Fund”), a debt/mezzanine fund managed by AfricInvest, a private equity and impact investment firm that has been successfully investing in African companies for the last 30 years. USAID’s investment was leveraged by this women-led, impact-first Fund to raise \$10M in capital from the U.S. International Development Finance Corporation (DFC) and thus far \$50M in private investment in order to scale innovations in the healthcare space. The Fund specifically aims to establish a resilient investment ecosystem for innovations that improve access to high-quality and affordable care and supplies in Africa for the most vulnerable in three critical healthcare areas: (1) supply chain transformation, (2) innovative care delivery, and (3) digital innovation. Recognizing the importance of women’s leadership in improving health security across Africa, the Fund will prioritize supporting women’s health services and investing in women-owned and led businesses.

Innovation Supporting USAID Strategic Health Priorities

USAID pursues all four types of innovation to improve outcomes across three strategic health priorities, while building sustainable and resilient health networks.

Priority 1-Preventing Child and Maternal Deaths: USAID has supported implementation of research to identify critical gaps, pilot, and scale-up innovative approaches in the maternal and child health and nutrition field. In the past ten years, USAID has helped save the lives of more than 9.3 million children and 340,000 women. About half (49.4 percent) of all deaths in low-income countries in 2019 were caused by communicable diseases, conditions arising during pregnancy and childbirth, and preventable diseases during the first five years of life. By contrast, only 7.5 percent of deaths in high-income countries were due to such causes. USAID works to prevent child and maternal death through a wide range of innovations, such as those highlighted below.

- ***Expanding uptake for innovations to support child and newborn health:*** USAID continues to support the scale-up of novel, low-cost innovations to meet the needs of children and newborns. For example, NEST360 (Newborn Essential Solutions and Technologies), a consortium of partners led by Rice University, supports systems strengthening and provision of a bundle of equipment to improve the care of small and sick newborns in Africa. USAID is collaborating with the Nigerian government to demonstrate the feasibility of implementing the bundle in public sector health facilities and scale the model across other Nigerian states. USAID also supported the implementation and training of the Every Second Matters for Emergency and Essential Surgery-Ketamine (ESM-Ketamine) package, which expands access to cesarean sections and other emergency and essential reproductive surgeries in rural Kenya when no anesthetist is available.
- ***A locally led, co-creation approach to support local maternal and newborn health innovations in Ghana:*** The Country Innovation Platform (CIP) is a pilot initiative in Ghana in collaboration with the Ghana Health Service, Grand Challenges Canada (GCC), and AMP Health to identify priority health needs and support a platform to develop innovations that can respond to those challenges. The CIP kicked off in February 2023 with a co-creation

workshop to scope needs in northern and western Ghana and define the criteria for assessing relevant innovations. GCC will next launch a call for related innovations and support them with catalytic funding, engagement with a network of innovation stakeholders inside and outside of government, and participation in an innovator cohort for cross-learning opportunities. The CIP aims to generate lessons learned about how to design an innovation process that is tailored to locally defined needs.

- **Advanced molecular methods for malaria parasite genetics:** Recent advances in molecular methods for analysis of malaria parasite genetics have opened new opportunities for early detection of particular parasite genotypes that can lead to diagnostic and/or treatment failure. These molecular tools (like next generation sequencing and bead-based serological assays) can play an important role in informing and optimizing malaria control policies and programming decisions, such as selection of effective first-line treatments. PMI funds sample collection and capacity strengthening to implement these methods in African laboratories, leveraging the investments of external partners, such as the Bill & Melinda Gates Foundation.

Priority 2-Controlling the HIV Epidemic: USAID is a key implementer of the President's Emergency Plan for AIDS Relief (PEPFAR). The Agency applies science, technology, and innovation to support the implementation of cost-effective, sustainable, and appropriately integrated HIV interventions at scale. Examples of innovations of HIV programming include the following:

- **Enhanced service delivery to promote HIV prevention in adolescent girls and young women (AGYW):** USAID has been at the forefront of utilizing a person-centered approach that empowers people to make informed choices about their care and treatment. The Catalyzing Access to New Prevention Products to Stop HIV (CATALYST) study aims to characterize and assess the implementation of an enhanced service delivery package providing informed choice of pre-exposure prophylaxis (PrEP) products. Similarly, the HIV Prevention Journey Tool was developed to support AGYW to explore methods that would align with their lifestyle, needs and personal preferences; and support healthcare providers to provide informed counseling based on client needs.
- **Driving innovation and impact in PEPFAR via research, development, and accelerated introduction of HIV prevention products:** USAID continues to expedite the research and development of HIV biomedical prevention products for women that, in addition to being safe and effective, will be acceptable, affordable, scalable and deliverable in the settings where they are needed most. USAID also supports the introduction and scale-up of approved products to accelerate their availability, acceptance, uptake, and impact in PEPFAR programs to ultimately achieve a world free from HIV and AIDS. Specifically, USAID is prioritizing the CATALYST study to assess the effective use of individual prevention products, as well as the feasibility of an integrated service delivery platform of PrEP products including long-acting injectable cabotegravir (CAB-LA).
- **Applying advanced analytics to tailor HIV treatment, improve client-centered services, and diversify patients' access and financing options:** USAID continues to leverage diverse applications of AI and ML to improve sustainable, affordable, and patient-centered HIV services. The Data Anomaly Detection Tool was built to support remote routine quality

monitoring by signaling data anomalies at facilities and enabling analysts at USAID's Office of HIV/AIDS and Missions, and Implementing Partners (IPs) to engage in targeted on-site quality reviews and improvement actions. The HIV Interruption in Treatment (HIV IIT) Root Cause Analysis tool collects and analyzes quantitative and qualitative data to assess the core issues behind a client's missed appointments and has been implemented in Burundi and Kenya. Finally, USAID is piloting the Data Quality Monitoring Application, a digital solution designed to facilitate regular data quality monitoring, support compliance with the broader data quality assurance requirements, enhance record keeping, and guide data quality improvement.

Priority 3-Combating Infectious Diseases: USAID-funded programs have achieved tremendous success against malaria, tuberculosis (TB), neglected tropical diseases, pandemic influenza, and other emerging threats. Recent USAID-supported innovations include the following.

- ***Procurement and distribution of a novel point of care test to guide safe administration of vivax malaria radical cure:*** *Plasmodium vivax* malaria infections, unlike *Plasmodium falciparum*, can lead to multiple relapsing infections if they are not appropriately treated. The only drugs available (primaquine and tafenoquine) for vivax treatment can cause severe hemolytic anemia in individuals with low glucose-6-phosphate dehydrogenase (G6PD) levels. Until recently, there were no field-friendly, point of care diagnostics available to assess for G6PD levels. Following a successful operational research study in Cambodia supported by PMI to evaluate the introduction of this novel diagnostic for screening G6PD deficiency, PMI has procured almost 90,000 tests for Ethiopia and Madagascar allowing them to provide this treatment safely.
- ***Support for the WHO Diagnostics Technical Advisory Group (DTAG) for NTDs to address the gap in adequate diagnostics:*** Target Product Profiles (TPPs) have attracted new small- and medium-sized manufacturers, increased and diversified donor investment, and all at a very low cost structure for such a dynamic and rapid innovative process with the World Health Organization (WHO) and diagnostic stakeholders. With the creation of the DTAG, a rapid convening and consensus process was created which resulted in eight target product profiles being generated and publicized in just two years. This has significantly reduced consensus time and publication of TPPs, catalyzed and diversified investments in developing and evaluating new NTD diagnostics for which USAID has awarded six grants to institutions developing and evaluating new diagnostics.
- ***Use of targeted genome sequencing to detect resistance to multiple TB medicines:*** While there is global progress in increasing access to drug susceptibility testing (DST) for rifampicin, detection of rifampicin resistance alone is not sufficient to put TB patients on optimal treatment regimens. The availability of targeted next-generation sequencing (tNGS) assays could enable real-time surveillance of resistance to multiple TB drugs and open the possibility for individualized treatment informed by the patient's full drug susceptibility profile. USAID is supporting the introduction of tNGS to evaluate the proof-of-principle for integrating targeted NGS into patient care to generate global guidance for the use of targeted NGS for DR-TB diagnosis.
- ***Leveraging digital tools for the vaccination service delivery process:*** The reach and real-time data digital technologies enable can help efficiently allocate resources, drive vaccine

demand, educate health workers, plan vaccination campaigns, and track their progress. However, experience with other infectious disease outbreaks, like Ebola, illustrates that digital systems implemented for emergency responses have limited impact unless they are designed to support information exchange, scalability, and sustainability. The Primer on Digital Solutions for COVID-19 Vaccination Service Delivery is an easy-to-use innovation delivery cheat sheet for leveraging digital solutions that improve vaccination service delivery—for routine immunization as well as during health emergency responses—while sustainably strengthening health systems.

Working Strategically and in Partnership

USAID works collaboratively in pursuit of innovation. This includes engaging the private sector in public-private partnerships, which can enable sustainable business models for innovations. For example, USAID supported private-sector researchers and social and behavior change experts to develop and disseminate the COVID Behaviors Dashboard as the data utilization arm of the COVID-19 Trends and Impact Survey. The Dashboard presents survey data from more than 114 countries and 38 million responses. Information from the dashboard was regularly presented to United Nations-related entities, regional centers for disease control, ministries of health, risk communication and community engagement committees, and researchers, among others. Through this public-private partnership, data and expert advice on knowledge, attitudes, and practices related to COVID-19 and vaccine demand reached tens of thousands of professionals around the world working to end the pandemic.

Innovative practices require cross-team collaboration, whether within USAID’s Bureau for Global Health, across the U.S. government (USG), and/or via external partnerships. In the Bureau for Global Health, more than seven innovations have been supported in partnership across two or more offices. There is also active coordination between USAID bureaus in advancing innovation, with the Center for Innovation and Impact (CII) closely engaging with the Bureau for Democracy, Development and Innovation’s (DDI) Private Sector Engagement Hub, Development Innovation Ventures (DIV), and other innovation advisors, as well as with the U.S. International Development Finance Corporation (DFC). This engagement includes supporting local innovators, ensuring cross-sharing of field activities, and GH Bureau technical assistance for review of proposals, agency policies, and program development.

Additional detail about USAID’s research and development activities, also are available in the Health-Related Research and Development (R&D) Report to Congress for Fiscal Year 2022, and in the multi-year *Global Health Research and Development Strategy (2017-2022)*