



**U.S. Agency for International Development
Report to Congress
on Global Health Innovations
for Fiscal Year 2018**

The U.S. Agency for International Development (USAID) submits this report pursuant to Section 2(a) of Public Law 115-411, the Global Health Innovation Act of 2017, which directs that:

The Administrator of USAID submit to Congress a report on the development and use of global health innovations in the programs, projects, and activities of the Agency. 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

The pace of progress in global health depends on the ability to seed, nurture, and spread innovation. The global-health community has set ambitious goals, and sourcing and supporting the development and adoption of innovations will be a critical factor in achieving these goals. Whether a new treatment regimen or vaccine, an innovative financing partnership, or a novel service-delivery approach, innovation has been a core part of USAID’s work in global health for decades. Vaccine vial monitors (VVMs), for example, are a simple but ground-breaking tool to track the heat exposure of temperature-sensitive medicines like vaccines. Because of a small catalytic investment made by USAID in 1996, Temptime Corporation has produced seven billion VVMs, which have allowed health-care professionals around the world to ensure the vaccines they deliver are efficacious and safe. Similarly, the Odon Device, a novel, easier-to-use tool devised by a car mechanic for use during obstructed delivery, has received funding through USAID’s Saving Lives at Birth (SL@B) partnership. This device is the first innovation in assisted vaginal delivery in decades and, when combined with surrounding services, can reduce maternal and fetal deaths because of prolonged and obstructed labor. The Odon Device has a commercial pathway to scale, as Becton Dickinson and Company (BD) has licensed the development rights and hopes to bring it to market in 2021.

Global Health Innovation at USAID

USAID defines “innovation” as the pursuit of novel approaches that lead to improvements in addressing development challenges, a guiding principle of the Bureau for Global Health and its **Center for Innovation and Impact (CII)**. Innovation involves an iterative and dynamic process that can result in four types of innovation:

1) Offerings, which include new products, drugs, diagnostics, vaccines, systems, and services. One example is the Pumani bubble continuous positive airway pressure (bCPAP) funded by the USAID SL@B Partnership, which provides non-invasive ventilation for newborns in respiratory distress at one-tenth the cost of traditional bCPAPs. It is now available in every District hospital in Malawi.

2) Delivery approaches, which include new means of reaching end-users, *e.g.*, through new channels or customer-engagement approaches. For example, the USAID SL@B Partnership has financed virtual-reality trainings delivered by smartphones that enable health-care workers to hone their rapid response when a newborn cannot breathe at birth.

3) Process innovations, which focus on novel enabling approaches and the development of a culture in which innovation can flourish. The 2018 implementation of an emergency supply-chain (ESC) playbook in Cameroon represents a process innovation. USAID, the Government of Cameroon, and multi-sectoral partners initiated an ESC framework and tested it through Ebola and Anthrax simulations. During an actual cholera outbreak, the ESC playbook allowed for the rapid quantification of regional needs, the identification of suppliers of health consumables, and an assessment of the cold-chain capacity for the oral cholera vaccine.

4) Finance innovations relate to business models and partnerships. An example is USAID's work to drive diagnostic innovations for Zika. Without a market incentive, manufacturers were not developing much-needed Zika rapid tests. To close this gap, USAID worked with the United Nation Children's Fund (UNICEF) to provide a \$10 million guarantee for the purchase of successfully developed diagnostics, which reduced the risk of investing in these products and accelerated their development.

USAID pursues all four types of innovation to improve global health across our three strategic priorities as described below, while building sustainable and resilient health institutions in the poorest regions of the world.

Strategic Priority 1—Preventing Child and Maternal Deaths: Over the last decade, USAID, with its partners, has helped save the lives of more than five million children and 200,000 women. Despite this progress, women and children still die every day from preventable causes. USAID works to prevent child and maternal deaths with a wide range of innovations, such as those mentioned below:

- ***Saving Infant Lives with Chlorhexidine (CHX):*** Since 2002, USAID and its partners have been scaling up CHX, an antiseptic that is safe and simple to use, easy to manufacture, and affordable. The use of CHX can lower the risk of severe infection by 68 percent and infant death by 23 percent. Local producers could manufacture the antiseptic locally, and through extensive market research, policy and advocacy work, and funding from the USAID SL@B Partnership, providers and the Ministry of Health integrated CHX into routine care in Nepal. This collaboration between the Nepalese Government and the private sector achieved national coverage in less than ten years, which saved more than 9,600 infant lives.
- ***Scaling Game-Changing Technologies to Halve Newborn Mortality by 2030:*** The Newborn Essential Solutions Technologies 360° (NEST360°) is a private-public partnership led by Rice University and a consortium of partners to scale a bundle of 17 technologies sustainably that address the leading causes of newborn death in sub-Saharan Africa. NEST360°, initially catalyzed by a USAID SL@B Partnership award, has since leveraged more than \$68 million from private foundations.
- ***Innovative Sourcing and Market-Shaping for Malaria Commodities:*** The President's Malaria Initiative (PMI) produced savings of more than \$22 million for procured commodities by promoting a diverse supplier pool, negotiating long-term contracts, expanding scale, and simplifying order processes. In addition, PMI standardized the shape, size, and color of insecticide-treated nets, which reduced costs and enabled greater responsiveness to program needs.

- ***Digital Application Offers Effective Contraception - Dot¹***: The efficacy trial of this innovative digital family-planning tool demonstrated effectiveness equal to hormonal methods of contraception. Dot identifies a woman’s fertile days so she can decide to time a pregnancy, to remain abstinent or use a barrier method, and the algorithm and machine-learning built into the app have both expanded the eligibility of its use and improved its efficacy. With USAID funding, Dot has the potential to reach many women interested in the healthy spacing and timing of pregnancies, which reduces high-risk pregnancies that threaten the lives of both the baby and mother.

Strategic Priority 2-Controlling the HIV/AIDS Epidemic: As a key implementer of the U.S. President’s Emergency Plan for AIDS Relief (PEPFAR), USAID applies science, technology, and innovation to support the implementation of cost-effective, sustainable, and appropriately integrated HIV/AIDS interventions at scale. Examples of innovation brokered by USAID under PEPFAR include the following:

- ***Supporting Research into Microbicides:*** Under PEPFAR, USAID has funded the development of microbicide products that women can use to protect themselves from HIV, of particular interest in Sub-Saharan Africa, where women make up 60 percent of HIV infections. USAID finances a range of microbicide innovations, from earlier-stage research for products like biodegradable implants to later-stage development and scale-up support for products such as vaginal rings and long-acting injectables. USAID also funds activities to prepare for, and accelerate the introduction of microbicides in the target markets where they can be most effective.
- ***Accelerating Access to HIV Medicines:*** With PEPFAR funding, USAID financed the rapid introduction and scale-up of the improved anti-retroviral HIV-treatment (ART) regimen tenofovir disoproxil fumarate, lamivudine, and dolutegravir (TLD) with supply-chain and drug-transition planning, as well as by working with global stakeholders on a ceiling-price agreement and an initial PEPFAR order that sent a market signal for faster production of TLD. For HIV-prevention, USAID employed a human-centered-design approach to create a brand and customer-engagement approach to increase the uptake of, and adherence to, oral pre-exposure prophylaxis (PrEP) among young women in sub-Saharan Africa.² These multifaceted approaches encompass offering, delivery, and finance innovations that are mutually reinforcing.
- ***Expanding Access to ART in the Private Sector:*** Led and developed by the USAID-funded Sustainable Financing Initiative under PEPFAR, this delivery and financing innovation allows private community pharmacists to support stable patients with PEPFAR-financed refills of anti-retrovirals, which decongests public facilities and improves the patient experience for persons who are living with HIV with the willingness and ability to pay a minimal service fee. Providers have referred approximately 14,500 patients to pick up their drugs at more than 300 private pharmacies across four States in Nigeria.

Strategic Priority 3-Combating Infectious Diseases: USAID-led efforts are strengthening health institutions around the world by building better capacity. Recent USAID-funded

¹ <https://www.tandfonline.com/doi/full/10.1080/13625187.2019.1581164>. *European Journal of Contraception and Reproductive Healthcare*. Hormonal contraception effectiveness equivalence with a typical-use failure rate of 5% and perfect-use failure rate of 1%.

² <https://www.conrad.org/launchingv>

examples include the following:

- ***Evaluating New Treatment Regimens for Multi-Drug-Resistant (MDR) Tuberculosis (TB)***: There is significant ongoing USAID-funded research on offering innovations to optimize TB regimens, improve the prevention of TB, and introduce new drugs. One specific example is USAID's collaboration with Janssen and Otsuka on an open-label Phase-3 randomized clinical trial to evaluate the efficacy and safety of an all-oral short regimen in MDR patients—a critical step toward bringing this much-needed treatment regimen to MDR patients.
- ***Successful Surgery with the Filaricel Anatomical Surgical Task Trainer (FASTT)***: USAID funded the development, pilot-testing, and use of a surgical simulator to train surgeons to operate on men who are suffering from filarial hydrocele. USAID is training surgeons in Ethiopia, Burkina Faso, Cameroon, and Mali with FASTT to perform hydrocelectomies and increase access to surgery. FASTT-trained surgeons have provided more than 1,800 corrective hydrocele surgeries because of this offering and process innovation.
- ***Preventing Epidemics with the Pen-Side Polymerase Chain-Reaction (PCR) Diagnostic Test***: This offering innovation enables the rapid detection of the highly pathogenic avian influenza (H7N9) virus, by providing results in two hours as opposed to the traditional test that takes two-and-a-half days. In 2017, during an outbreak of H7N9, USAID helped finance the Vietnamese Government to pilot this technology and implement quickly effective and cost-efficient activities in inspection and control to prevent the spread of the virus into Vietnam.

Working in Partnership

USAID works collaboratively in pursuit of innovation with partners across USAID, other U.S. Government Departments and Agencies, and externally. This includes engaging the private sector in public-private partnerships, which can enable sustainable business models for innovations. For example, the USAID SL@B Partnership funded Australia's Monash University to develop a novel aerosol delivery system for oxytocin, recommended by the World Health Organization to use at every birth to prevent postpartum hemorrhage. However, oxytocin must be refrigerated and injected by skilled health care workers, which limits its impact in resource-poor settings. The USAID-funded innovation is an affordable, heat-stable, simple-to-administer form of the drug that has the potential to save 146,000 lives over eight years. Johnson & Johnson³ has since signed on to a development partnership with USAID, which will help bring this much-needed innovation to scale.

Coordination across USAID, the U.S. Government more broadly, and externally is an important aspect of the Agency's work. For example, within USAID, the Bureau for Global Health works with USAID's Global Development Lab on Development Innovation Ventures (DIV), which provide tiered funding and venture assistance to pilot innovative solutions, build evidence, and scale the most-effective solutions, with 46 awards in health to date. Similarly, USAID works in close coordination with other U.S. Government entities, such as the Centers for Disease Control and Prevention within the U.S. Department of Health and Human Services on malaria, and the Office of the U.S. Global AIDS Coordinator within the U.S. Department of State on HIV. Additionally, some of USAID's multi-stakeholder partnerships include GAVI (the Vaccine

³ <https://www.medianet.com.au/releases/173640/>

Alliance), Helping Babies Breathe, Project Last Mile, the Aspen Management Partnership for Health, the Reproductive Health Supplies Coalition, and the IVCC (a product-development partnership of industry, academia, and other public-health stakeholders that facilitate the development, delivery, and impact of novel and improved vector-control tools and solutions). These partnerships engage other donors, corporations, and implementers and help foster multiple types of innovation.

USAID has an increasing focus on *finance innovation*. The private sector's growing interest in investing in health creates new opportunities for USAID and partners to mobilize additional, more sustainable, and more efficient resources to improve health outcomes. For example, the *Utkrisht Development-Impact Bond* is a finance innovation that aims to reduce the number of maternal and newborn deaths by improving the quality of care in private health facilities in Rajasthan, India. In this outcomes-based financing structure, private capital from the UBS Optimus Foundation covers the up-front costs of improving clinics, while USAID and Merck for Mothers will pay back the investment only if the project meets certain targets.

As a cross-cutting approach, USAID also seeks to promote systemic health innovations, such as through the *Inclusive Health Access Prize*,⁴ which will reward evidence-based solutions that increase the accessibility, affordability, accountability, and reliability of essential health care. USAID will facilitate access to financial and other support so that proven models may obtain maximum reach and impact. In addition, the *Community Health Roadmap*⁵ will coordinate, align, and increase investments in primary care at the community level. Through this low-cost process innovation, USAID is convening an array of funders and private-sector partners to structure existing investments and mobilize new investments, including UNICEF, the Rockefeller Foundation, the Bill & Melinda Gates Foundation, and the World Bank.

USAID's Commitment to Strengthening Innovation

USAID is positioned to support the amplification of innovation across programs, through a centralized hub of shared services and expertise located in the Bureau for Global Health's **Center for Innovation and Impact (CII)** that applies business-minded approach to the development, introduction, and scale-up of health innovations to accelerate impact against important health challenges. CII invests seed capital in the most-promising ideas and applies a rigorous, market-oriented approach to cut the time required to transform discoveries in the lab to impact on the ground. To date, CII has funded more than 150 innovations, of which 25 are scaling up or transitioning to scale. CII is collaborating on projects in more than 40 countries. CII amplifies the work of partners by collaborating with USAID's Bureaus and Independent Offices, country Missions, and outside stakeholders.

CII also works to ensure that USAID, and the global-health community writ large, are earlier adopters of cutting-edge technologies and approaches. CII accelerates the use of these potential game-changers to create health impact at scale, including through partnerships and market-shaping strategies to explore the role of unmanned aircraft systems, artificial intelligence, and human-centered design in global health.⁶

⁴ <https://www.usaid.gov/healthaccessprize>

⁵ <https://www.communityhealthroadmap.org/>

⁶ <https://www.usaid.gov/cii/uavs-global-health>; <https://www.usaid.gov/cii/ai-in-global-health> and <https://www.usaid.gov/cii/human-centered-design>

Most recently, CII published *“Innovation Realized: Expanding the Path to Health Impact”*—a suite of resources to support the use of innovation throughout USAID. This work more clearly defines innovation in the context of the Agency’s work and lays out practical ways that USAID teams can identify opportunities and apply innovation.

In addition to the targeted strategic funding described above, several policies and structures at USAID further promote innovation in the Agency’s work in global health. The Agency’s *Acquisition and Assistance Strategy* [outlines](#) key changes to enable and equip our workforce and systems to advance self-reliance through effective partnering and procurement reform. The USAID **Private-Sector Engagement Policy** promotes more proactive and co-creative engagement with private-sector partners, while the **Risk-Appetite Statement** designates innovative modalities for acquisition and assistance as areas for which the Agency has a high-risk appetite. Also, the USAID **Leadership Philosophy** highlights informed risk-taking and inspires curiosity, creativity, and innovation, to help to create an organizational culture that fosters innovative activities.

Over the last 55 years, USAID has employed innovations in offerings, delivery approaches, processes, and finance to make enormous progress in global health in partnership with many other stakeholders across the globe—all of which has made remarkable progress in improving health and saving lives in unprecedented numbers. Building on this strong foundation, USAID will continue to invest in innovation and strategic collaborations to design, develop, and deploy the next generation of innovative solutions crucial to meeting the global-health challenges of the future and accelerating progress toward improving and saving lives.
