USAID Global Health Research and Development Strategy 2023-2028

Executive Summary

The U.S. Agency for International Development (USAID) is pleased to present its new Global Health Research and Development Strategy 2023-2028. USAID submits this strategy pursuant to Section 7019(e) of Division K of Public Law 117-103, the Department of State, Foreign Operations, and Related Programs Appropriations Act, 2022, which incorporates by reference the requirements of the Joint Explanatory Statement that provides:

> *"The USAID Administrator shall also develop a new multi-year strategy on global health research and development, which shall be submitted to the Committees on Appropriations and posted on the USAID website not later than 180 days after enactment of the Act. Such strategy should include:*
> *(I) how USAID will work across programs to implement a comprehensive research and development approach;*
> *(2) plans to collect and use input from the Global Health Bureau, consultations with nonprofit and other private sector partners, and the heads of other relevant Federal agencies, including CDC, the National Institutes of Health, and the Biomedical Advanced Research and Development Authority;*
> *(3) plans to coordinate with such stakeholders in support of innovative global health product development; and*
> *(4) specific investment and target goals for research and product development across disease areas*."

This strategy describes USAID's renewed commitment to research and development (R&D) and use of new, innovative health products and technologies; the implementation and scale-up of real world, evidence-based research and learning to improve health outcomes globally; and the strengthening of both local health research and development capacity and global research and development partnerships.

The United States government has long recognized how scientific and technological innovation, data, and evidence are central to the development and implementation of sound policies and the delivery of equitable programs. Investments in global health protect Americans at home and abroad, save lives, strengthen fragile states, and promote social and economic progress.[1] USAID plays a critical role in investing in research and development (R&D) that has led to life-saving breakthroughs in prevention, diagnosis, and treatment of global diseases, and to the uptake at scale of critical health and development interventions. Harnessing the power of research and learning has resulted in more efficient and effective programs and advancements in efforts to prevent maternal and child deaths, control the HIV/AIDS epidemic, combat infectious diseases and emerging threats, and strengthen health systems.

[1]https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/27/memorandum-on-restoring-trust-in-government-through-scientific-integrity-and-evidence-based-policymaking/

Over the next five years, USAID will continue to concentrate on those areas where it is uniquely qualified and has a comparative advantage, pursuing a vision of research and innovation translated into action to improve the health, well-being, and resilience of people around the world. USAID will support collaborative monitoring, evaluation, research, and learning (MERL) from the local to the global levels, generating evidence on interventions, policies, approaches, products, and technologies that increase the impact of health programs globally while sustainably strengthening country research and development systems. In order to accomplish this, USAID will focus on four interrelated objectives:

1. To accelerate the development, introduction, scale-up, and sustained equitable access to and use of health products, technologies, tools, and approaches to address critical unmet needs and mitigate emerging challenges;
2. To identify, generate, utilize, and scale-up high-quality evidence to support the adoption, implementation, and impact of life-saving health and development behaviors, approaches and interventions;
3. To strengthen the capability and resilience of local stakeholders, institutions, programs, and partnerships to conduct monitoring, evaluation, research, and learning and utilize evidence to improve health outcomes in a systematic, equitable, inclusive, and sustainable manner to further USAID's commitment to localization; and
4. To strengthen research and development partnerships among countries and development partners to improve coordination and strengthen open, shared data and evidence for decision making and planning.

The U.S. government's investments in global health R&D help build stronger, more equitable communities, countries, and global partnerships. These investments strengthen health systems, foster stability and economic growth globally, and help the global community prevent and respond to emerging diseases, including the COVID-19 pandemic. The vision of R&D is to advance the Administration's use of MERL to use data and learning to contribute innovations, measure, learn, and help partner countries improve the health outcomes of their populations. This includes population health approaches such as strengthening primary health care, as well as a commitment to localization. The true challenge is to collaboratively deepen and accelerate efforts in order to maintain progress and sustainably improve equitable health outcomes worldwide.

Global Health Research and Development: Accelerating Success

For more than 50 years, the U.S. Agency for International Development (USAID) has played a pivotal role in saving lives and improving the health of populations around the world through evidence-based research and development programs. Thanks to the critical support of Congress and the American people, USAID has led and contributed to major gains in global health by collaborating with host governments and many other partners to strengthen the capacity of local and global health programs to improve health and well-being. Between 2000 and 2020, collective efforts in tuberculosis (TB) treatment saved over 66 million lives and supported the development and clinical trials of over 25 drugs and combination treatments.[2] Similarly, since the launch of the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) in 2003, over 21 million lives have been saved through HIV prevention and treatment, and over 20 countries reached epidemic control of HIV/AIDS.[3] USAID's investments in voluntary family planning and reproductive health (FP/RH) have supported women and couples in over 30 countries to achieve their desired family size, while also contributing to the development of nearly every modern contraceptive method available today.[4] In response to the 2012 global Child Survival Call to Action, USAID scaled up maternal and child health (MCH), family planning, nutrition, and malaria interventions to prevent child and maternal deaths (PCMD) in 25 high-need priority countries. This focus has enabled USAID to help save the lives of 9.3 million children and 340,000 women in those countries since then.[5]

However, despite dramatic reductions in child mortality over the last 30 years, substantial progress remains to be made to improve maternal and neonatal morbidity and mortality, particularly in sub-Saharan Africa.[6] The world also observed the rollback of many health and development gains due to the COVID-19 pandemic, during which global health systems suffered from disruptions to routine health interventions and lifesaving services.[7] For example, there were an estimated 14 million more malaria cases documented in 2020 than in 2019, and 24 nations recorded increases in malaria mortality.[8] While the full extent of the COVID-19 pandemic is yet to be fully understood, collaborative efforts by USAID, partner governments, multilateral institutions, non-governmental organizations, and other partners continue to support the continuity of basic services, provide social and economic support, and work to both prevent and address the impact of the COVID-19 pandemic on the broader global health system.[9]

These successes were made possible by USAID's support for innovative global health MERL; focus on identifying problems, developing and testing novel approaches, and rapidly adapting solutions; and investments to build and utilize local research and development capacity. In collaboration with local partners, USAID's global health MERL develops targeted technologies

[2]https://cdn.who.int/media/docs/default-source/hq-tuberculosis/tb-report-2021/factsheet-global-tb-report-2021.pdf?sfvrsn=86011b1e_5&download=true
[3] https://www.state.gov/wp-content/uploads/2022/05/PEPFAR2022.pdf
[4] https://www.usaid.gov/sites/default/files/documents/2022.06.15_PRH-FPRH-Program-Overview.pdf
[5] https://www.usaid.gov/global-health/health-areas/maternal-and-child-health
[6] https://www.unfpa.org/publications/trends-maternal-mortality-2000-2017
[7] https://www.who.int/publications/i/item/WHO-2019-nCoV-EHS-continuity-survey-2021.1
[8] https://www.who.int/publications/i/item/9789240040496
[9] htPBtps://www.usaid.gov/coronavirus

and generates practical implementation evidence and tools. These learnings are directly applied to make country programs more efficient, equitable, sustainable, and cost-effective, thereby enabling countries to introduce and, if appropriate, scale up interventions more rapidly to reach more people. USAID-funded R&D has led to many other key successes, including over 50 years of commitment to build data for evidence-based decision-making from the Demographic and Health Survey (DHS) Program; the development and adoption of more effective strategies to prevent and reduce maternal, child, and newborn mortality and malnutrition, such as oral rehydration salts (ORS/Zinc Vitamin A); groundbreaking innovations in new and existing contraceptive methods; development and scaling up of the use of evidence-based High Impact Practices (HIPs) to improve family planning programming; support for introduction of lifesaving vaccines; use of chlorhexidine as a broad-spectrum antiseptic for umbilical cord care among neonates; prophylactic applications of antiretroviral drugs to prevent HIV infections; new drug formulations for malaria; and new treatment regimens for drug-resistant tuberculosis (TB).

R&D must remain a vital component of USAID's efforts to solve health problems. The highly mobile and interconnected nature of our world has contributed to both the emergence and rapid spread of a variety of health threats. USAID's investments in R&D, and those of its partners, are necessary to develop new breakthroughs in prevention, detection, and treatment of emerging threats as well as ending longstanding global scourges such as HIV/AIDS, TB, and malaria; to drive improvements in reproductive, maternal, child and newborn health; and to more effectively strengthen health systems. Many poor health outcomes persist because of the complexity of adapting existing or potential solutions to fit different contexts. This strategy is a renewed commitment to reach vulnerable and marginalized populations, and to address inequities by understanding subnational variations, testing innovations to extend effective service, and strengthening key elements of health systems. R&D is crucial to understanding how to better tackle these implementation challenges. Lessons learned internationally can also be applied domestically to help equitably reach disadvantaged populations in the United States and low and middle income countries (LMICs).

In addition, USAID's global health research partnerships, commitment to supporting science and the scientific method in LMICs, and recognition of the importance of engaging with the private sector and civil society organizations have helped to build reliable scientific capacity and global research networks. Improved local R&D, paired with strengthened collaboration and coordination across other donors, research institutions, networks, multilateral agencies, governments, and other stakeholders at the global level, has the potential to reinvigorate research and development efforts. Ultimately, focusing on partnerships is critical to centering country ownership and capacity while supporting countries on the pathway to sustainable and resilient health systems.

Vision, Mission, and Objectives of the Strategy

Vision: Research is translated into timely action to improve health, well-being, and resilience of people around the world.

Mission: To support strategic, locally-led research, evaluation, and learning from community to global levels, generating high-quality, timely evidence for innovation and utilization across interventions, policies, approaches, products, and technologies as the foundation for impactful, equitable global health and development programs.

To achieve its global health R&D mission, USAID will focus on four **objectives.**

1. **Health technologies, tools, and approaches:** To accelerate the development, introduction, scale-up, and sustained equitable access to and use of health technologies, tools, and approaches to address critical unmet needs and mitigate emerging challenges.
2. **Implementation science, knowledge management, and research utilization**: To identify, generate, utilize, and scale-up high-quality evidence to support the adoption, implementation, and impact of life-saving health and development behaviors, approaches and interventions.
3. **Ethical, locally-led R&D systems:** To strengthen the capability and resilience of local stakeholders, institutions, programs, and partnerships to conduct monitoring, evaluation, research, and learning and utilize evidence to improve health outcomes in a systematic, equitable, inclusive, and sustainable manner to further USAID's commitment to localization.
4. **Partnerships and collaboration:** To strengthen R&D partnerships among countries and development partners to improve coordination and strengthen open, shared data for decision making and planning.

This new strategy outlines USAID's global health research objectives and describes the main approaches that the Agency will employ to achieve those goals across different technical areas and diseases. This strategy builds upon the 2017-2022 Global Health Research and Development Strategy, and was informed by and vetted with a variety of stakeholders, both within and outside of the U.S. government. These stakeholders were consulted to provide feedback on the importance of global health R&D, USAID's unique role in global health R&D, and the adequacy and appropriateness of the strategy's revised objectives.

USAID's Role in Global Health Research and Development

USAID coordinates its global health research closely with other U.S. government agencies, including the National Institutes of Health, the U.S. Centers for Disease Control and Prevention, the Food and Drug Administration, and the Department of Defense. Complementing the work of other agencies, USAID's work emphasizes research that is directly applicable to local and global

health programs, and elicits global lessons learned that can be relevant to the domestic health context.

USAID's comparative advantages in R&D include the Agency's strong in-country presence, implementation expertise, capacity to translate research into programs, and its engagement with partner governments and local communities. USAID staff and partners use their knowledge of the local context, programs, and development constraints to help inform prioritization to ensure research efforts ultimately result in sustainable impact where the need is greatest, and ensure that research and development investments include investments in local system capacity to lead and sustain the work. USAID is well positioned to catalyze locally-led research and support partner countries and communities to develop and apply solutions that have global relevance and local applicability. For example, USAID engages local partners in specific research investments to ensure research alignment with country priorities and develop capacity as a component of the research implementation.

USAID's Localization Vision renews our commitment to shift more leadership for priority setting, project design, implementation, and measuring results to the people and institutions with the capabilities and credibility to drive change in their own countries. USAID's approach aims to empower local actors and actively listen to local voices to ensure efforts are responsive to local priorities, draw upon and strengthen local capacities and resources, and remain accountable to local communities. In this way, the results are more likely to be effective and sustained. Along these lines, USAID's R&D investments will continue and strengthen efforts to shift power to local actors in response to local challenges, centering locally-led development. USAID's MERL activities will also contribute to broader Agency methods and metrics to document and accelerate progress on localization by reporting on the proportion of MERL programming that engages local organizations, as well as the proportion of USAID funds provided directly to local partners.[10]

In addition, stakeholders reinforced USAID's capacity to form strong partnerships as a key asset to maximize the impact of global health research efforts. This includes partnerships with host governments, other U.S. government agencies, private companies, bilateral and multilateral agencies, donors, non-governmental and faith-based organizations, academia, and others within civil society that USAID engages throughout the research process. These relationships enable USAID to play an important convening role, bringing partners together to engage in collaborative global health MERL and to collectively disseminate and utilize the results of these investments.

As an Agency with longstanding expertise across sectors, USAID also enlists diverse partners from a range of areas, such as economic growth, democracy and governance, and food security to inform its global health efforts. USAID takes a multi-sectoral approach to achieving its health objectives, working to help countries implement more sustainable and holistic programs that allow people to live healthier and more productive lives.

[10]https://www.usaid.gov/news-information/speeches/nov-4-2021-administrator-samantha-power-new-vision-global-development

USAID's Approach to Global Health Research and Development

Over the last five years, USAID's strategy for global health R&D has continued to evolve, including through 1) strengthening the implementation of Collaborating, Learning, and Adapting (CLA) principles across USAID investments; 2) incorporating systematic evidence generation and knowledge creation across the entirety of the MERL continuum; and 3) implementing critical Agency priorities and cross-cutting approaches.

CLA is a set of practices that improve our development effectiveness by creating explicit, systematic application of collaboration, learning, and adaptation throughout USAID's R&D investments. It supports the use of the co-creation process allowing for broader stakeholder engagement and ownership. A focus on timely, appropriate, and feasible MERL systematically incorporated into real world programs can facilitate improved research utilization and translation, strengthen adaptive management, and help to illuminate research priorities as well as programmatic challenges and gaps. Embedding rapid CLA approaches enabled programs to quickly pivot as needed during the COVID-19 response, and has also proven effective when embedded in longer-term health system strengthening efforts. For example, USAID has implemented rapid implementation research methods to help countries implement, assess, adapt, and scale-up community health policies.

These approaches align with the existing "research to use" framework in USAID's current and prior strategies, and will continue to guide USAID's new global health R&D strategy. This framework is divided into four interconnected and iterative phases below, and has been updated for this strategy (see Figure 2).

- **Define:** Identifying the problem or need through stakeholder engagement and local leadership, monitoring, evaluation, research synthesis, knowledge management and information sharing/knowledge translation to action.

- **Design:** Potential solutions or existing interventions to the identified problem are evaluated using applied implementation research, which assesses a range of attributes such as the efficacy, effectiveness, acceptability, accessibility, feasibility, and cost-effectiveness of proposed solutions.

- **Develop:** Prepare for the introduction of the new or refined approach and/or intervention by using implementation science, market research, political economy analyses, and health system assessments to better understand the acceptability, accessibility, feasibility, and cost-effectiveness of health interventions under both controlled and real-world conditions.

- **Deliver:** Introduce or implement the approach and/or intervention with the aim of achieving equitable, sustained scale of the solution in priority populations or geographic

areas in order to improve health at the country level and foster collaborative learning at the global level.

An important aspect of USAID's approach is the use of multi-disciplinary quantitative and qualitative methods. These methods can be utilized across biomedical research, epidemiology, demography, mathematical modeling, as well as social science fields such as behavioral science, anthropology, economics, and political science. USAID global health R&D also utilizes best practices from the private sector, such as early and comprehensive product launch planning. By using these complementary methods and drawing on the expertise of USAID's global partners, the Agency is able to develop better local solutions and address disease burden, risk factors, behaviors and norms, structural factors, and other health determinants to inform health strategies and approaches.

USAID's R&D investments and partnerships are guided by broader policies and principles of the Bureau for Global Health and USAID. These include prioritizing locally-led and inclusive development, adapting to and mitigating the impacts of climate change, reducing inequities, and strengthening health systems. Aligned with USAID priorities, USAID's global health R&D will follow the following principles.

1) Prioritize locally led development, local systems change, and local capacity strengthening. GH R&D should incorporate local stakeholder feedback, create space for local leadership, fund local partners where feasible and appropriate, advocate globally for locally-led research and development, and work to strengthen local R&D capacity. This includes incorporating principles of ethical research integrity into our work and ensuring USAID investments reflect and uphold the highest standards of evidence-based scientific research.
2) Include climate change adaptation or mitigation considerations where feasible and appropriate. Including climate considerations throughout the R&D program cycle may include identifying ways to contribute to slowing the pace of climate change, and/or to adapting to climate-related stressors.
3) Reduce inequities by proactively seeking to understand needs and priorities of marginalized groups and ensuring their inclusion both in our programming and the systems that our investments aim to strengthen. GH R&D should contribute to equitably meeting population needs across the life course, and to supporting equitable health systems that afford every individual a fair opportunity to attain their highest level of health regardless of social or demographic factors, with particular emphasis on understanding gender dynamics and the health and well being of underserved, socially excluded, and vulnerable populations such as ethnic minorities, women, youth, LGBTQI+, as well as special needs populations with mental health support or disabilities.
4) Take a systems approach to global health research and development. This includes, but is not limited to, understanding the health system and structural barriers to and opportunities for GH R&D; strategically aligning and integrating across portfolios and across sectors, including centering primary health care as the foundation of the health system; and considering how to leverage USAID's substantial global health presence

and investments to meet urgent needs while strengthening health systems for the long term, and planning for sustainability and achieving results at scale.

Objectives of USAID's Global Health Research and Development Strategy

1. HEALTH TECHNOLOGIES, TOOLS, AND APPROACHES

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

Effective new or refined products, technologies, tools, and approaches serve a critical role in addressing pressing health issues across the spectrum of prevention, diagnosis, and treatment. These technologies may build on or replace those already in use or take an innovative or more user-centered approach in addressing a health problem. Important gaps in scientific evidence also exist regarding the safety and efficacy of various approaches overall and for subgroups (e.g., females and males), as well as what factors influence the disease development, transition, and population burden.

Whether a concept for a new technology or improved intervention lives up to its promise depends not only on its effectiveness in highly-controlled trials, but also on whether it is designed for and responsive to intended populations. Innovative technologies, approaches, and tools should be effective, cost-effective, and meet users' needs and desires, while also having attributes that support introduction, scale-up, and sustainability. Investments in country-based digital technologies and data systems will align to the priorities of USAID's *Vision for Action in Digital Health*. USAID's approach is to "begin with the end in mind" to ensure technologies and interventions prioritized for development and introduction will ultimately be appropriate for the intended context and recipients, while also meeting the evolving needs of intended users. USAID can uniquely capitalize on its country-specific knowledge and implementation expertise to ensure designs and strategies account for user and provider needs, resource-limited service delivery challenges, and other constraints from inception to scale-up.

USAID will employ the following actions to achieve this objective:

Prioritize R&D based upon health impact potential: USAID will continue to collaborate closely with private and public partners, using objective criteria and evidence to develop informed decisions on what new technologies and research will best respond to critical unmet public health needs and emerging threats. USAID will also leverage these relationships to develop well-defined target priorities and populations for new technologies. Critical product characteristics should include safety, efficacy, cost-effectiveness, acceptability to both beneficiaries and providers, delivery feasibility, sustainability and overall potential for public health impact.

Intensify private sector engagement: USAID recognizes the power of the private sector as a partner to research and serve target populations. The Agency will continue to strategically use Global Development Alliances and proven mechanisms such as Grand Challenges and Broad Agency Announcements to enable partnership and risk-sharing with the private sector, leveraging complementary expertise to develop innovative and sustainable solutions to complex public health challenges.

Ensure cohesive "end-to-end" coordination and planning: The development and introduction of global health technologies and more effective approaches requires the skills and input of a number of partners. USAID and its partners will continuously strive to strengthen the efficiency of partnership structures and utilize collaborative work-planning, which clearly outlines the responsibilities of the various partners, the resources required, the risk at different stages, and go/no-go decision criteria. Best practices outlined in USAID's IDEA to IMPACT series will continue to serve as a guide to help practitioners accelerate impact through better coordination and earlier planning for product introduction and scale.

Evaluate progress, risk, and priorities systematically: USAID will regularly and systematically evaluate the progress of research and technologies by assessing risk and progress at every stage. Independent analyses of issues related to regulatory constraints, safety, manufacturability, acceptability, cost-effectiveness, and feasibility of scaling up to population-level coverage informs decisions, thereby enabling the adjustment of strategies, priorities, and risk mitigation measures. By using this rigorous approach, USAID will increase the efficiency of its R&D funding and enable maximum health impact.

To manage risk, USAID staff provide oversight of awards and other funded activities to ensure appropriate biosafety and biosecurity controls, protocols, and training. USAID works with implementing partners as well as relevant host country partners to ensure adherence to and reporting on rigorous safety protocols in line with U.S. and global standards. USAID works in partnership with other U.S. Government agencies — including the Department of Health and Human Services (the National Institutes of Health, Centers for Disease Control and Prevention, and the Biomedical Advanced Research and Development Authority), the Department of State, U.S. Department of Agriculture, and other relevant U.S. government partners engaged in biosafety and biosecurity practices. USAID does not fund any Dual-use Research of Concern (DURC) or Gain-of-Function (GoF) Research.

Employ market mechanisms and private sector tools: USAID will continue to utilize market shaping, innovative financing mechanisms, and other market-based tools to identify and overcome market inefficiencies for a more successful launch and accelerated scale-up of new technologies and improved interventions. By addressing transaction costs, insufficient market information, and imbalanced risks, USAID can use its purchasing power, technical knowledge, and convening power to leverage the expertise and active engagement of the private sector. Private sector tools include employing social and behavioral research methods that actively engage potential beneficiaries, providers, and other stakeholders throughout the development

and introduction process to ensure decisions are informed by the needs and expectations of those benefiting from the product or intervention.

Achievement of this objective will result in:

- Accelerating development and introduction of technologies that have the potential of having a high impact on improving health outcomes;
- Identifying which interventions are most effective against high priority health problems.
- Generating new knowledge that will have applicability to health globally, including in the United States;
- Addressing market inefficiencies, leveraging private capital, and partnering with the private sector to develop new and refined technologies and accelerating access to them;
- Designing innovative technologies and end-to-end analyses that result in reduced risk and more efficient and cost-effective investments while considering end-users, providers, stakeholders, and local contexts;
- Refining existing health products to lower cost, reduce waste, simplify delivery, and increase acceptability among users and providers; and.
- Testing how certain products can impact overall client health and establishing better information and counseling, further empowering individuals to make informed health care decisions.

Illustrative Examples of USAID's Work under Objective 1

- The MATRIX consortium works to develop a range of HIV prevention products that are acceptable, affordable, scalable and deliverable by providing a platform for efficient, benchmark-driven portfolio management. The consortium brings together U.S. and African-based researchers and experts engaged with early-stage (R&D on novel HIV prevention products, social and behavioral research (SBR) and market and business case development to advance products that address the unmet needs of user populations in low and middle income countries.
- USAID co-funded the Evidence for Contraceptive Options and HIV Outcomes (ECHO) Trial as a response to emerging global concern about the risk of HIV acquisition among women at high risk of HIV using hormonal contraception, specifically progestogen-only injectables. The ECHO trial was designed to compare HIV incidence among women using three contraceptive methods, including one progestogen-only injectable, DMPA. The three-year, multi-country clinical trial showed no substantial difference in HIV risk among women who were using any of the three contraceptive methods evaluated, and all methods were safe and highly effective. This global evidence prompted a change in global and national guidelines, ensured clients across the world were counseled with the most up-to-date evidence, and reaffirmed the importance of offering high-quality, voluntary family planning services and HIV prevention information to all women and couples.
- The Kampala Slum Maternal Newborn Health (MaNe) implementation research project in Uganda successfully partnered with the Kampala Capital City Authority (KCCA) to address a critical issue for emergency transport of pregnant women and infants: the very limited availability of just six public ambulances for an estimated urban population of 2.5

million people. To overcome the lack of coordination which led to frequent delays in ambulance dispatch, KCCA partnered with MaNe to design and test a mobile phone application (app) called the Kampala Digital Emergency Transport System (KDETS) to request, refer, deploy, and track ambulances. The mobile app facilitates communication between referring facilities, ambulance drivers, and receiving facilities. The built-in GPS allowed the central call center to track ambulance locations and dispatch the ambulance closest in proximity to the referring facility, with directions for drivers to the requesting and receiving facilities to mitigate delays during interfacility transport of patients to lifesaving care and improve driver accountability from real-time tracking. Pre-referral notification to the receiving referral facility also allowed the staff to prepare for the incoming emergency referral cases, saving time and reducing the potential for medical errors associated with patient handovers.

2. IMPLEMENTATION SCIENCE

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

Although new health technologies, tools, and practices are critical to addressing unmet health needs, an even larger gap exists between the development of evidence-based policies, programs, and interventions and their efficient and effective translation, introduction, and ultimately, implementation at scale. It is critical not only to know what interventions to provide or conduct, but also how to provide them most equitably, effectively and efficiently in specific contexts and under specific constraints. This is why USAID prioritizes implementation science inclusive of adaptive management and implementation research to understand how to evaluate, in real time, new and existing interventions with a focus on understanding barriers and facilitators, practical introduction, scale-up, and sustainability. Although many pilot interventions may show results on a small scale under highly controlled conditions, the transition to implementation at scale under real-world conditions is often much more complicated. Failure to address these issues can delay roll-out, contribute to unnecessary costs, and limit impact. In the context of limited resources, and as needs grow in complexity and scale-up volume increases, implementation research provides an evidence-based approach to trade-offs and prioritization, factoring in acceptability, feasibility, and costs that may be ignored with traditional research and development.

USAID's approach is grounded in engagement of a broad set of critical stakeholders, including marginalized populations, throughout the research-to-use process, starting with planning and prioritization, moving to introduction, and including rigorous study of these processes to identify bottlenecks and course-correct in real time. To generate the political and stakeholder commitments that will ultimately enable public health impact, it is essential to ensure research seeks to understand the local context (e.g., gender dynamics, cultural traditions), is embedded in real-world policy, practice, and implementation, and is locally-led and co-developed with partner country stakeholders to generate locally relevant evidence. At the same time, many findings about what works and what does not work with regard to implementation have

relevance beyond a single country. Hence, USAID also supports cross-country collaboration and knowledge exchange to share emerging lessons and experiences. The successes of one country in addressing implementation challenges often inspire leaders in other countries to take action to revise their own policies, plans, and practices. This practical, country-led implementation research is often at the forefront for identifying emerging threats to sustained health development and novel areas of USAID work. Examples include changing epidemiology and needs in countries related to non-communicable diseases, mental health, injuries; recent Covid pandemic and polio outbreaks; and natural and human-made disasters (including conflict areas).

USAID will employ the following actions to achieve this objective:

Develop and regularly update, when appropriate, prioritized research or learning agendas within and across countries: USAID's Bureau for Global Health provides technical assistance to encourage field missions to contribute country-level evidence to knowledge synthesis efforts under prioritized research and learning agendas, and to incorporate the research and learning questions into their own program design and management. In parallel, USAID will engage and collaborate with key partners to share findings, reach consensus on how to address evidence gaps, and identify the most promising practices for testing, refinement, and scale-up.

Embed implementation science in programs with real-time feedback: Beginning in the early stages of planning, USAID will proactively integrate research and learning approaches into the implementation platforms it supports. Continuous feedback loops between the embedded research and programs/interventions will enable timely improvements on an ongoing basis, while also strengthening the capacity of implementers to understand, conduct, and use research. This also supports responsiveness to evolving country contextual needs.

Synthesize data and strengthen use of evidence for decision-making: USAID will support collaborative reviews and analyses of evidence to compile practical knowledge drawn from multiple field experiences. This includes identifying and supporting the implementation of high impact practices within health system strengthening and service delivery programs. USAID will support testing of innovations and promising practices for improving service delivery and strengthening health systems, identification and synthesis of evidence on highly effective practices, and widespread implementation of these approaches. Areas of interest might include the use of systems practice in global health programs, strengthening linkages between communities and local health systems, improving integrated primary health care service delivery, and more.

Achievement of this objective will result in:

- Increasing the number of feasible and cost-effective interventions adapted and implemented at scale;
- Identifying new innovations in global health service delivery and health system strengthening practice;

- Reducing the lag time between scientific breakthroughs and widespread access;
- Improving the ability of USAID and partners to use research results to inform and adapt programs in their local contexts;
- Supporting a culture that promotes the generation and use of evidence to inform decisions;
- Addressing bottlenecks in prevention and control of infectious diseases; and
- Increased and equitable access to and use of quality health interventions, including reaching vulnerable and marginalized groups.

Illustrative Examples of USAID's Work under Objective 2

- USAID is currently supporting meaningful youth-led local development and testing of digital interventions focused on reproductive health information and linkages to relevant products and care.
- USAID is currently planning for a five-country Implementation Science study, CATALYST, to characterize and assess provision of multiple HIV prevention methods for adolescent girls and young women (AGYW). This will provide data and evidence to policy makers and national governments on an optimal HIV prevention package.
- USAID supports implementation research to strengthen community health and primary health care implementation. This includes research exploring the rollout of a community health policy in one country, which will inform community health strategy implementation at the country level and globally. In another country, USAID has supported research to understand the impacts of the government's Primary Care Provider (PCP) Network initiative. Results informed the promotion of the country's equity objectives for Universal Health Coverage and contributed to global knowledge on equity-enhancing strategies.

3. RESEARCH AND DEVELOPMENT SYSTEMS

To strengthen the capability and resilience of local stakeholders, institutions, programs, and partnerships to conduct monitoring, evaluation, research, and learning and utilize evidence to improve health outcomes in a systematic, equitable, inclusive, and sustainable manner to further USAID's commitment to localization.

The COVID-19 pandemic has demonstrated the need for nimble R&D systems capable of rapidly learning and responding. While there is substantive scientific and technical capacity among individuals, institutions, and networks in USAID partner countries, the systems that support them are often overburdened, under-resourced, and fragile. This lack of capacity can have detrimental global effects, which can extend to the United States, such as through delayed identification of and response to infectious disease outbreaks until after a disease has begun to spread beyond national borders. Therefore, building the capacity of partner countries to respond more quickly to potential outbreaks is important to protect the safety of the global community as well as Americans here at home.

Similarly, strengthening the capabilities of local researchers and capacity of research institutions to conduct effective, embedded implementation research and learning supports the timely and sustained adoption, implementation, and impact of context-specific behaviors and interventions that can improve health and development programs and save lives. This necessarily includes health system capacity to manage knowledge and utilize evidence to improve health outcomes in a systematic, equitable, inclusive, and sustainable manner.

Strengthening individual and system capacity empowers local talent, including women and others often excluded from research careers, and enables communities and countries to conduct their own research without external assistance, often leading to global benefits. USAID has consistently supported efforts in this area by partnering with country institutions, such as universities and policy think tanks, on research projects often involving a training and/or mentoring component to ensure sustainability. As USAID supports locally-led research and development systems in developing countries, the Agency also draws on its extensive networks of domestic and global academic and research institutions, private companies, multilateral agencies, other donors, implementing partners, and Missions, to develop strong global partnerships, which continue after USAID's support ends. The configuration of these partnerships have changed with the pandemic opening opportunity for greater localization and country leadership with support globally, leveraging what can be done with remote virtual and hybrid support.

Through these efforts, USAID engages individuals within institutions that may not traditionally focus on science and technology, such as non-governmental organizations and diverse government agencies that use the knowledge and technology generated through research for cross-sectoral benefit. For example, through collaborations with the livestock and agricultural sector, capacity can be built to detect diseases in the food supply before they spread to humans. USAID's efforts also complement those of other U.S. Government agencies such as the National Institutes of Health and the Department of Defense, which are more focused on building the capacity of a different cadre of scientists who will eventually help to form a productive research community in country. Building on its existing relationships, USAID seeks to ensure a systematic approach to strengthening research capabilities and resilience of local organizations and institutions to better implement, monitor, and evaluate health research activities, use information to inform decision-making, and promote knowledge sharing.

USAID will employ the following actions to achieve this objective:

Strengthen institutional research capacity: USAID will partner with U.S.-based, global and country academic and research institutions to build the capacity of local institutions and systems in LMICs to conduct mutually beneficial, high-quality, and efficient research. This will include building relevant research management systems, including financial, administrative, and quality assurance capacity, while strengthening systems used by ministries of health and other partners for research-related policy development, oversight, and prioritization, and to support research and evidence use in policy-making and management.

Build research capacity of emerging leaders: USAID will help to foster environments that provide better opportunities for young scientists and public health professionals and mentorship opportunities for senior scientists in the United States and in developing countries to design and lead research with local, regional, and global relevance and ownership while promoting diversity, equity, inclusion, and accessibility (DEIA) in the R&D workforce in both the United States and in developing countries.

Expand international research networks: USAID will facilitate knowledge sharing and learning across and within countries through supporting global and regional networks, systematic multidisciplinary analyses of advances and challenges, web-based knowledge-sharing platforms, and efforts to engage stakeholders to build consensus within and across global, national, and local settings.

Engage partners including civil society and community advocates to ensure responsive research: USAID will continue to partner with civil society to ensure research follows Good Participatory Practice (GPP) guidelines while being responsive to communities and effectively disseminating and interpreting results for the public. These efforts nurture trust in the research endeavor and enable clear communication of the relevant findings locally and globally.

Improve systems for data management, collaborative data analysis, and data platforms: USAID will provide focused support to improve data management systems that contribute to research and research utilization within programs. The Agency will also strengthen mechanisms that facilitate open-data sharing and collaborative analysis of data from research studies and from real-world public health programs.

Continue to monitor and mitigate the impact of R&D operations on the environment, while also transforming R&D operations, research facilities, and activities to mitigate and adapt climate impacts. This could include research related to increasing renewable energy use in health facilities, improving innovative waste management practices, and promoting sustainable laboratory practices particularly sustainable supply chains.

Achievement of this objective will result in:

- Increasing capacity of public and private actors in USAID partner countries to conduct and utilize research without depending on external donor assistance;
- Strengthening individual and institutional capacity, contributing to self-sustaining health research systems in partner countries and fruitful long-term regional and global research partnerships;
- Increasing productivity of young scientists and public health professionals to lead research and implementation science projects and to publish manuscripts;
- Increasing diversity of young scientists, public health professionals, and senior scientists as part of the Biden Administration's commitment to to advance diversity, equity, inclusion, and accessibility;

- Sharing results globally based on high quality research, which can inform analysis of topics such disease trends, surveillance, and risk factors, and contribute to a strengthened evidence base across USAID health priorities; and
- Increasing capacity of public and private actors in USAID partner countries to mitigate climate risks that can impact R&D activities and respond to climate shocks.

Illustrative Examples of USAID's Work under Objective 3

- Since 2001, USAID has supported thousands of scientists in LMICs working on the global effort to design, develop, and test HIV vaccine candidates. Today, this support is ongoing via USAID's partnership with the International AIDS Vaccine Initiative (IAVI) through a project known as Accelerate the Development of Vaccines and New Technologies to Combat the AIDS Epidemic (ADVANCE). Under ADVANCE, scientific capacity strengthening is at the core of all activities, including IAVI's Leadership Development Program (LDP) that positions African and Indian scientists to take the lead in fashioning, driving, and supporting the scientific research enterprise. The initiative offers opportunities to early- and mid-career scientists to develop their skills to become the next generation of science leadership in their respective fields of expertise. USAID provides early- and mid-level career investigators with enhanced skills training including scientific communication, biostatistics, research ethics, social and behavioral research, epidemiology, and clinical trial operations. USAID also supports scientists to build independent scientific networks and provides technical assistance as needed for scientists writing manuscripts for publication, grant proposals, and obtaining independent funding for projects.
- USAID has, through its support to the World Health Organization (WHO) Special Programme for Research and Training in Tropical Diseases (TDR) and the TREAT TB project, implemented capacity building for tuberculosis-related research programs by training public health workers to conduct research using data from their own programs. Through a year-long process involving three week-long trainings coupled with ongoing mentoring from an experienced researcher, participants propose a research topic to improve service delivery in their context, gather and analyze data from the programs on which they work, and then write a paper and policy brief. While USAID's support for the program (SORT IT) has been specific for TB research, this highly practical approach is now being applied by WHO-TDR and its partners to build the research capacity of implementers working on many other diseases in a rapidly expanding number of countries throughout the world.

4. PARTNERSHIPS AND COLLABORATION:

To strengthen research and development partnerships among countries and development partners to improve coordination and strengthen open, shared data for decision making and planning.

USAID's comparative advantage in convening fruitful partnerships is central to the Agency's global health R&D approach. USAID uses a deliberative approach to partnerships and collaboration that builds upon localization and capacity development in countries. This includes partnerships with host governments, other U.S. Government agencies, private companies, bilateral and multilateral agencies, donors, non-governmental and faith-based organizations, academia, and other stakeholders within civil society. For example, USAID recognizes that governments and private entities have complementary strengths and leverages these through diverse, dynamic, and mutually beneficial public-private partnerships that enable resources to be stretched further to achieve development outcomes more effectively and sustainably.

As part of the deliberative process, USAID links research, knowledge management, and research occurring within USAID's communities of practice with external collaboratives, communities of practice, and networks to facilitate South-to-South learning that is more accountable and more responsive to changes in country. This includes regional and global networks supported by multilateral agencies like WHO and UNICEF as well as other global and regional donors. Through the Partnership for Maternal Newborn and Child Health (PMNCH) and Countdown to 2030, for example, evidence and data is used as benchmarks for country progress and shared learning with various constituencies involved in country policy making and decision making. Technical partnerships and collaborations on emerging issues have been key to advancing areas, often multi-sectoral in nature, such as urban health, inclusive development, non-communicable diseases, mental health, and injuries.

Effective partnerships are a key aspect of taking a systems approach to global health research and development. Collaboration is critical for 1) contributing to our joint understanding of global opportunities and barriers through sharing of data and knowledge, 2) supporting strategic alignment and integration across programs, partners, and sectors, and 3) facilitating new models of working that can lead to sustainability and achieving results at scale.

USAID will employ the following actions to achieve this objective:

Strengthen knowledge management: Collaborate with partners across all technical areas - and across all the full continuum of monitoring, evaluation, research and learning - to ensure the shared accessibility of key data and knowledge that can inform and improve uptake of priority health evidence, technologies, tools, and approaches. This includes continued investment in knowledge management efforts, to facilitate effective global and local utilization of R&D findings, results, and best practices.

Expand collaborations to strengthen decision-making: USAID is a key convener of partnerships with host governments, other U.S. Government agencies, private companies, bilateral and multilateral agencies, donors, non-governmental and faith-based organizations, academia, and other stakeholders within civil society. USAID will expand efforts to broker knowledge exchanges and ensure representation of all voices, with the goal of strengthening our collective global, regional, and country decision-making capacity.

Achievement of this objective will result in:

- Strengthened global coordination and collaboration regarding the availability and use of data for decision-making at global, regional, and country levels.
- Reduced inequities by centering local partners and communities in research and development partnership efforts.
- Timely, more accountable responses to changing context in countries.
- More efficient and effective use of global resources for R&D.

Illustrative Examples of USAID's Work under Objective 4

- Hormonal IUD introduction: The hormonal intrauterine device (IUD) is a highly effective, long-acting reversible contraceptive with proven non-contraceptive benefits and was developed with support from USAID. The method had not been available at scale in LMICs due to access barriers including high commodity prices, service delivery constraints, and lack of understanding of potential demand in these markets, though it has been available in the U.S. for over 20 years. In 2015, USAID convened an interagency hormonal IUD working group with participation from diverse stakeholders to coordinate a learning agenda and access strategy. This platform led to improved harmonization of investments across multiple donors and data collection approaches. Research results were combined in papers and presentations to global and country stakeholders. Based on emerging evidence and a desire to expand contraceptive method choice, governments in several countries have made the decision to scale up the hormonal IUD in the public sector and both USAID and UNFPA now include two hormonal IUD products in their catalogs.
- Respectful Care/Respectful Maternity Care (RC/RMC)**:** USAID support to national reproductive, maternal, newborn, child and adolescent health (RMNCAH) programming respects clients' rights, values, and needs, while recognizing the importance of an enabling environment for the provider to achieve quality provision and for the patient to have a positive experience of care. A multi-country survey identified how 20 countries were performing against a multi-level framework involving both the health system (national to local level) and the community (e.g., social and behavior change, social accountability). Based on the survey and a consultation with USAID Missions and partners, the framework was refreshed and learning was prioritized to better understand and address factors affecting the provider-client interface during service provision in a manner that supports the needs and values of both parties. The RC WG is planning a "Respectful Care" Learning Collaborative across Africa, Asia and Latin America to share resources, materials and learnings on implementation of respectful care across RMNCAH services, and to identify and fill in research gaps in our understanding of factors that contribute to (or detract from) respectful care, as well promising approaches and best practices for achieving respectful care in varied contexts.
- Potential Serious Bacterial Infections (PSBI) in Young Infants: Newborn sepsis is a rapidly progressing life threatening condition that can lead to death and disability. USAID working in partnership with WHO, UNICEF, the Gates Foundation, and Save the Children/Saving Newborn Lives engaged researchers, policy makers, and program

implementers to undertake a systematic and collaborative learning agenda in Africa and Asia to develop an evidence-based approach to manage suspected sepsis also known as possibly serious bacterial infections where referral to a health facility is not possible. While this approach does not replace the gold standard of hospitalization, it offers a safe evidence-based approach to rapidly provide care for sick newborns. This work led to a new WHO guideline and implementation in at least 24 countries.

- Neglected Tropical Diseases (NTDs): USAID's Neglected Tropical Diseases program supports a dynamic NTD diagnostic prioritization, target product profile (TPP), product evaluation and expedited review process with WHO. The Diagnostic Technical Advisory Group (DTAG) has ensured a unified approach for identifying and prioritizing the diagnostic needs for NTDs and resulted in numerous diagnostics products through the development pipeline at an accelerated rate. Eighteen TPPs have been designed and published since 2019, and ten products have been or are being prototyped for field performance evaluations to improve the diagnostic capacity of NTD mapping, monitoring and evaluation.
- HIV Vaccine Research: USAID supports collaborative HIV vaccine research led by African scientists, working across different countries, and involving extensive partnerships with pharmaceutical companies, non-governmental organizations (NGOs, U.S. academic institutions, and other donors. One example of such collaborative research is the IAVI G003 trial, a phase I study to test an innovative HIV vaccine antigen that was developed by IAVI scientists and will be delivered via RNA through a partnership with the company Moderna and with co-funding from the Bill and Melinda Gates Foundation. The trial is currently being conducted at the Center for Family Health Research (CFHR) in Kigali and the Aurum Institute in Tembisa, South Africa, while laboratory immunologic assays of the samples will be completed in Kenya by the KAVI-Institute for Clinical Research (KAVI-ICR) in Nairobi and the Kenya Medical Research Institute-Centre for Geographic Medicine Research-Coast (KEMRI-CGMRC) in Kilifi. These clinical research centers (CRCs) are part of a larger network of African CRCs supported by USAID that will continue to collaborate in important research studies to advance the field toward the long-term goal of a safe and effective HIV vaccine.

Conclusion

The USAID Global Health Research and Development Strategy 2023–2028 will guide USAID's work in research and development over the next five years. The Strategy demonstrates USAID's commitment to prioritizing health-related research and development as a critically important component of the larger effort to achieve the Agency's health and development objectives. Further, this document identifies common goals and approaches to global health research across USAID's technical areas and will remain flexible to adapt as priorities and goals change over time.

The challenge now is to regain and sustain the progress made to date, while deepening and accelerating USAID's efforts to achieve its global health and development objectives. Informed

by cutting-edge evidence and analysis, USAID will continue working to identify the most promising opportunities to capture, generate and apply evidence to influence the adoption, implementation, and health impact at scale of priority life-saving health and development interventions, while also working to accelerate the development, introduction, scale-up, and sustained use of health technologies, tools, and approaches to address critical unmet needs and emerging challenges. USAID and its partners will continue to maintain and expand global and regional research partnerships and networks, and to strengthen the capability and resilience of local stakeholders, institutions, and systems to generate the right knowledge at the right time and to utilize that evidence to improve health outcomes in a systematic, equitable, inclusive, and sustainable manner.