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USAID Health-Related Research and Development Progress Report

An Update on the 2011–2015
Health Research Strategy



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Front Cover Photo: Johns Hopkins

USAID's Fighting Ebola Grand Challenge team from Johns Hopkins University gained user feedback on their redesigned personal protective suit and hood from health care workers at Médecins Sans Frontières' Ebola Treatment Center in Conakry, Guinea.

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An Update on the 2011–2015
Health Research Strategy



PREFACE

In 2015, the global community established the Sustainable Development Goals (SDGs) and celebrated gains in reducing maternal, newborn, and child mortality. However, the vision of a world where all countries achieve under-5 mortality rates on par with industrialized countries is not guaranteed. Research played a pivotal role in the establishment of key milestones that will be critical to achieving newly outlined goals. In the words of President Barack Obama, “Science is more essential for our prosperity, our security, our health, our environment, and our quality of life than it has ever been before . . . our obligations as Americans are not just to ourselves but to all posterity.”

I am pleased to introduce the **U.S. Agency for International Development’s (USAID’s) 2015 Health-Related Research and Development Progress Report**. Guided by a multi-year health-related research strategy and specific research goals, USAID’s research and development portfolio continues to answer President Barack Obama’s call through its investments in scientific research, technology, and innovation. USAID’s work provides the evidence base for the introduction and scale-up of simple and affordable health interventions to improve the lives of families in the poorest nations. The fact that we can define our goals in terms of Ending Preventable Child and Maternal Deaths, Achieving an AIDS-Free Generation, and Protecting Communities from Infectious Diseases is a testament to the significant progress that has been made. The momentum that has carried us this far must be sustained, and we must continue to recognize the importance of a systematic approach to research, innovation, and research utilization in achieving this vision.

USAID uses scientific research to help build the capacity of health systems around the world to prepare for, identify, and respond to public health emergencies. Disease outbreaks in 2015 emphasized the importance of strong health systems – the absence of which can result in the rapid spread of infectious diseases such as Ebola and Zika. USAID’s work with the international community and local partners to fight Ebola demonstrated the necessity of increasing global collaboration. Through Fighting Ebola: A Grand Challenge for Development – a partnership with the whole of U.S. Government, including USAID, the White House Office of Science and Technology Policy, the U.S. Centers for Disease Control and Prevention, and the Department of Defense – solutions for healthcare workers, such as new personal protective equipment, were developed that are safer, more comfortable, and help facilitate provision of care. We used a rigorous process of evidence-generation to help end the epidemic, restore primary health services, and bolster health systems to prevent future outbreaks from becoming global threats.

Additionally as a result of USAID support, advances in combating malaria with two new drugs are in the final stages of clinical trials – offering potential alternatives to current therapies, which are beginning to be threatened by antimicrobial resistance. Progress continues on developing a range of options for women-initiated tools for HIV prevention, including support for a pivotal study of the dapivirine vaginal ring. Investments directed at strengthening national TB strategies and programs have helped enable access to new and improved drug therapies in countries with the highest rates of TB, drug-resistant TB, and HIV-associated TB. Through global collaborations, advancements in the field of implementation research have helped enable the generation of new knowledge to improve implementation, scale-up, and overall health status. Finally, our experience in partnering with the private sector has enabled us to better mobilize resources, broaden our design efforts, and strengthen implementation for more effective outcomes in host countries.

Advances in health research and innovation are the building blocks for public health and economic growth. If we are to achieve our public health goals, we must continue to invest in and support research and development, introduction, and scale-up of breakthrough tools, technologies, and interventions. The challenge before us is to sustain and expand the progress and achievements that have led to saving and improving millions of lives around the world.



Ariel Pablos-Méndez

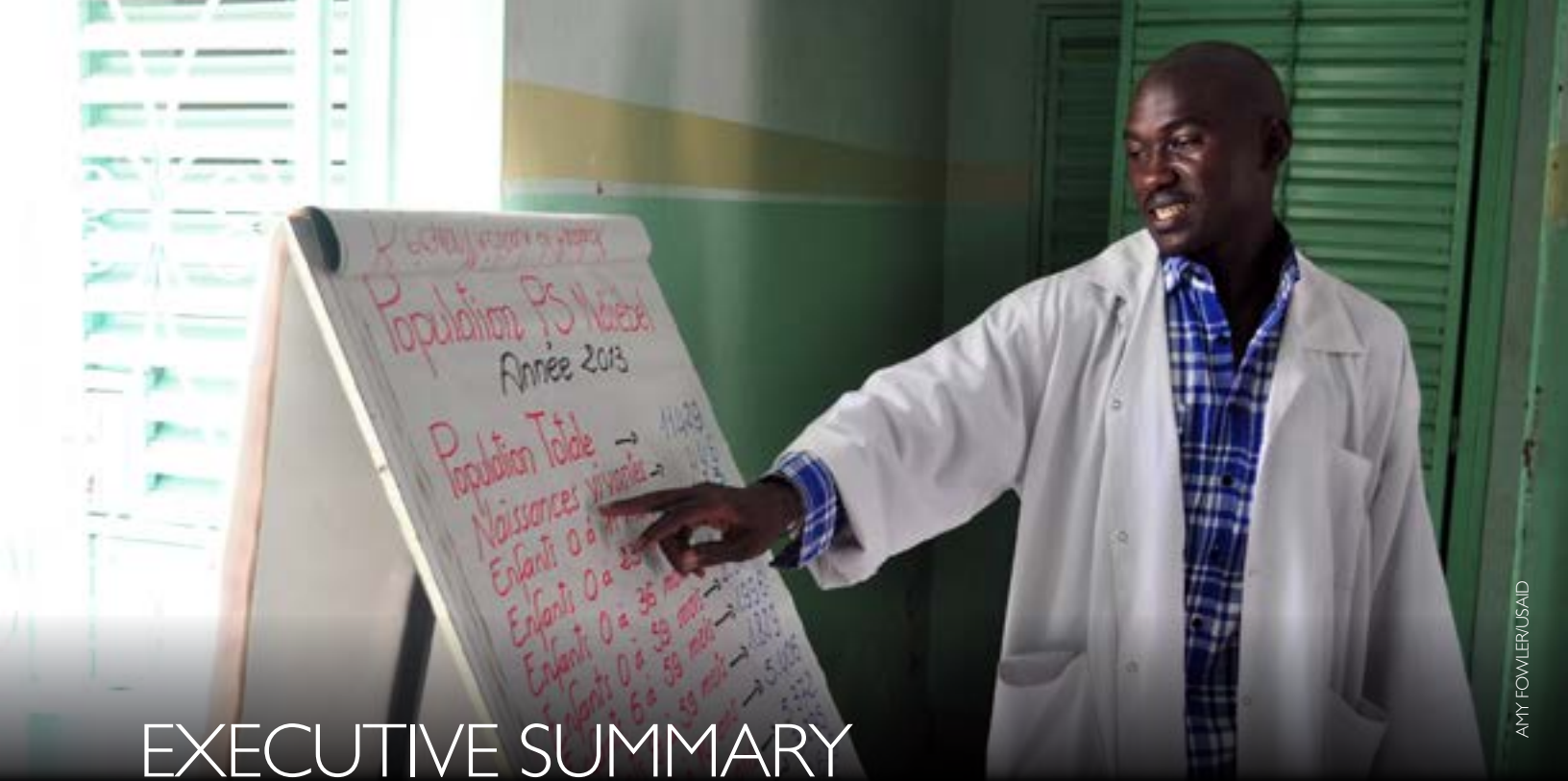
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ACRONYMS

bNAb	Broadly neutralizing antibody
CHW	Community health worker
CHX	Chlorhexidine
CII	Center for Accelerating Innovation and Impact
COR-NTD	Coalition on Operations Research in Neglected Tropical Diseases
CPAP	Continuous positive airway pressure
DPV+LNG	Daprivine+levonorgestrel
DR-TB	Drug-resistant tuberculosis
GHSA	Global Health Security Agenda
EPCMD	Ending Preventable Child and Maternal Deaths
HSS	Health systems strengthening
IAVI	International AIDS Vaccine Initiative
iCCM	Integrated community case management
IFA	Iron/Folic Acid
LiST	Lives Saved Tool
LNS	Lipid nutrient supplements
LF	Lymphatic filariasis
MDR-TB	Multidrug-resistant tuberculosis
NIH	National Institutes of Health
NTD	Neglected tropical disease
ORS	Oral rehydration solution
PDP	Product development partnership
PEPFAR	U.S. President's Emergency Plan for AIDS Relief
PMI	President's Malaria Initiative
PPE	Personal protective equipment
PrEP	Pre-exposure prophylaxis
TAF	Tenofovir alafenamide fumarate
TB	Tuberculosis
TFV+LNG	Tenofovir+levonorgestrel
UNICEF	United Nations Children's Fund
USAID	U.S. Agency for International Development
WASH	Water, sanitation and hygiene
WHO	World Health Organization
XDR-TB	Extensively drug-resistant tuberculosis



AMY FOWLER/USAID

EXECUTIVE SUMMARY

The U.S. Agency for International Development's (USAID's) 2015 Health Related Research and Development Progress Report provides a final update of a 5-year strategy. In response to Public Law 112-74 in 2011, the USAID Bureau for Global Health introduced its 5-year strategy on health-related research and development and outlined the Bureau's process to support uptake of global health products and interventions. This report is subdivided by operating units and provides progress updates to key health research goals specific to each unit. Highlights of this year's report include advances in the following areas:

Ending Abuse and Disrespect in Health Services: Abuse and disrespect during maternity care has been documented and observed globally. Women who choose to give birth at home without a skilled healthcare provider, as a result of having experienced or heard about abuse and disrespect, are more likely to suffer complications, as are their newborns. A research study in Kenya drawing on host-country leadership and parallel advocacy led to a **35 percent reduction in disrespectful maternity care and the development of a World Health Organization (WHO) statement** on the prevention

and elimination of abuse and disrespect during facility-based childbirth. Evidence gathered from these studies is also driving scale-up efforts in Kenya and Tanzania with active engagement and interest from several other countries.

Treating Newborn Sepsis: Infections in newborns, which can rapidly progress to life threatening conditions, can be effectively managed through timely treatment with antibiotics. Infections are among the leading causes of newborn death in developing countries, accounting for 420,000 annual deaths. Studies in South Asia and Africa document that 68 percent to 98 percent of families do not go or cannot access hospital-based inpatient care. USAID and partners supported research that **demonstrated the safety of a combination of injectable and oral antibiotics delivered by trained health workers in lower level health facilities.** Drawing on this research, a newly released WHO policy recommends hospitalization as best but also advises governments that newborns can be safely treated with antibiotics as outpatients. Ongoing implementation research and evaluation is guiding safe introduction and adaptation in countries such as Bangladesh.



Developing Effective and Affordable Medicines for the Treatment of Malaria:

USAID contributes to the drug development pipeline through its support for the Medicines for Malaria Venture. Two novel classes of malaria drugs (OZ439 and KAE609) that have been shown to be efficacious as single-drug treatments have entered late-stage clinical trials in combination with partner drugs. These **new treatments offer the greatest hope for an alternative to artemisinin-based combination therapies.** MMV048, another novel antimalarial compound and the first antimalarial molecule discovered by an African-led team, entered early-stage clinical trials.



Addressing Behaviors that Affect Family Planning:

To address norms affecting family planning, including child marriage and gender-based violence, community-based interventions showed that girls who were offered conditional livestock transfers were 50 percent and 66 percent less likely to marry before the age of 18 in Ethiopia and Tanzania, respectively. In northern Uganda, community-based interventions tailored to life stages **reduced gender-based violence by 16 percent and in-**

creased use of voluntary family planning by 10 percent. USAID is working with policymakers and program managers to tailor these community-based behavioral interventions to target adolescents.



Advancing Understanding around Malnutrition, Birth, and Growth Outcomes:

Preventing stunting requires a deep understanding of how nutritional supplementation affects the “1,000 days” between pregnancy and a child’s 2nd year. USAID-supported studies in Malawi and Bangladesh are examining the effects of lipid-based nutrient supplements and micronutrient powders alongside other health interventions for pregnant women and children under 2. Initial findings from Malawi have **resulted in five high-impact journal publications this year**, with several more anticipated. These studies are contributing to the global evidence base on the impact of nutrition-specific interventions on birth outcomes and child growth and will shape the direction of programming and investments by USAID and the global community.



Developing New Tools for Women-initiated HIV Prevention:

Given that women and girls account for more than half of the 34 million people living with HIV worldwide, USAID continues to prioritize research toward the long-term goal of developing a range of options for women to protect themselves from HIV. A pivotal USAID-supported **study indicated that the dapiv-**

irine vaginal ring has strong potential as one such tool, while USAID also continues to advance ideas for other prevention products for women, including lower-cost tablets, injectable agents, and biodegradable implants.



Advancing the Foundation for an HIV Vaccine:

USAID continues to support the exploration of genetic, viral, and immunological correlates that may be capable of blocking the virus. Efforts are ongoing to further characterize antibodies isolated from an ongoing research study, which is the largest longitudinal study of HIV infection among Africans. It has **enabled the landmark discoveries of new broadly neutralizing antibodies**. This body of work will lead to an improved understanding of envelope immunogens, which are thought to be critical for an HIV vaccine.



Advancing Rapid Diagnosis of Tuberculosis (TB):

USAID-supported modeling studies provide policymakers with information vital to selecting cost-effective diagnostic tools to improve patient outcomes and limit transmission of TB. Using a novel approach called “virtual implementation,” these studies link transmission modelling with operational modelling. Working in close collaboration with the National TB Program in Tanzania, the modeling study evaluated the impact of alternative diagnostics on patients, health systems, and the population. The study **identified three strategies as cost-effective in Tanzania**, including 1) the full

scale-up of GeneXpert; 2) same-day use of LED fluorescence microscopy; and 3) targeted use of GeneXpert for diagnosis of presumptive TB cases with HIV infection.



Strengthening Health Systems:

Health system failures, especially in low- and middle-income countries with weak economies, contribute to preventable morbidity and mortality. USAID is working with the United Nations Children’s Fund (UNICEF) to address this issue by **developing a tool that estimates the impact of health system strengthening on lives saved** at the country level. These estimates will allow donors and countries to make more evidence-based investments.



Innovation to Respond to the Ebola Crisis:

While personal protective equipment (PPE) offers critical protection, it can also be a great source of discomfort and stress for healthcare workers. In hot climates like the areas stricken by Ebola in West Africa, PPE cannot be worn for more than 40 minutes, severely limiting the amount of time healthcare workers can care for patients. To help workers on the front lines provide better care and stop the spread of Ebola, USAID and partners developed the Fighting Ebola Grand Challenge for Development – a program that **enabled innovators from the global community to quickly identify and deliver practical and cost-effective solutions**, while forging the public-private partnerships necessary to test and scale up these solutions.



AMY FOWLER/USAID

MATERNAL AND NEWBORN HEALTH

Each day, approximately 830 women die from preventable causes due to childbirth or pregnancy, and 41 percent of all under-5 deaths are among newborns or babies in the first 28 days of life. Though much progress has been made to understand and combat these health problems, the world's poor continue to miss out on the full benefits of progress made in health. To advance the Agency's goal of Ending Preventable Child and Maternal Deaths (EPCMD), the U.S. Agency for International Development (USAID) has redoubled its efforts to support the generation and translation of evidence on innovations and established best practices that can be scaled up to save more women and children's lives.

Goal 1: Develop and introduce evidence-based interventions for care during pregnancy and at birth

USAID research on Respectful Maternity Care, or conversely reducing abuse and disrespect, has catalyzed global action around this issue using a dual-pronged approach of research and advocacy in parallel. An implementation research study in Kenya documented a 35 percent reduction in disrespectful care and laid the foundation for an ongoing USAID mission scale-up effort. The

study also identified some factors that may contribute to higher reporting of abuse and disrespect including delivering at night, previous deliveries, and being unmarried. This effort has contributed to a shift in the way we speak about quality of care and the importance of patient experiences and has resulted in a World Health Organization (WHO) statement on the prevention and elimination of abuse and disrespect during facility-based childbirth. Research and scale-up efforts are now actively underway in Kenya and Tanzania, and several other countries have shown interest in moving this agenda forward with the ultimate goal of improving maternal health outcomes and ending preventable deaths.

Goal 2: Strengthen and standardize obstetric care for the prevention, management, and treatment of fistula

The duration of catheterization following fistula repair can vary. A USAID-funded study of women that received simple genital fistula repair showed a 3 percent failure rate after 7 days postoperative bladder catheterization compared to a 4 percent failure rate after 14 days, demonstrating that reducing the practice to half the time was less costly and equally effective. These results have the potential to dramatically reduce the burden

USAID's research investments have brought awareness to the challenges and solutions that can impact a mother and her baby's chance of survival.

HEALTH RESEARCH GOALS

1. Develop and introduce evidence-based interventions for care
2. Strengthen and standardize care for prevention and management of fistula
3. Support interventions to reduce birth asphyxia
4. Support community interventions to treat and prevent newborn infections
5. Develop approaches to integrate maternal, family planning, and newborn health
6. Assess approaches to improve access to quality health interventions
7. Develop tools to measure mortality and morbidity

PRIORITY COUNTRIES

- Afghanistan
- Bangladesh
- Democratic Republic of Congo
- Ethiopia
- Ghana
- Haiti
- India
- Indonesia
- Kenya
- Liberia
- Madagascar
- Malawi
- Mali
- Mozambique
- Nepal
- Nigeria
- Pakistan
- Rwanda
- Senegal
- South Sudan
- Tanzania
- Uganda
- Yemen
- Zambia



Women gather at a self-help meeting to discuss illness recognition and care seeking, as part of a USAID-funded research project in Uttar Pradesh, India.

of fistula repair surgery for women and increase facility capacity to provide fistula repair by reducing hospitalization time, cost, and discomfort. To facilitate adoption of this innovative practice, USAID's global fistula program developed an algorithm for post-repair catheterization and disseminated this to country program managers.

Goal 3: Design, evaluate, and introduce evidence-based interventions to reduce newborn morbidity and mortality from birth asphyxia

Antenatal corticosteroids administered to pregnant women at risk of imminent preterm birth plays a critical role in improving outcomes for neonates. Recent evidence shows that antenatal corticosteroids should only be administered in high functioning facilities, due to the intensive monitoring and follow-up required. USAID has been working with WHO to draft guidelines and will continue to work with low- and middle-income country health programs on research studies to better understand the roll-out, adherence, and impact of the new guidelines on preterm outcomes. Additionally, USAID is supporting the development of a simple tool to identify women who are likely to have a premature birth – one of the critical indications for corticosteroid use.

Goal 4: Develop, test, and introduce community-based health interventions to treat and prevent newborn infections

Infections are among the leading causes of newborn death in developing countries, accounting for 420,000 of the world's annual 2.8 million neonatal deaths. Studies in South Asia and Africa document that 68 percent to 98 percent of families do not go to a hospital for antibiotic treatment. In settings where families cannot or will not access hospital care to treat newborn sepsis, USAID and partners supported research that demonstrated the safety of a combination of a regimen of injectable/oral antibiotics by trained health workers in lower level health facilities. Drawing on this research, a newly released WHO policy continues to recommend hospitalization as best but also advises governments that newborns can be safely treated for antibiotics as outpatients. This work is undertaken as part of a managed USAID research-to-use process including ongoing implementation research/evaluation to guide the safe introduction and adaptation in countries such as Bangladesh.

Goal 5: Develop scalable approaches for integrating maternal, family planning, and neonatal health services

In Tanzania, USAID supported the efforts of a Government of Tanzania community health worker (CHW) task force to carry out embedded research to support the government's efforts to develop a national CHW program. This included mapping CHWs, understanding recruitment and deployment, and assessing the community's views on the CHW's role. This research has been critical in the development of a training curricula, refining the government's guidelines and framework for integrating CHWs across vertical health programs and within the continuum of care for maximum effectiveness.

Goal 6: Assess evidence-based approaches to improve the access and utilization of quality maternal, neonatal, and child health interventions

USAID also uses a strategic partnership model to engage and build the capacity of civil society with host country governments. A project in Kenya is generating

evidence on effective maternal, newborn, and child health approaches and community units. By expanding and strengthening community units and advocating at the local and national levels, community groups were able to help select and retain a cadre of community health volunteers. The active engagement of sub-county health management teams led to retraining of more than 450 traditional birth attendants to community birth referral agents and led to significant increases in service utilization, particularly antenatal care and skilled attendance at birth.

Goal 7: Develop standardized criteria and effective tools for measuring maternal and perinatal mortality and morbidity

USAID promoted a multi-country qualitative study to systematically document patterns of illness recognition and pathways to seeking care among families of mothers and newborns who are sick or dying (see photo). The findings showed that recognition of danger signs around pregnancy and childbirth is generally strong, but newborn symptom recognition is not. The study also emphasized that families seek care differently for mothers than for newborns, with country and cultural contexts of paramount importance. These results will inform more effective maternal and newborn health programming.

Modeling the scale of the impact of USAID's efforts to end preventable deaths is essential to understanding the impact of our investments. USAID has supported the refinement and use of the Lives Saved Tool (LiST), which uses a complex model of inputs derived from demographic, epidemiologic, and program coverage data to provide countries with guidance on a list of the potential impacts of mortality reduction if evidence-based interventions were implemented at scale. LiST is now being refined to enable sub-national planning projections to lower levels of the health system.



ANDREA KELSEY/TRACTION/JIRC

CHILD HEALTH

Each year, approximately 2.5 million children under 5 die from pneumonia, diarrhea, and malaria – preventable diseases that can often be treated with increased access to simple, low-cost interventions. To advance the health of children, U.S. Agency for International Development (USAID) research efforts are focused on providing the evidence base to advocate for high quality and cost-effective interventions with proven impact on the major causes of child mortality. By identifying gaps in service delivery and finding the most appropriate channels to reach caretakers, USAID hopes to ensure the healthy growth and development for the world's most vulnerable children.

Goal 1: Support research to inform the uptake of iCCM

Integrated community case management (iCCM) was developed to extend case management of childhood illnesses (e.g., diarrhea, fever, cough/fast breathing, and malnutrition) beyond health facilities so that more children could have access to timely lifesaving treatments. In Kenya, a USAID-funded study that assessed the impact of iCCM demonstrated improvements in the coverage and quality of services at both the community and facility levels, as well as improved early care seeking and continuum of care. For

example, the percentage of children taken to a provider on the first day of fever increased by 53 percent. In addition, the capacity of community health volunteers to manage sick children improved. Knowledge on the ability to assess danger signs went from 32 to 93 percent. And, findings showed that the iCCM intervention resulted in 96 percent of community health volunteers being able to accurately perform and interpret a malaria rapid diagnostic test. This study demonstrated the positive value of iCCM in a country where policymakers were previously skeptical of its value.

Goal 2: Evaluate interventions to increase the use of efficacious diarrhea treatments

Diarrhea is one of the leading causes of death among children under 5. Many of these deaths are related to dehydration and can be prevented with low-cost care such as oral rehydration solution (ORS) in combination with zinc. However, unnecessary use of antibiotics and antidiarrheals has persisted in many settings. Given that the private sector is a significant source of treatment for diarrhea in many countries, behavioral change research was conducted in Ghana to measure the effects of an intervention on private sector care seek-

A young boy walks with a bucket to collect clean water from an urban community sanitation block, which is a USAID-funded research site for a sanitation improvement intervention (Maputo, Mozambique).

HEALTH RESEARCH GOALS

1. Support research to inform the uptake of iCCM
2. Evaluate interventions to increase the use of efficacious diarrhea treatments
3. Develop cost-effective approaches to decrease acute lower respiratory infections
4. Develop and test scalable approaches to improve drinking water quality and access, use of sanitation, and hygiene behaviors

PRIORITY COUNTRIES

- Afghanistan
- Bangladesh
- Democratic Republic of Congo
- Ethiopia
- Ghana
- Haiti
- India
- Indonesia
- Kenya
- Liberia
- Madagascar
- Malawi
- Mali
- Mozambique
- Nepal
- Nigeria
- Pakistan
- Rwanda
- Senegal
- South Sudan
- Tanzania
- Uganda
- Yemen
- Zambia



KHRC

An expectant mother, who was previously using a three-stone fire, is examining a stove that uses liquefied petroleum gas in Ghana.

ing for diarrhea management. Treatment behaviors (e.g., motivation, attitudes, and intentions) were assessed in more than 750 participants across 3 regions of Ghana. Zinc use increased from 1 percent to 36 percent, and ORS use from 38 percent to 66 percent. Antibiotic use dropped by almost half, and antidiarrheal use also decreased. Almost all caregivers who gave ORS to treat diarrhea also correctly gave zinc. These findings suggest that a similar intervention could be effective in other settings where there is a need for rapid scale-up of ORS + zinc and high reliance on the private sector.

Goal 3: Develop cost-effective approaches to decrease acute lower respiratory infections

More than 40 percent of the world's population cooks using solid fuels. In children under 5, household air pollution caused by cooking with solid fuels is a leading risk factor for pneumonia. In girls and women, there is increased risk for severe burns from open fires and increased susceptibility for violence against those who need to leave secure communities to gather wood and other resources. In response to former Secretary of State Hillary Clinton's initiative to introduce clean cooking technologies into 100 million households by 2020, USAID invested in cross-sectoral research on the drivers and barriers to adoption and sustained use of cleaner

cooking technologies in low- and middle-income countries. Results from studies in India and Uganda highlighted the importance of behavior change to achieve impact. Studies showed that clean cookstove adoption, or a willingness to experiment with clean technologies, was influenced by factors such as community ownership of the intervention, as well as flexible financing options such as free trials, rebates, and installment payment options. Current research is evaluating the impact of a Ghana Ministry of Energy's program to promote clean cooking by distributing clean fuels, like liquified petroleum gas, to a greater percentage of the population. The research will be the first systematic evaluation of the program and will help identify barriers and drivers to clean cooking technology uptake. Additionally, USAID's investment in this area has influenced the investment of other key stakeholders on previously overlooked issues of adoption and appropriate use of stoves.

Goal 4: Develop and test scalable approaches to improve drinking water quality and access, use of sanitation, and hygiene behaviors

Interventions that ensure safe drinking water, proper handwashing, and correct and consistent use of basic sanitation can reduce diarrhea in children under 5 by 25 percent to 50 percent. Water, sanitation

and hygiene (WASH) research activities seek to develop, evaluate, implement, and refine new and existing technologies for point-of-use water treatment, safe water storage, hygiene, and sanitation and to improve operations in existing household water treatment and hygiene promotion programs.

A USAID-funded research project is investigating the science behind habit formation and analysis of the costs of not washing hands. Using the costing methodology of the World Bank's Water and Sanitation Program, this study aimed to determine the economic implications if no measures were taken to increase handwashing with soap among child caretakers. The effects of WASH in schools were assessed through a longitudinal study in 64 intervention schools and 64 comparison schools to measure whether WASH improvements lead to improved learning outcomes measured by attendance/absenteeism and pupil-teacher contact time. The study showed a reduction in student absenteeism of more than 30 percent in schools with improved access to WASH services and education about key hygiene behaviors. These findings can be used to advocate for governments to expand access to WASH in schools and provide support to guarantee the operation, maintenance, and sustainability of WASH services.



ANDREA KELSEY/TRACTION/IRC

A mother and her children are enrolled in a USAID-funded study to determine if access to shared sanitation facilities in urban areas improves child health. Children under 5 are measured and reassessed on various indicators of health (Maputo, Mozambique).



AMY FOWLER/USAID

MALARIA

The progress against malaria in the last 10–15 years has been impressive. Since 2000, malaria deaths in Africa have dropped by 66 percent among all age groups and by 71 percent among children under the age of 5. Worldwide, more than 6 million lives have been saved, a vast majority of which have been children. Without sustained and vigilant efforts, these gains could be quickly reversed, and successful investments in malaria control could be lost. New tools, including a highly effective vaccine, novel antimalarial drugs, and innovative vector control methods are needed to further support malaria prevention and control efforts.

Goal 1: Develop safe and effective vaccines for *Plasmodium falciparum* malaria

The U.S. Agency for International Development (USAID) Malaria Vaccine Development Program continues its efforts to develop a highly effective vaccine against the malaria parasite responsible for most malaria mortality, *Plasmodium falciparum*. USAID's support concentrates on reducing the number of new cases, while other funders focus on vaccines to assist in elimination/eradication of both *P. falciparum* and *P. vivax* (a less virulent parasite).

The Malaria Vaccine Development Program, with partners, has conducted extensive studies of multiple vaccines against all three stages of parasite (prior to entry in the liver; in the liver; and in the blood stream) in animal and human models. The GlaxoSmithKline malaria vaccine, RTS,S/AS01 (Mosquirix), is the most advanced malaria vaccine to date. A large trial of the vaccine involving approximately 15,000 infants and young children in 7 countries in sub-Saharan Africa showed moderate but significant protections against clinical malaria in both infants aged 6–12 weeks and young children aged 5–17 months after 3 doses, which waned substantially by 18 months. In October 2015, the WHO Strategic Advisory Group of Experts on Immunization and the Malaria Policy Advisory Committee met to discuss these results. Given the adverse event signals and the need to expand the routine immunization program through additional immunization visits to implement the four-dose schedule required to achieve the protective efficacy seen in the trial setting, this joint group of experts concluded that further evaluation was necessary before a recommendation regarding use of the vaccine could be made.

A mosquito net hung over this sleeping area prevents mosquitoes from biting the family sleeping under it. Evidence from PMI-supported research on the durability of insecticide-treated nets continues to inform programs and policies.

HEALTH RESEARCH GOALS

1. Develop safe and effective vaccines for *Plasmodium falciparum* malaria
2. Develop effective and affordable medicines for the treatment and prevention of malaria
3. Develop new, effective insecticides for improved vector control
4. Improve malaria control program implementation and impact

PRIORITY COUNTRIES

- Angola
- Benin
- Democratic Republic of Congo
- Ethiopia
- Ghana
- Greater Mekong Subregion
- Guinea
- Kenya
- Liberia
- Madagascar
- Malawi
- Mali
- Mozambique
- Nigeria
- Rwanda
- Senegal
- Tanzania
- Uganda
- Zambia
- Zimbabwe



USAID DELIVER PROJECT

A woman holds her child and her new long-lasting insecticide-treated net in Madagascar.

Goal 2: Develop effective and affordable medicines for the treatment and prevention of malaria

Antimalarial drug resistance has been one of the greatest threats to malaria control over the past 50 years. Resistance to artemisinin drugs, the primary component of artemisinin-based combination therapies, has been documented in a number of countries in the Mekong subregion but has not yet been detected in sub-Saharan Africa. If such resistance were to emerge in sub-Saharan Africa or other malaria-affected regions, it would greatly set back global malaria control efforts. USAID contributes to the drug development pipeline through its support for the Medicines for Malaria Venture, a non-profit foundation established in 1999 that supports discovery, development, and delivery of new, affordable antimalarial drugs through effective public-private partnerships.

Two novel classes of malaria drugs (OZ439 and KAE609) that have been shown to be efficacious as single drug

treatments have entered late-stage clinical trials in combination with partner drugs. These new treatments offer the greatest hope for an alternative to artemisinin-based combination therapies. MMV048, another novel antimalarial compound and the first antimalarial molecule discovered by an African-led team, entered early-stage clinical trials. Rectal artesunate, a pre-referral treatment for severe malaria, is now under review for WHO drug prequalification. Finally, the first quality-approved, co-blistered drug formulation to be used for seasonal chemoprevention of malaria in children achieved WHO-prequalification status, a critical step to allow global procurement.

Goal 3: Develop new, effective insecticides for improved vector control

Research and development of new insecticides and insecticide formulations for public health use is a high priority for the global malaria community. The effectiveness of both long-lasting insecticide-treated nets and indoor residual spraying for malaria prevention in many African countries is being jeopardized by the spread and intensification of insecticide resistance, particularly resistance to pyrethroids, which are the only insecticides currently approved for use on insecticide-treated nets. For example in 2011, pyrethroid-resistant populations of *Anopheles gambiae* mosquitoes were prevalent in western and central Africa but were rarer in southern and eastern Africa. Today, pyrethroid resistance is widely spread across the continent, and the exposure time required to kill mosquitoes has increased tenfold in some populations over a single year. Moreover, the number of insecticides that are currently approved for public health use is limited, and no new insecticides have been registered for such use since the mid-1980s.

The Innovative Vector Control Consortium is an international public-private partnership whose aim is to foster

research and development of new vector control products and tools for public health. USAID provides support to this consortium to contribute to its insecticide development pipeline, including its work to advance three novel insecticide candidates to the final stages of development by 2019. USAID support has included:

- Two large portfolios of new insecticide development with Bayer and Syngenta. Back-up vector control compounds were selected and evaluated for early development studies.
- UNITAID approved the \$65.1 million NgenIRS proposal, developed in collaboration with USAID and other global partners, with the aim to dramatically accelerate the market entry of next generation indoor residual spraying products.

Goal 4: Improve malaria control program implementation and impact

USAID, through the President's Malaria Initiative (PMI), funds operational research across all interventions to improve uptake and scale-up, to preserve intervention effectiveness in the face of resistance, and to assess how to incorporate new interventions and adjust existing interventions in response to changes in malaria epidemiology. Results from research studies that have informed programs and policies include developing new guidelines for insecticide-treated net durability that will be rolled out in 2016 in Angola, Kenya, Malawi, Mozambique, Senegal, and Zambia and improvements in case management policy in Senegal to test fever cases for malaria that previously would have gone undiagnosed.



USAID

POPULATION AND REPRODUCTIVE HEALTH

It is estimated that 222 million women in developing countries want to space or limit births but are not using a modern method of family planning. Factors that contribute to this unmet need include concerns about side effects, inadequate or inaccurate information among couples, and poor access to reproductive health services.

Goal 1: Refine, develop, and introduce new contraceptive methods

In 2015, initial work was completed on the development of a low-cost, safe, and effective biodegradable contraceptive implant that would last for 1–2 years, thus filling a critical gap in the contraceptive method mix between the 3-month injectable and the 5-year implant. Three complementary technologies were tested for proof-of-concept in the laboratory, with two moving into the next stages of development with leveraged support from the Bill & Melinda Gates Foundation.

Additionally, preclinical development continued on multipurpose prevention technologies designed to prevent unintended pregnancy and protect against HIV and potentially other sexually transmitted infections. Two types of multipurpose vaginal rings, tenofovir+levonorgestrel (TFV+LNG) and dapivirine+levonorgestrel

(DPV+LNG), advanced to clinical studies (although the second TFV gel trial showed unexpected results due to non-adherence, TFV is still considered a potent anti-HIV compound). The TFV+LNG ring began clinical testing in 2014 and will be completed by early 2016. The DPV+LNG ring may enter clinical testing mid-2016, in collaboration with the National Institutes of Health.

Goal 2: Improve and expand access to family planning methods in developing countries

A U.S. Agency for International Development (USAID) study in India evaluated a government-run program to prevent child marriage through conditional cash transfers. This program involved provision of money to families under the condition they do not marry off their daughters as children. Results showed that the conditional cash transfer significantly improved girls' schooling participation through eighth grade but did not have a significant effect on age of marriage of enrolled girls. The evaluation suggests that long-term change in social norms cannot rely on financial incentive programs alone but rather require multi-sectoral interventions that are intentionally designed to affect health behaviors.

USAID's research investments in family planning and reproductive health have provided evidence to show that gender equity, healthy relationships, and positive birth outcomes can be strengthened by engaging both mothers and fathers.

HEALTH RESEARCH GOALS

1. Refine, develop, and introduce new contraceptive methods
2. Improve and expand access to family planning methods in developing countries
3. Develop and introduce effective, scalable service delivery models to increase the healthy timing and spacing of pregnancies

PRIORITY COUNTRIES

- Afghanistan
- Bangladesh
- Democratic Republic of Congo
- Ethiopia
- Ghana
- Haiti
- India
- Kenya
- Liberia
- Madagascar
- Malawi
- Mali
- Mozambique
- Nepal
- Nigeria
- Philippines
- Pakistan
- Rwanda
- Senegal
- South Sudan
- Tanzania
- Uganda
- Yemen
- Zambia



AMY FOWLER/USAID

A healthcare worker demonstrates Cycle Beads, an option for voluntary family planning using the Standard Days Method (Mbour I Health Post in the Community of Ndiebel, Thies, Senegal).

USAID also supports a multi-country study on the effectiveness of community-based approaches to prevent child marriage in sub-Saharan Africa. Interventions include community awareness, educational support through provision of uniforms, and livestock transfers conditional upon girls remaining unmarried and enrolled in school. Results showed that the conditional livestock transfer delayed marriage among girls aged 15–17 in Tanzania and Ethiopia by 66 percent and 50 percent, respectively. Community awareness and educational support delayed marriage by 66 percent and 94 percent, respectively, among girls aged 12–14 years in Ethiopia. These results highlight the need for age-segmented approaches to delay marriage among adolescent girls. Data from Burkina Faso is expected next year.

In post-conflict communities in northern Uganda, a USAID project developed and tested a package of life-stage interventions among very young adolescents, older adolescents, newly married couples, and new parents. Pilot results showed that this project increased gender equitable attitudes and behaviors, reduced gender-based violence, and increased use of family planning. Young husbands exposed to the intervention were more likely to help with childcare or household chores. Older adolescents and newly married or parenting adolescents exposed to the interventions were 11 percent more likely to talk to their partner about the timing of their next child and to discuss family planning use. Among newly married or parenting 15–19 year olds, gender-based violence reduced by 16 percent, and family planning use increased by 10 percent by the end of the project. Adults who participated in the project's activities were 11 percent more likely to speak with young people about gender equality and positive couple relationships, including how to avoid pregnancy and partner violence.

Also in northern Uganda, USAID has supported an initiative to address gender norms that trigger the use of violence with children and intimate partners. A mentoring program involving young fathers was combined with a community poster series to build positive parenting practices and relationship skills and to stimulate community-wide reflection on fatherhood norms, parenting practices, and intimate partner violence. Results have shown significant, positive associations with reduced use of harsh physical punishment and intimate partner violence; positive parenting practices; and positive parent and couple communication. Longer-term follow-up re-

vealed the program participants were less likely to use violence with their partners and less likely to use physical punishment with their children.

In Benin, USAID supported a social network approach to influence social barriers to address unmet need for family planning. A package of social network activities were developed, implemented, and tested. Research revealed that interventions were linked to increased discussions about family planning within social networks and perceived support for family planning use, leading to increased use of modern contraceptive methods. This approach is now being scaled up in other parts of Benin, in partnership with local organizations.

Goal 3: Develop and introduce effective, scalable service delivery models to increase the healthy timing and spacing of pregnancies

A USAID-funded analysis examined the effects of meeting women's need for contraception on maternal and child deaths, based on Demographic and Health Survey data from 45 countries. The analysis showed how family planning helps promote healthy timing and spacing of pregnancy. The report estimates the maternal and child deaths that could be averted by satisfying unmet need for contraception among women in 4 high-risk fertility categories, i.e., a birth occurring at too young an age (< 18 years), too old an age (>35 years), with inadequate spacing (< 3 years birth-to-birth) and at high parity (more than 4 births per woman). By meeting the need for contraception among these high-risk categories of women, maternal deaths could be reduced by 70 percent, averting 109,000 out of the 155,000 maternal deaths projected for 2015.



THE SPRING PROJECT/ISI (HAITI)

NUTRITION

U.S. Agency for International Development's (USAID's) investments in nutrition are aimed at preventing malnutrition, particularly in the 1,000 days between pregnancy and a child's 2nd birthday, when optimal nutrition plays a major role in the foundation for health throughout the lifespan. Research efforts include large-scale studies of specialized nutrition products tailored for the nutrient needs of vulnerable pregnant women and their children and analyses of innovative nutrition programming and policy tools.

Goal 1: Strengthen and expand the evidence base on integrated multisectoral approaches to improve nutrition outcomes, including reducing stunting and maternal and child anemia

Research was conducted to assess the feasibility and acceptability of using handheld video cameras and small portable projectors to share key nutrition messages. Participants reported that the approach was feasible and acceptable, and most interviewed participants retained knowledge on maternal, infant, and young child nutrition and hygiene practices including recommended breastfeeding practices. More than two-thirds of participants also shared information with others. The local partner has since

used their own resources to continue making videos on maternal, infant, and young child nutrition and hygiene practices, and this approach was adapted for a similar program in Niger.

Also in Niger, surveys were administered to assess the effectiveness of facilitated discussions coupled with community video messaging on hygiene and infant and young child feeding. Preliminary findings indicate that 6 months after video introduction the percent of households with a handwashing station increased from 13 percent to 50 percent, and there were improvements in positive infant and young child feeding practices.

A USAID project in Bangladesh promoted improved agriculture, nutrition, and hygiene practices through farmer nutrition schools by delivering nutrition and hygiene messages to mothers of young children and teaching them home food production techniques. In 2014, a study of handwashing practices suggested that the presence of Tippy Taps (simple handwashing devices) next to latrines and cooking areas, combined with effective messages about their use, can improve hygiene practices, which have a favorable impact on long-term nutrition outcomes.

During a USAID-supported training for health facility staff on anthropometry, a child is measured for length on a Shorr board. Participants observe the appropriate technique (Haiti).

HEALTH RESEARCH GOALS

1. Strengthen and expand the evidence base on integrated multisectoral approaches to improve nutrition outcomes, including reducing stunting and maternal and child anemia
2. Support implementation research for improved diet diversity and quality
3. Develop, refine, and expand use of state-of-the-art measurement tools for nutrition programs and policies

PRIORITY COUNTRIES

- Bangladesh
- Cambodia
- Democratic Republic of Congo
- Ethiopia
- Ghana
- Guatemala
- Haiti
- Kenya
- Malawi
- Mali
- Mozambique
- Nepal
- Rwanda
- Senegal
- Tajikistan
- Tanzania
- Uganda
- Zambia



THE SPRING PROJECT/JSI

USAID supports the evidence-based practice of complementary feeding interventions targeting children under 2 (Niger).

Goal 2: Support implementation research for improved diet diversity and quality

While universal salt iodization is a fundamental public health intervention to prevent iodine deficiency disorders, USAID is working to answer remaining questions about whether current universal iodization levels meet the needs of pregnant women and infants. Related studies are examining the role of processed foods in total salt intake and implications for iodization programs, and future studies are planned to evaluate the extent to which the current indicator of sufficient iodine intake is an appropriate measure in key populations.

An assessment tool developed with USAID funding was used to evaluate iron/folic acid (IFA) distribution and consumption in 18 additional countries. The research identified patterns of distribution and consumption in each country and highlighted four sequential "falser points" where systems may be weakest: proportion of women who (1) received antenatal care; (2) received IFA tablets; (3) consumed IFA tablets; and (4) the number of tablets consumed. Cross-country analysis of results from all 22 countries studied thus far found that although many women take some iron-folic acid supplements, very few of them consume close to the full recommended dosage, ranging from less than 1 percent in Ethiopia to 38 percent in Nepal. This information identifies areas for future work and

the need to strengthen national distribution and consumption.

Multi-year studies investigating the potential of specialized food products for promoting healthy growth are nearing completion.¹ A Bangladesh study investigated the effect of providing a lipid-based nutrient supplement (LNS) to women during pregnancy and 6 months postpartum and another formulation of LNS to their children age 6–24 months. Preliminary results indicate that LNS supplementation during pregnancy reduced newborn stunting, wasting, and small head size, especially for children of younger mothers and those experiencing significant food insecurity. A related study in Malawi focused on the relationship between the provision of a specialized food product during pregnancy and birth outcomes, with results expected in 2016.

USAID recently supported research in Ghana to assess the diets of young children. Findings on nutrient inadequacies in northern Ghana are being used to inform social and behavior change communication targeting caregivers on optimal feeding practices, including the improvement of mothers' nutrition to ensure the benefits of lactation. In Nigeria, a USAID project is conducting a multi-year study to assess the effectiveness of adapting UNICEF's Infant and Young Child Feeding Counseling Package in improving infant and young child feeding behaviors when implemented at scale. The package will

be rolled out nationally and is currently being tested in two areas – Kajuru and Kauru.

Goal 3: Develop, refine, and expand use of state-of-the-art measurement tools for nutrition programs and policies

Following the completion of research in Guatemala on the optimal combination of locally available foods for young children, a feasibility study was carried out to determine the acceptability of recommendations to feed children a more diverse diet using available foods. Based on the findings, recommendations were adapted to increase the presence of foods from animal origin and complement the diets with specific fortified foods.

The measurement of mid-upper arm circumference is used in children to assess acute malnutrition (see photo below). However, no globally accepted standards currently exist for adults, adolescents, or pregnant or lactating women. USAID has supported a systematic review and in 2015 supported a secondary data analysis to explore if standardized mid-upper arm circumference cutoffs can be used to identify acute malnutrition among pregnant women and adults. These data will contribute to the development of global recommendations for a simple method of identifying acute malnutrition.

¹ <http://www.fantaproject.org/research>.



THE SPRING PROJECT/JSI (HAITI)

Measuring mid-upper arm circumference.



©VSO/ADRIANE OHAN

HIV AND AIDS

With the U.S. Agency for International Development's (USAID's) programmatic assistance, today there are 20 percent fewer HIV infections than 10 years ago, and more than 15 million people are on antiretroviral therapy. Still, an estimated 2 million people are newly infected with HIV every year. In sub-Saharan Africa, 1 in 20 adults is living with HIV, and in the Middle East and North Africa, new infections have increased by more than 35 percent in the last decade. USAID's research agenda maximizes the reach of technically sound, cost-effective, and sustainable HIV and AIDS interventions. Given that women and girls account for more than half of the 34 million people living with HIV worldwide, a particular focus of USAID's research efforts is developing and introducing new women-initiated prevention tools that can provide a range of options to combat HIV.

Goal 1: Develop, test, and introduce microbicides for women to reduce the risk of HIV infection

In early 2016, two trials of the dapivirine vaginal ring for HIV prevention announced their results. This was a landmark moment in the field of microbicides research, as these studies were the first to test the efficacy of a non-gel microbicide delivery system. One trial, ASPIRE,

was funded by the National Institutes of Health (NIH), while the other study, the Ring Study, was funded by USAID and other donors. Results from the 2 studies were consistent with one another, with each reporting modest protection of about 30 percent. However, among women 21 and younger, there was no significant protection, while in women older than 21, the protection was substantial, with point estimates of 37 percent and 56 percent in the 2 studies. Adherence was higher in older women, which could explain the differences observed by age. The USAID-supported Ring Study is continuing, now with all participants receiving the active product, and more extended follow-on studies are being planned. Adherence in such trials may be higher when women know they are receiving an effective product. Overall, the results suggest the ring has strong potential as one tool for women to combat HIV.

Other enhanced formulations, dosing regimens, and delivery systems are also being developed and tested to address previously observed adherence challenges for product users. A new more-potent form of oral Pre-Exposure Prophylaxis (PrEP), tenofovir alafenamide fumarate (TAF), is in development and could prove to have fewer side-effects and be more acceptable to users than the currently available

A field trainee practices a procedure for testing for HIV at a Stage 2 Clinic in Samfya, Zambia.

HEALTH RESEARCH GOALS

1. Develop, test, and introduce microbicides for women to reduce the risk of HIV infection
2. Accelerate development and clinical testing of novel HIV vaccine candidates and build global capacity for vaccine research
3. Strengthen the programmatic evidence base for HIV and AIDS prevention, care, and treatment to achieve epidemic control

RESEARCH SITES

- Cote d'Ivoire
- Dominican Republic
- Ethiopia
- Ghana
- Haiti
- India
- Italy
- Kenya
- Lesotho
- Malawi
- Mozambique
- Namibia
- Rwanda
- Senegal
- South Africa
- Sweden
- Swaziland
- Tanzania
- The Netherlands
- Uganda
- United Kingdom
- United States
- Zambia
- Zimbabwe



The dapivirine vaginal ring provides a new, woman-controlled method of HIV prevention.

forms of PrEP. In addition, given the very low dosage required, TAF-containing oral PrEP is expected to cost much less to manufacture. USAID is also supporting development of products with new mechanisms of actions and longer-acting formulations, including integrase inhibitors, entry blockers, and a biodegradable implant.

Anticipating interest in PrEP and new microbicide formulations once they receive regulatory approval, USAID and partners are now working to prepare relevant countries for the introduction and access programs that will be needed to deliver these products to the women who need them most. These programs will address service delivery, gender issues, product and package design, and resistance concerns. Donor coordination will ensure effective use of resources.

Goal 2: Accelerate development and clinical testing of novel HIV vaccine candidates and build global capacity for vaccine research

With support from USAID, the International AIDS Vaccine Initiative's (IAVI's) Research & Development has deepened their engagement and partnerships with global collaborators, establishing centers of scientific excellence, transferring HIV vaccine science capabilities to Africa and India, and informing national policymakers on the importance

of HIV research. In addition to conducting Phase I trials of novel vaccine candidates with African partner institutions to provide data on whether these candidates are suitable for use in African settings, the trials enhance local immunology capabilities and regulatory capacity. These scientific efforts, coupled with in-country policy and advocacy work to train future African leaders in the field of HIV vaccine research and development, contribute to increased country ownership and direct domestic investments.

USAID continues to support the exploration of genetic, viral, and immunological correlates associated with the development of powerful broadly neutralizing antibodies (bNAbs) capable of blocking the virus. Efforts continue to further characterize antibodies isolated from Protocol C, the largest longitudinal study of HIV infection among Africans, and Protocol G, the study that enabled the landmark discoveries of new bNAbs. IAVI expanded its immunogen design work through collaborative research between the HIV Vaccine Translational Research Laboratory in India, the Human Immunology Lab in London, and African Clinical Research Centers already engaged in Protocol C to study the immunology of the neutralizing antibody response. USAID also supports the YR Gaitonde Center for AIDS Research and Education, Chennai, India, to expand Protocol G. This work will lead to an improved understanding of envelope immunogens, which are thought to be needed for an HIV vaccine, particularly during acute infection in Africa study volunteers, while developing pathways for South-South collaboration between Africa and India on immunogen based research.

Goal 3: Strengthen the programmatic evidence base for HIV and AIDS prevention, care, and treatment to achieve epidemic control

USAID's HIV Implementation Science portfolio supports the U.S. President's Emergency Plan for AIDS Relief (PEPFAR), which seeks to achieve sustainable epidemic control and to reach the Joint United Nations Programme on HIV/AIDS' 90-90-90 global goals: 90 percent of people with HIV diagnosed, 90 percent of those on antiretroviral therapy, and 90 percent of them virally suppressed by 2020. In order to achieve these outcomes,

PEPFAR embraces an "implementation science" framework to improve the uptake, translation, and implementation of research into service delivery practices. USAID's agenda emphasizes methodological rigor, programmatic context, and sound scientific principles in support of prevention, care, and treatment research.

Our current portfolio provides stakeholders with the data and evidence needed to improve services and inform policy and ultimately achieve 90-90-90. Current activities include:

- Implementation Science APS Awards: 10 studies in 10 countries designed to answer critical questions across the HIV prevention, care, and treatment continuum and to strengthen the integration of HIV services with other health programs.
- An operations research project that includes more than 20 studies and focused evaluations in 14 countries to improve the efficiency, effectiveness, scale, and quality of HIV and AIDS treatment, care, and support, and prevention of mother-to-child transmission of HIV programs.
- A gender-based violence project that identifies and addresses gaps in gender-based violence prevention and service delivery through intensive monitoring and evaluation of gender based violence programs.
- A project that researches and evaluates innovations and HIV program implementation and measures the feasibility, impact, and effectiveness of different approaches, strengthens capacity among local research institutions, and promotes data dissemination and utilization of study findings by policymakers and stakeholders. In its first year, this project initiated 15 studies in 14 countries.

Read the expanded Global Health HIV and AIDS research section at: <https://www.usaid.gov/what-we-do/global-health/health-related-research-and-development-progress-report>



TUBERCULOSIS

Tuberculosis (TB) is one of the deadliest diseases in the world, predominantly affecting the most vulnerable – men, women, and children whose immune systems are already weakened through malnourishment, disease, or other factors. In 2014, approximately 9.6 million people developed TB, including 3.2 million women and 1 million children, and 1.5 million people died from it.

Of the 9.6 million people who developed TB last year, approximately 3.5 million of them did not receive quality-assured treatment and care because they were not properly diagnosed and/or were not reported to national TB programs. Many of these individuals die from TB, while those who survive the disease infect people around them, fueling the TB epidemic.

The current global TB epidemic is complicated by the increase in the number of people developing drug-resistant TB (DR-TB). The growing DR-TB epidemic threatens to reverse recent gains in combating TB globally. The World Health Organization (WHO) reported that an estimated 480,000 cases of multidrug-

resistant (MDR-TB) occurred in 2014 making up about 3.3 percent of all new TB cases. DR-TB is associated with poor treatment outcomes. While more than 85 percent of TB patients who are notified are successfully treated, WHO reports that globally only approximately 48 percent of individuals diagnosed with and treated for both MDR-TB and extensively drug-resistant TB (XDR-TB) are successfully treated.

Despite advances in TB prevention and treatment, progress toward eliminating TB continues to be hampered by the lack of point-of-care tools to detect TB and MDR-TB (particularly among people living with HIV), the unavailability of effective, well-tolerated drugs that could shorten TB and MDR-TB treatment courses, and the absence of a vaccine to prevent it.

The U.S. Agency for International Development (USAID) continues to invest in research activities aimed at improving the detection and treatment of TB and MDR-TB, preventing TB development and transmission, and strengthening TB service delivery.

Workers participate in a practical exercise on Xpert® data in Kazakhstan. Xpert® MTB/RIF is a USAID-supported technology designed to better diagnose drug-resistant and HIV-associated TB.

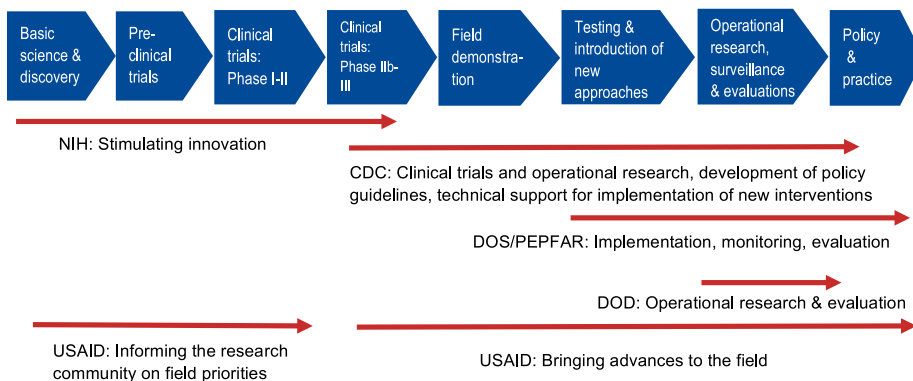
HEALTH RESEARCH GOALS

1. Evaluate diagnostic tools to more effectively detect TB in individuals with and without HIV
2. Develop regimens that improve the treatment of MDR-TB
3. Conduct operations research for improving TB program performance and management of TB-HIV co-infection

PRIORITY COUNTRIES

- Afghanistan
- Armenia
- Bangladesh
- Burma
- Cambodia
- Democratic Republic of Congo
- Ethiopia
- Georgia
- India
- Indonesia
- Kazakhstan
- Kenya
- Malawi
- Mozambique
- Nigeria
- Philippines
- South Africa
- South Sudan
- Tajikistan
- Tanzania
- Turkmenistan
- Uganda
- Ukraine
- Uzbekistan
- Zambia
- Zimbabwe

New TB technologies and approaches continuum: U.S. Government agency roles



USAID and other U.S. Government agencies collaborate on the development, testing, roll-out, and assessment of new tools and approaches to combating TB. This figure demonstrates how various agencies work together to bring research findings to the field. Adapted from Reach-Prevent-Cure: 2015–2019 U.S. Government TB Strategy

Goal 1: Evaluate diagnostic tools to more effectively detect TB in individuals with and without HIV

Each year, about 30 percent of new TB cases go undetected and continue to contribute to the transmission of tuberculosis and, therefore, compromise efforts to control and prevent active disease. The availability of new TB diagnostic tools offers the opportunity for early identification and treatment of these individuals. During this reporting period, USAID has supported modeling studies that provide policymakers with the key information needed to select the most cost-effective diagnostic tools to improve patient outcomes and limit the transmission of TB in their communities.

These modeling studies used a novel approach known as virtual implementation that links transmission modelling with operational modelling. Working in close collaboration with the National TB program in Tanzania, the modeling study has evaluated the impact of GeneXpert and alternative diagnostics for tuberculosis on patients, health systems, and population. The study identified three strategies as cost-effective in Tanzania. These three strategies included: 1) the full scale-up of GeneXpert; 2) same-day use of LED fluorescence microscopy; and 3) targeted use

of GeneXpert for diagnosis of presumptive TB cases with HIV infection.

Goal 2: Develop regimens that improve the treatment of MDR-TB

USAID is supporting a number of research activities aimed at improving the treatment of TB and MDR-TB. USAID is supporting the implementation of the STREAM study that aims to determine whether a standardized 9-month regimen, which has previously been used in Bangladesh with excellent treatment outcomes, can achieve comparable success with slight regimen modifications in different settings. The study is being implemented in six sites in four countries: Ethiopia, Mongolia, South Africa, and Vietnam. The study completed the enrollment of 420 patients and is now in the follow-up period. Early data on the study are expected in early 2018. USAID is building on the STREAM study infrastructure to evaluate the efficacy and safety of new MDR-TB treatment regimen that will contain the newly U.S. Food and Drug Administration-approved TB drug (Bedaquiline). Two new treatment regimens will be evaluated, one focusing on further reducing treatment duration to 6 months and the other on removing the injectable drugs that are known to cause major side effects to patients, thus making it an all oral regimen, which may increase treatment adherence.

USAID also continues to support the TB Alliance Project, a product development partnership (PDP), in the implementation of the STAND trial. STAND is a Phase III clinical trial of combination treatment including Moxifloxacin, Pyrazinamid, and the new drug, Pretomanid, for the treatment of TB and MDR-TB with the aim of shortening the treatment duration. The STAND clinical trial has started enrolling patients. Through the TB Alliance, USAID is also supporting the Nix TB study, which is a rescue treatment regimen for the treatment of XDR-TB. Finally, USAID is also supporting other Phase II trials of new TB treatment combinations as well as activities related to community participation in clinical trials and support at global and country levels for early adoption and introduction of new TB treatment regimens.

Goal 3: Conduct operations research for improving TB program performance and management of TB-HIV co-infection

During this reporting period, 54 USAID supported operational research studies were completed, and the results of 15 studies were disseminated in the countries where they were implemented. More than half of the completed studies were looking at issues related to Universal Access (56 percent), 15 percent focused on the programmatic management of MDR-TB, and 11 percent were related to epidemiology/monitoring and evaluation.

A study conducted in Ethiopia showed that 40 percent of MDR-TB patients were unaware of their HIV status, and in those who were screened, approximately 17 percent of them were HIV infected, showing a high HIV prevalence among those with MDR-TB and the need to increase HIV screening in this population. A study carried out in Tajikistan showed that migration out of country, moving within country, side effects, and being a retreatment case were significantly associated with a lack of follow-up. Studies in Indonesia showed that engaging former TB patients or family health nurses increased referral of suspected TB cases.



GORILLA DOCTORS

GLOBAL HEALTH SECURITY AND DEVELOPMENT

The recent emergence and spread of diseases such as H7N9 avian influenza, Middle East Respiratory Syndrome Coronavirus, and Ebola in West Africa are clear reminders of how vulnerable the increasingly interconnected world is to zoonosis – diseases that can be transmitted to humans from animals. Because these diseases can quickly surface and spread, they pose serious concerns to public health, economic, and development sectors.

To protect against the potential consequences associated with emergence of a pandemic threat, comprehensive disease detection and response capacities are needed, especially in locations where threats are most likely to emerge.

The U.S. Agency for International Development's (USAID's) investments seek to aggressively preempt and combat diseases that could spark future pandemics. Building on work that began in 2009, USAID continues to lead in supporting surveillance of high consequence viral families circulating in certain animal species living in Africa and Asia. USAID couples this information with social science research that describes behaviors and practices that evoke viral spillover and spread from animals to humans. In addition, USAID is building the capacity of

national workforces to use this information for early detection and effective response to future threats.

In February of 2014, the Obama Administration launched the Global Health Security Agenda (GHTSA). In an effort to promote a "world safe and secure from global health threats posed by infectious diseases." The GHTSA has multiple objectives that aim to:

1. **Prevent** and reduce the likelihood of outbreaks.
2. **Detect** threats early.
3. **Respond** to outbreaks effectively and rapidly.

Goal 1: Develop and introduce surveillance methods to increase pathogen detection

USAID continues to generate new surveillance data on microbes circulating in wildlife populations with highest priority given to rodent, bat, and nonhuman primate species. To date, more than 56,000 animals have been sampled in 20 countries on 3 continents, Africa, Asia, and South America, where new pandemic threats are likely to occur. Using a newly developed set of viral pathogen detection protocols, as well as a global network of

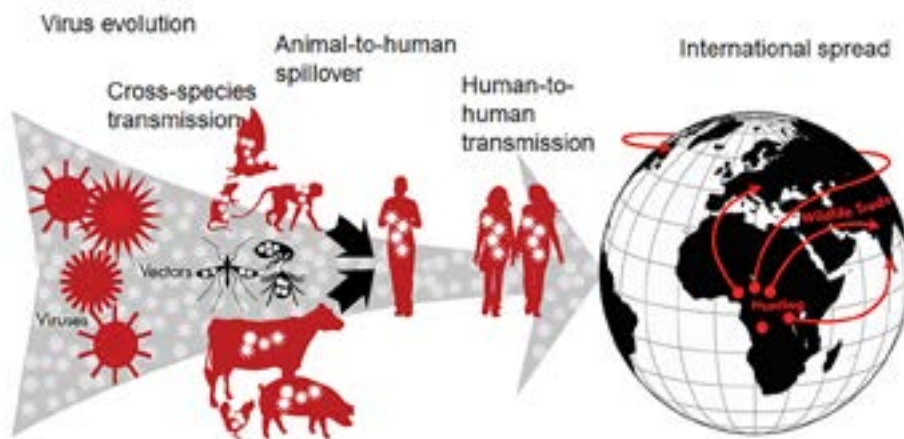
A bat that was captured for humane sample collection will be tested for evidence of viral pathogens as part of a USAID-funded research project (Rwanda).

HEALTH RESEARCH GOALS

1. **Develop and introduce surveillance methods to increase pathogen detection**
2. **Develop and test methods to improve the understanding of risk including how human behavior contributes to the risk of disease emergence**

PRIORITY COUNTRIES

- Bangladesh
- Benin
- Burkina Faso
- Cambodia
- Cameroon
- Chad
- China
- Cote d'Ivoire
- Democratic Republic of Congo
- Egypt
- Ethiopia
- Gabon
- Ghana
- Guinea
- Guinea Bissau
- India
- Indonesia
- Jordan
- Kenya
- Lao PDR
- Liberia
- Malaysia
- Mali
- Mongolia
- Mozambique
- Myanmar
- Niger
- Nigeria
- Philippines
- Republic of Congo
- Rwanda
- Senegal
- Sierra Leone
- South Africa
- South Sudan
- Sudan
- Tanzania
- Thailand
- Togo
- Uganda
- Vietnam



Pandemic properties of zoonotic viruses spill over from animals to humans and spread by secondary transmission among humans; adapted from Kreuder J.C., et. al., Spillover and Pandemic Properties of Zoonotic Viruses with High Host Plasticity. *Nature: Scientific Reports*. 2015 Oct. 7; 5:14830.

laboratories, more than 800 novel viruses have been discovered. These protocols have also been used to characterize two current pandemic threats: H7N9 avian influenza and MERS coronavirus.

This information feeds into a global database and contributes to mapping microbial distribution and characterizing the risk associated with different human/animal interactions. Information is publically available online (<http://data.predict.global>) through a suite of digital disease detection tools utilizing online informal sources to enhance real-time intelligence for emerging global health threats.

In Uganda and Malaysia, ongoing research is investigating the pathogen diversity across different types of development (urban, peri-urban, and undeveloped). This study will help clarify the impact of human activity on wildlife and microbial diversity and provide some initial insight into how those settings provide new opportunities for animals and humans to interact.

USAID continues to generate surveillance data in Bangladesh, China, and Vietnam on influenza viruses circulating in farm animals, including swine, poultry, and wild birds. This information will shed light on the distribution, diversity, seasonality, and evolution of a family of viruses that has caused four pandemics in the past century.

Goal 2: Develop and test methods to improve the understanding of risk including how human behavior contributes to the risk of disease emergence.

In high-risk areas for pandemic threats, specific practices of communities and industries such as the oil, gas, and mining sectors can put people at risk. To protect against potential pandemics, it is necessary to systematically identify high-risk areas and practices and how those can be changed.

By re-analyzing the “hotspot” maps of high-risk areas with new datasets, USAID’s implementing partners found a stronger relationship between disease emergence risk, human population growth, and regions rich in wildlife. New high-resolution risk maps have been produced to provide subnational information on the highest risk areas. These maps not only show that the underlying drivers of diseases vary by region, but also indicate that diseases emerge primarily from changes in land use, agricultural intensification, and associated secondary factors (e.g., bushmeat hunting and consumption) in locations with the most zoonosis.

USAID is assembling the most comprehensive and detailed information available to date on the emergence of zoonotic diseases by using findings that say that the highest risk of disease transmission is associated with human and domestic animal

interaction with wildlife. This includes interactions in wildlife hunting, animal crop raiding, and wildlife consumption practices. The data is used to guide surveillance, prepare for pandemics, and develop disease prevention and control strategies.

USAID is also conducting in-depth research to locate high-risk populations and identify social preferences, customs, and behaviors that are linked with risky contact between humans and animals. For example, USAID projects will use prior characterization of the wild animal meat trade and the level of biosecurity infrastructure existing in markets in the Democratic Republic of Congo, Indonesia, Laos, and Vietnam to understand the amount and types of wild animal meat that moves through markets, the value chain, and how meat is handled. Ultimately, this information will allow for the development and testing of interventions that reduce risk.

Significant Research Achievements

- USAID isolated for the first time and characterized the binding receptor from a SARS-like coronavirus from a Chinese horseshoe bat, showing that the virus was able to bind to the human ACE-2 cell receptor suggesting that direct transmission to humans from bats is possible.
- Viral discovery curves are critical to efficient research, as they demonstrate that the size of the “zoonotic pool” may not be as large as often believed and that the cost of global surveillance and discovery efforts could well be far less than the cost of a single pandemic. Over time, USAID can make a significant contribution to our knowledge of viral diversity in wildlife.



END IN ASIA, TH360

NEGLECTED TROPICAL DISEASES

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

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

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

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

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

Goal 1: Support innovative approaches in disease mapping

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

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

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

HEALTH RESEARCH GOALS

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

PRIORITY COUNTRIES

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



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

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

Goal 2: Develop new laboratory diagnostics and tools

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

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

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

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

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

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

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

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

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

Goal 4: Develop tools to manage morbidity

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

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

Goal 5: Deliver a macrofilaricide for onchocerciasis and lymphatic filariasis

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



HEALTH SYSTEMS STRENGTHENING

AMY FOWLER/USAID

Health systems strengthening (HSS) research comprises a diverse collection of questions, approaches, and methods that examine all influences on and the effects of health policies and system performance on health outcomes. The results from HSS research are used to stimulate creative solutions to problems that constrain system performance and the achievement of an optimal state of health. HSS research at the U.S. Agency for International Development (USAID) aims to build the evidence base to inform better decision-making by policymakers in low- and middle-income countries.

Goal 1: Identify practical solutions through applied research

In Malawi, researchers are applying an assessment tool to assess the quality of care of patients with febrile illness and to inform a new collaborative approach for addressing the systemic issues and clinical gaps in care. Lessons learned will help institutionalize capacity to examine and improve quality of care in Ending Preventable Child and Maternal Deaths (EPCMD) countries. Initial field-tests identified clear gaps in diagnosing malaria using rapid diagnostic tests; incomplete and inaccurate record keeping; lack of trust in results; lack of records for follow-up of a negative test result; and inconsistent performance of procedures.

In Gujarat, India, researchers are evaluating community actions to strengthen people-centered services and improve accountability to maternal healthcare and responsiveness of health services. This research will enhance the understanding of how governance initiatives affect accountability in the health system and how marginalized groups use priority services. The study found evidence of improved awareness of maternal health entitlements, utilization of antenatal and delivery care, and monitoring and review of service delivery performance.

Researchers in Senegal are investigating the barriers to and opportunities for using mobile money in performance-based financing schemes. The case study will contribute to global learning about improved quality, accessibility, and affordability of health services by enabling access to mobile-based savings, insurance, and credit. Preliminary results suggest that the performance-based financing program would realize modest benefits from transitioning to mobile money payments, particularly for distribution of individual bonuses within participating clinics. Benefits include improved transparency regarding payments and increased beneficiary trust and engagement in performance-based financing program activities.

Evidence from health systems strengthening interventions involving pharmaceuticals reveal the importance of ensuring that essential drugs and other medical inputs are affordable and available to patients when needed.

HEALTH RESEARCH GOALS

1. Identify practical solutions through applied research
2. Synthesize, share, and promote the use of evidence
3. Develop, refine, and test tools and frameworks

PRIORITY COUNTRIES

- Afghanistan
- Bangladesh
- Democratic Republic of Congo
- Ethiopia
- Ghana
- Haiti
- India
- Indonesia
- Kenya
- Liberia
- Madagascar
- Malawi
- Mali
- Mozambique
- Nepal
- Nigeria
- Pakistan
- Rwanda
- Senegal
- South Sudan
- Tanzania
- Uganda
- Yemen
- Zambia



K. BHADARI/RTI

Evidence from HSS interventions, such as health worker trainings designed to improve service delivery, shows a positive impact on quality of care and uptake of healthy behaviors.

Researchers in Uganda are investigating the overall effectiveness (including cost), field implementation processes, and provider acceptability of different knowledge management methods used to improve the quality of care related to safe male circumcision. End-line data are currently being cleaned and analyzed. Results are expected in 2016.

Goal 2: Synthesize, share, and promote the use of evidence

USAID commissioned and published a ground-breaking review of the evidence on the Impact of HSS on Health (see right). The review identified 13 types of HSS interventions with positive, quantifiable effects on health status (morbidity, mortality, etc.) and health system outcomes, including improved service provision or quality, increased service utilization, uptake of healthy behaviors, and financial protection. The findings of the report document the value of investing in HSS.

A landscape analysis was conducted on the development status of Essential Packages of Health Services for the 24 EPCMD countries to determine their progress

toward universal health care and explore how government policies contribute to service, population, and financial coverage of the package. Findings indicate that all EPCMD countries have defined essential packages; however, these packages do not always include all interventions of global health priority programs, and do not always translate directly into financial protection and equitable access.

Goal 3: Develop, refine, and test tools and frameworks

Analysts are designing an operational framework to measure pharmaceutical system performance. The analysts will pilot the framework in selected EPCMD countries to make refinements, test indicators and data collection tools, and develop a manual. The framework will be used to identify priority areas for investment and to measure and demonstrate progress over time.

USAID is collaborating with the United Nations Children's Fund (UNICEF) to model the link between HSS and lives saved by developing and vetting an impact matrix, which summarizes the quantitative evidence from a comprehensive review of the literature on HSS effects on mitigating health system performance bottlenecks. In the future, this vetted matrix will be incorporated into "UNICEF's EQUIST" tool and be applied at country level. The tool will provide the data and evidence to help policymakers and advocates articulate and quantify the health impacts of HSS activities, contributing to more evidence-based HSS investment decisions.

There is a growing need to better understand health financing and domestic resource mobilization. In the area of domestic resource mobilization, USAID is collaborating with WHO on institutionalizing national health accounts, which involves the development and use of norms, standards, and measurement tools to track health resources, as well as estimate the economic consequences of illness, the cost and effects of interventions,

financial catastrophe/impoverishment, and social exclusion. These health accounts will continue to provide information regarding financial flows within the health system, which is vital for decision-making and public administration reform.

USAID is also determining how to effectively incorporate basic improvement competencies into medical education by building upon an improvement training syllabus developed in Kenya with the Ministry of Health, and by drawing on a Quality Improvement Competency Framework for pre-service education and in-service training. This work is complementary to the Medical and Nursing Education Partnership Initiatives. Products and lessons learned will be shared broadly via a virtual global forum with EPCMD countries.



This report presents a significant body of evidence linking HSS interventions to measurable impact on health for vulnerable people in low- and middle-income countries (www.hfgproject.org/impact-hss-health/).



FRANCIS GONZALES

SOCIAL AND BEHAVIOR CHANGE

Children in Kanpur, India, use mobile phones to listen to health messaging from the USAID-funded Sesame Workshop.

Even the most effective health intervention, in an ideal health system, will not improve health outcomes if it is not adopted by patients and providers. Likewise, simple behaviors such as handwashing practiced at the individual and community levels can improve health outcomes only when practiced. Although international donors including the U.S. Agency for International Development (USAID) have long supported social and behavior change programs, there remains a lack of high-quality data, evidence and standards on social and behavioral change programs in global health. In response, USAID is concentrating on creating improved standards on program design, quality assurance, contracting and procurement, monitoring, reporting, and evaluation of social and behavior programs, with the goal of improving standards for the broader community of research practice.

Six recent initiatives to improve these global standards and practices are described below:

- To address the lack of collective evidence on effective social and behavioral change interventions, USAID convened an Evidence Summit to identify and assess the effectiveness and efficiency of social and behavior change interventions

based on the existing scientific evidence across priority health areas. Findings from this summit are being used to develop prioritized research agendas going forward.

- To promote best practices in behavior change interventions, we identified the key “accelerator” and related behaviors determining progress in priority health areas on disease prevention and treatment, their indicators, and levels.
- To improve ability to access data on priority behaviors, we are developing an interactive platform to track the accelerator behaviors across priority health areas in USAID-supported countries and map these levels against their projected impacts on lives saved using modeling data.
- To build consensus with international partners, we have engaged World Health Organization to create an international working group with National Institutes of Health, United Nations Children’s Fund, North American Aerospace Defense Command, the Norwegian Institute of Public Health, and United Nations Population Fund to guide the international community

on how to weigh evidence and assess the strength of recommendations of scientific research in social and behavior change for priority health areas. This international collaboration described above will also develop a consensus and implement common reporting standards for scientific evidence for social and behavior change.

- To connect the learning and insights with governments and civil society organizations worldwide, in conjunction with Unilever, InBev, and other partners, we are building, populating, and sharing web-based “institutes” containing data on behaviors, existing evidence, programming standards, data, and common indicators.
- To improve the responsiveness of methods currently in practice, USAID is working with the White House Social and Behavioral Sciences Team to introduce new tools and measurements in the behavioral sciences (rapid randomized control trials, big data use, near real time tracking) into USAID’s and other partners’ health programs including the Peace Corps.

Accelerator Behaviors Have the Highest Potential to Help Prevent Child and Maternal Deaths

To speed up country-level progress on reducing preventable child and maternal deaths, a USAID-funded website was launched this year for use by USAID missions and other stakeholders in the 24 Ending Preventable Child and Maternal Deaths (EPCMD) priority countries. This website provides information, data, and tools to help integrate quality programming related to the 10 Accelerator Behaviors into health portfolios.

The approach is simple but powerful. By focusing on integrating the most robust, evidence-based behaviors into each country's health programming, we can accelerate progress toward USAID's goal to save the lives of 8 million children and 350,000 women by 2020. Identifying these Accelerator Behaviors is an ongoing research process, and behaviors and intervention resources will be updated as new evidence emerges.



For more information on the 10 Accelerator Behaviors, visit the Transform/Accelerate website: <http://acceleratorbehaviors.org/index>.

CENTER FOR ACCELERATING INNOVATION AND IMPACT

Accelerating Innovation and Impact: Bringing Global Health Innovation to the World's Poor

The global health community is filled with promising ideas and solutions to save lives across the poorest regions of the world. Whether an idea lives up to its promise depends not only on its brilliance, but also on whether it can be introduced in a timely fashion and delivered at scale. In the global health community, "scale-up" is a widely used concept; in practice, it remains elusive. The process of introducing and "scaling up" global health innovation can be complex, lengthy, and resource intensive. As a result, innovation often takes years, sometimes decades, to reach its intended users. To overcome these challenges, The U.S. Agency for International Development (USAID) established the Center for Accelerating Innovation and Impact (CII) to promote and reinforce these business-minded approaches and help accelerate impact against some of the world's most important health issues. By applying these forward-looking practices to USAID's health investments, the Center invests seed capital in the most promising ideas and applies a rigorous, private-sector approach to cut the time it takes to transform "discoveries in the lab" to "impact on the ground."

Saving Lives in Nepal: Testing Our Model Spotlight on Chlorhexidine

Chlorhexidine (CHX) – one of several products that USAID has guided from

research to impact – has been shown to reduce neonatal mortality by up to 23 percent when applied to a newborn's umbilical cord after birth. Given its high efficacy, simplicity of use, and low-cost, USAID aims to introduce CHX in at least 10 countries by 2016.

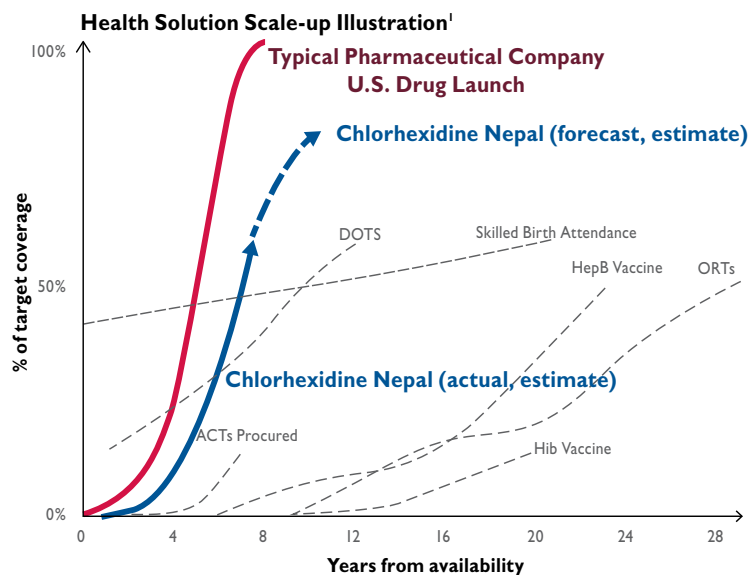
The scale-up of CHX in Nepal through the Saving Lives at Birth Grand Challenge served as a real-time test case for how applying rigorous, private-sector approaches to product introduction and scale-up can accelerate impact.

Applying many of the same delivery tools found in CII's IDEA to IMPACT: A Guide

to Introduction and Scale of Global Health Innovations, the introduction of CHX in Nepal has been rapid with strong adoption by target users. In fact, coverage rates are mirroring best-in-class levels seen with ideal launches in the private sector:

With coverage rates still rising, chlorhexidine is used in 69 of the 75 districts in Nepal, covering nearly 65 percent of all births and has saved more than 7,000 babies.

USAID's role in CHX highlights how early investment in promising ideas and rigorous product introduction planning can – and is – accelerating impact and saving lives.



¹ Estimates based on CII analysis and extrapolations from early, non-statistically significant reporting.

The Center promotes and reinforces innovative, business-minded approaches to address key bottlenecks in development, introduction, and scale-up by:

1

CATALYZING INNOVATION AND LEVERAGING PARTNERSHIPS

2

IDENTIFYING MARKET TOOLS AND BEST PRACTICES FOR ACCELERATION

3

ACCELERATING INTRODUCTION AND SCALE-UP

Our Achievements

- I. To meet ambitious goals of ending preventable child and maternal deaths, there is a need for new innovation. The **Saving Lives at Birth Grand Challenge**, a highly-regarded international partnership that has leveraged \$80 million from other donors, has sourced a robust pipeline of 94 potentially game-changing innovations from across the world. These innovations have reached more than 1.5 million women and newborns and, with several already starting to scale, saved more than 10,000 lives.

To address key gaps in the Ebola response, USAID's **Fighting Ebola Grand Challenge** has invested in 14 game-changing innovations out of more than 1,500 ideas, including reimagined Ebola suits and cutting-edge wearable sensors to track patient vital signs remotely.

- II. CII has developed a dynamic suite of **hands-on tools capturing best practices and private sector principles** coupled with decades of global health experience. The tools:
- Support improved planning for product introduction and uptake.
 - Highlight lessons and practices for shaping inefficient markets.
 - Match challenges along the health-care continuum with relevant, innovative financing solutions.
- III. Putting the tools into practice, CII has provided **strategic product introduction and scale-up support** to numerous commodities, including chlorhexidine, Amoxicillin DT, Microbicides, ORS/Zinc, bubble CPAP (continuous positive airway pressure), and the Odon Device. CII is also applying **innovative financing** to speed access to lifesaving commodities and mobilize new capital.

1

CATALYZING INNOVATION AND PARTNERSHIPS

- Invest seed capital in promising innovations
- Provide acceleration support to advance innovations
- Catalyze partnerships to leverage expertise and resources



2

IDENTIFYING MARKET TOOLS AND BEST PRACTICES

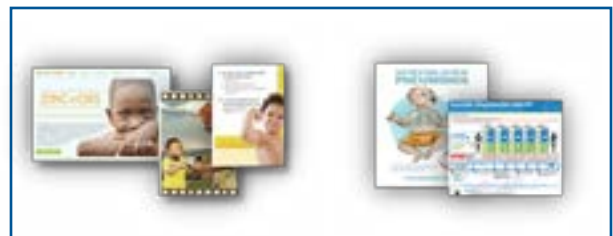
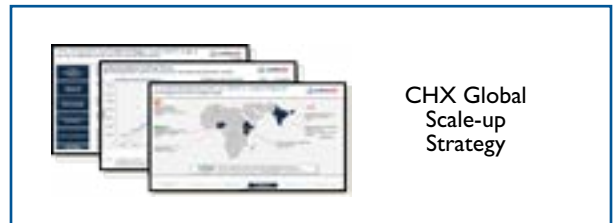
- Engage diverse set of luminaries to identify cutting edge practices and eliminate road blocks
- Capture and disseminate best practices/tools to maximize impact



3

ACCELERATING INTRODUCTION AND SCALE-UP

- Facilitate a fast launch and path to scale
- Support innovative financing and create a healthy market
- Support demand-generation efforts and marketing campaigns





AMY COTTER/USAID

SAVING LIVES AT BIRTH

A GRAND CHALLENGE FOR DEVELOPMENT

Cross River, Nigeria

Saving Lives at Birth: A Grand Challenge for Development – a partnership with USAID, the Government of Norway, The Bill & Melinda Gates Foundation, Grand Challenges Canada, the U.K.'s Department for International Development, and the Korea International Cooperation Agency – is a global call for innovative ideas around prevention and treatment, approaches, and technologies that aim to reduce infant and maternal mortality around the time of birth.

This past year, the Saving Lives at Birth partners announced their continued support of the program, as well as an increased focus on advancing the most successful and transformational innovations as they transition to scale. To date, the first iteration of our Saving Lives at Birth Grand Challenge has produced 94 game-changing innovations, includ-

ing the Odon device for obstructed labor, a uterine balloon tamponade for postpartum hemorrhage, and a bubble CPAP device for acute respiratory distress in newborns. Many of the program's successful initial investments are already having an impact as they begin to scale. To date, these innovations have benefited more than 1.5 million women and newborns, saving at least 10,000 lives.

Two of the Saving Lives at Birth grantees, Monash University and PATH, are working to develop unique and innovative solutions to increase the reach of oxytocin, a lifesaving medicine. Delivery of oxytocin is the current standard of care to treat women suffering from postpartum hemorrhage – a major cause of maternal mortality globally, especially in low-resource settings. However, universal access to this essential

medicine is currently limited due to the requirement for refrigeration, consumables (needles, syringes, etc.), and a lack of trained medical personnel to administer the drug. Monash University is currently conducting a landscape and stakeholder analysis for their simple, affordable, and heat-stable inhaled delivery system for oxytocin. PATH has developed a heat-stable oxytocin fast-dissolving tablet for sublingual administration and is currently testing the effectiveness of this simple, needle-free approach to prevention of postpartum hemorrhage in South Africa.





Redesigned personal protective equipment



An Ebola patient in Sierra Leone tests the wearable sensor



DripAssist™ technology

FIGHTING EBOLA

A GRAND CHALLENGE FOR DEVELOPMENT

The Grand Challenge model was used to crowd source for innovations to help fill critical gaps identified at the start of the Ebola epidemic.

The Fighting Ebola: A Grand Challenge for Development partnership with USAID, the White House Office of Science and Technology Policy, the U.S. Centers for Disease Control and Prevention, and the Department of Defense, called for a global response to help identify critical new solutions to help healthcare workers provide better care to their patients, and in just one month, the Challenge generated close to 1,500 ideas.

The Center for Accelerating Innovation and Impact (CII) is now supporting 14 innovations identified for their potential to reinforce the response to current and future Ebola outbreaks.

Some of the most promising ideas include:

- Redesigned personal protective equipment submitted by the Johns Hopkins Center for Bioengineering Innovation and Design and Jhpiego.
- Wearable patient sensor that measures patient vital signs by The Scripps Translational Science Institute in Partnership with PhysiQ and Rhythm Diagnostic Systems.
- Low-cost, battery-powered infusion monitor that delivers IV fluids with precision to patients (DripAssist™), eliminating the risk of fluid overload by ShiftLabs.
- Long-lasting, spray-on barrier that creates electro-static fields that kill and repel microbes on treated surfaces by SPR Technologies.

To promote the success and long-term sustainability of these innovations, USAID is working to ensure that each innovator is able to access the partners necessary to ensure the relevance and market viability of their product or platform. These partners have helped several grantees conduct user testing of their products in West Africa, allowing them to receive critical feedback from both healthcare workers and patients. The Bureau also has facilitated partnerships between the innovators and potential manufacturers and is helping them develop partnerships and strategies to promote the sustainability of their innovations and ensure that these technologies have a lasting impact.



Appendix: Funding for Target Health Goals

Health Area	Health Research Goals	FY 2014 obligated funds	FY 2015 expected funds
Maternal and Newborn Health	1. Develop and introduce new and improved evidence-based interventions for care during pregnancy and at birth.	\$3,182,203.25	\$2,343,297.25
	2. Strengthen and standardize high-quality obstetric care for the prevention, management, and treatment of fistula.	\$200,000.00	\$250,000.00
	3. Design, evaluate, and introduce evidence-based interventions to reduce newborn morbidity and mortality from birth asphyxia.	\$200,000.00	\$331,746.00
	4. Develop, test, and introduce community-based health interventions to treat and prevent newborn infections.	\$108,000.00	\$998,737.00
	5. Develop scalable, cost-effective approaches for integrating maternal and neonatal health services.	\$229,000.00	\$754,000.00
	6. Assess evidence-based approaches to improve the access and utilization of quality maternal, neonatal, and child health interventions.	\$2,079,740.25	\$2,890,387.25
	7. Develop standardized criteria and effective tools for measuring maternal and perinatal mortality and morbidity.	\$35,000.00	\$2,681,301.00
	Total	\$6,033,943.50	\$10,249,468.50
Child Health	1. Support implementation research to inform the uptake of integrated community case management.	\$302,619.00	\$74,957.00
	2. Develop and test cost-effective approaches to decrease the incidence of childhood injuries and acute lower respiratory infections due to household air pollution.	\$244,933.33	\$319,071.00
	3. Evaluate interventions to increase the use of efficacious diarrhea treatments.	\$200,000.00	\$200,000.00
	4. Develop and test scalable approaches to improve drinking water quality, access, use of sanitation, and hygiene behaviors.	\$963,004.00	\$1,336,116.00
	Total	\$1,710,556.33	\$1,930,144.00
Nutrition	1. Strengthen and expand the evidence base on integrated multisectoral approaches to improve nutrition outcomes, including stunting and maternal and child anemia.	\$1,780,203.00	\$1,806,834.00
	2. Support implementation research for improved diet diversity and quality.	\$2,644,212.00	\$1,958,733.00
	3. Develop, refine, and expand use of state-of-the-art measurement tools for nutrition programs and policies.	\$450,809.00	\$472,140.00
	Total	\$4,875,224.00	\$4,237,707.00
Family Planning and Reproductive Health	1. Refine, develop, and introduce new contraceptive methods.	\$8,195,000.00	\$9,220,000.00
	2. Improve and expand the use of family planning methods in developing countries.	\$14,062,000.00	\$15,265,000.00
	Total	\$22,257,000.00	\$24,485,000.00
HIV and AIDS	1. Develop and introduce microbicides for women to reduce their risk of HIV infection.	\$45,000,000.00	\$45,000,000.00
	2. Accelerate the development and clinical testing of novel HIV vaccine candidates.	\$28,710,000.00	\$28,710,000.00
	3. Strengthen the evidence base to improve HIV and AIDS prevention, care, and treatment programs.	\$8,725,000.00	\$4,143,750.00
	Total	\$82,435,000.00	\$77,853,750.00

Health Area	Health Research Goals	FY 2014 obligated funds	FY 2015 expected funds
Malaria	1. Develop safe and effective vaccines for <i>Plasmodium falciparum</i> malaria.	\$7,282,302.00	\$7,100,000.00
	2. Develop effective and affordable medicines for the treatment and prevention of malaria.	\$1,500,000.00	N/A
	3. Develop new effective insecticides for improved vector control.	\$2,000,000.00	\$2,000,000.00
	4. Improve malaria control program implementation and impact.	\$3,124,735.00	\$3,243,135.00
	Total	\$13,907,037.00	\$12,343,135.00
Tuberculosis	1. Develop diagnostic tools to more effectively detect TB in individuals with and without HIV.	\$1,200,000.00	\$615,000.00
	2. Develop shorter TB regimens that are effective against all forms of TB, can be used with antiretroviral therapy, are suitable for children, affordable, and easily managed in resource-limited settings.	\$8,748,000.00	\$11,892,000.00
	3. Conduct operations research for improving TB program performance and management of TB-HIV.	\$4,642,000.00	\$3,442,102.00
	4. Build TB research capacity through infrastructure support.	\$4,829,000.00	\$8,752,034.00
	Total	\$19,419,000.00	\$24,701,136.00
Neglected Tropical Diseases	1. Drugs for Neglected Diseases Initiative, Macrofilariicide Program.	N/A	\$400,000.00
	2. Coalition on Research for Neglected Tropical Diseases.	N/A	\$500,000.00
	Total	\$-	\$900,000.00
Global Health Security and Development	1. Develop and introduce surveillance methods to increase pathogen detection.	\$7,000,000.00	\$8,000,000.00
	2. Develop and test methods to improve the understanding of risk, including how human behavior contributes to the risk of disease emergence.	\$5,000,000.00	\$7,000,000.00
	3. Grand Challenges for Development: Fighting Ebola.	N/A	\$8,900,000.00
	Total	\$12,000,000.00	\$23,900,000.00
Health Systems Strengthening	1. Identify practical solutions through applied research.	\$1,444,014.00	\$1,054,600.00
	2. Synthesize, share, and promote the use of evidence.	\$1,280,900.00	\$1,836,793.00
	3. Develop, refine, and test tools and frameworks.	\$1,555,634.00	\$2,064,806.00
	Total	\$4,280,548.00	\$4,956,199.00
Total Funding		\$166,918,308.83	\$185,556,539.50

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