SECTION A: PROGRAM DESCRIPTION

The U.S. Agency for International Development (USAID), through the Control and Elimination Program for Neglected Tropical Diseases (CEP-NTD), seeks to support disease-endemic countries to control and/or eliminate NTDs with proven, cost-effective public health interventions. Building on the successes that have been achieved through previous USAID investments to expand national, integrated NTD programs, CEP-NTDs will continue to support countries in their advancement towards the attainment of global elimination goals, and to support them to effectively access and leverage the drug donations needed to control NTDs that cannot be eliminated with current strategies. The USAID NTD program results framework is provided in Appendix A.

Over the next five years, USAID's NTD program will focus on the following priorities:

- Support countries to efficiently and effectively complete treatment requirements for all communities endemic for lymphatic filariasis (LF) and trachoma and then verify and document success for disease elimination as a public health problem via the World Health Organization (WHO) dossier process.
- Assist select countries among USAID-supported countries to meet WHO requirements for verifying the elimination of transmission of Onchocerciasis, including support for dossier development and submission.
- Support countries to achieve adequate funding levels and to technically and operationally manage their own NTD control programs (e.g., schistosomiasis, onchocerciasis, soil-transmitted helminthiasis) as work for elimination diseases is completed and as USAID support is reduced or phased-out.
- Support countries to "mainstream" NTD programs into the broader national health system such that, for example, NTD programs are adequately funded and included in their annual budgets, NTD control and morbidity management responsibilities are clearly designated within the existing workforce and job descriptions, NTD indicators are included and monitored among national health indicators, and national policies are in place to empower the workforce to fulfill essential NTD activities.
- Maximize efficiencies and program effectiveness through leveraging and complementing related health sectors including malaria, basic education, water, sanitation, hygiene, and maternal and child health to reach greater numbers with NTD interventions. This is envisioned to be accomplished through the development of coordinated country-level work plans in countries where USG-supported NTD control programs overlap with programs in other development sectors.

Current list of USAID-supported countries: Benin, Bangladesh, Cambodia, Cameroon, Burkina Faso, Democratic Republic of Congo, Ethiopia, Ghana, Guinea, Haiti, Indonesia, Laos, Mali, Mozambique, Nepal, Niger, Nigeria, Philippines, Senegal, Sierra Leone, Tanzania, Togo, Uganda, Vietnam.

USAID may revise this list for its onward programming, and include expansion into new countries, depending on funding availability and other factors.

CEP-NTDs is authorized under the Foreign Affairs Act and is subject to 2 CFR 200 "Uniform Administrative Awards Requirements, Cost Principles, and Audit Requirements for Federal Awards."

Background

Neglected Tropical Diseases (NTDs) cause significant morbidity and mortality worldwide. More than one billion people - one-seventh of the world's population - suffer from one or more NTDs. Often the source of deep stigma, NTDs cause disability, severe disfigurement, and blindness. These diseases affect the world's most vulnerable populations with devastating, lifelong disabilities that contribute to ensnaring individuals, families, and even entire communities in poverty.

Seven of the most prevalent NTDs - lymphatic filariasis (LF), trachoma, schistosomiasis, onchocerciasis, and the three soil-transmitted helminth infections (ascariasis, trichuriasis, and hookworm infection) - can be targeted through a highly effective integrated community treatment approach using freely-donated drugs that have been proven safe and effective, and can be delivered by trained non-health personnel. This approach, known as mass drug administration (MDA), provides a single dose medication to all eligible individuals in an affected community generally once or twice a year. When implemented without interruption over three to seven years, MDA can significantly control the burden of NTDs and in some cases, elimination can be achieved. USAID focuses on these "preventive chemotherapy" (PCT) diseases because of the readily available interventions and availability of drugs donated to countries for free by pharmaceutical companies.

Acknowledging the devastating effect of NTDs on vulnerable populations, six prominent pharmaceutical companies established drug donation programs to contribute to the global fight against NTDs. These donations can be accessed only if national NTD programs can demonstrate that they have a need for the drugs and the ability to distribute them to affected communities.

USAID's Neglected Tropical Diseases Program was established in 2006 at the direction of Congress to 1) expand the provision of proven effective NTD interventions, such as mass drug administration, 2) leverage drug donation programs, and 3) integrate vertical programs to treat as many people as possible at the same time. The program was mandated to focus on NTDs that

can be addressed through mass drug administration and benefited from existing donation programs.

The combination of donated medicines from pharmaceutical companies and USAID's track record of successfully scaling up these NTD interventions, make the NTD program the Agency's largest private-public partnership. For every dollar that USAID invests, $26 worth of donated drugs is leveraged.

Investments in global health create pathways out of poverty. Preventing and controlling NTDs is central to ending extreme poverty within the next two decades. USAID's NTD Program supports the achievement of broader development goals, such as USAID's goals of ending extreme poverty and the WHO Sustainable Development Goals (SDGs) 1 and 2 ("to end poverty in all its forms" and "to ensure healthy lives and promote well-being for all, respectively), which includes ending NTDs by 2030. The control and elimination of NTDs primarily contributes to the Bureau for Global Health's third strategic objective, "Protecting Communities from Infectious Diseases." Additionally, USAID's NTD Program supports the World Health Organization's NTD Roadmap, which established targets and milestones for the global control, elimination, and eradication of NTDs by 2020[1].

The global impact of USAID's NTD program has been transformative. Over the last ten years, USAID has provided over 2 billion treatments to 936 million people and leveraged USD $15.7 billion in donated drugs from the private sector. Due to the program's focus on partnerships and integrated delivery platforms, it has achieved an average treatment cost of 63 cents per person or 29 cents per treatment. Additionally, USAID investments have accelerated the development and implementation of quality program tools, established best practices, and informed global policy, thus, setting the standard for national NTD programs worldwide.

At the start of the program, elimination of any of the diseases was not considered to be feasible in much of the world. Over the years, however, USAID's massive scale-up and commitment to quality have resulted in 198 million people living in communities no longer requiring treatment for LF and 84 million people living in communities no longer requiring treatment for trachoma. This success has demonstrated that elimination of LF and trachoma is indeed achievable. Additionally, the integrated approach has strengthened Ministry of Health programs for those diseases requiring longer-term control strategies (e.g., schistosomiasis, onchocerciasis, and soil-transmitted helminthiasis) by raising the profile of all NTDs via more robust programs and preventing morbidity for millions more people.

The proposed program builds on more than a decade of USAID investments in controlling and eliminating NTDs. Since 2006, USAID has invested the greatest portion of its NTD funding in the following areas:

[1] http://www.who.int/neglected_diseases/NTD_RoadMap_2012_Fullversion.pdf

- Mapping for seven targeted diseases across each country to determine disease prevalence and the required treatment regimens;
- Supporting countries to access pharmaceutical donation programs to provide essential treatments to all eligible populations through needs forecasting and the submission of drug applications;
- Supporting countries with planning, logistics, community awareness, and administration to provide integrated NTD treatment packages to at-risk communities for multiple NTDs;
- Conducting assessments, based on WHO guidelines, to measure the impact of treatment programs, thus, determining whether diseases are being controlled or eliminated as public health problems;
- Promoting political commitment by disease-endemic country governments to integrate formally vertical programs and build capacity for Ministry of Health staff to manage and operate those programs.

To achieve its congressional mandate, USAID established four-year stages/phases for the NTD program. Starting with a *proof of concept stage* in 2006, USAID's NTD Program proved that disease-specific vertical country programs could be integrated to address overlapping disease burdens in an effective and efficient manner. During those first four years, USAID provided targeted technical and programmatic support to enable countries to become eligible to receive and distribute donated drugs from pharmaceutical companies. The NTD program achieved unexpected success and was able to meet its five-year targets within three years. As the original beneficiary country programs achieved scale, the NTD program began its *expansion stage*. Between 2011 and 2015, USAID's NTD program expanded from 15 countries to 31 countries globally. Additionally, new tools and best practices were developed and disseminated in conjunction with the WHO. The progress also facilitated the increased investment of the United Kingdom's Department for International Development (DFID) and private philanthropists.

Currently, the NTD program is in an *acceleration stage* where maintaining coverage rates for mass drug administration, evaluating impact, and removing barriers for effective implementation are the core of current programming and where seventy percent of available resources are invested. By 2020, 70 percent of currently supported countries are projected to stop treatment for LF and trachoma. In future stages, the NTD program will redouble efforts to document country program successes by working with countries to verify and submit evidence of elimination to the WHO, develop strategies to bolster countries that are not on track to meet elimination goals, and collaborate with host-country governments to identify sustainable delivery platforms for diseases targeted for control.

To achieve the goals from each stage of the program, USAID has awarded four cooperative agreements and one grant for implementation support throughout its 10-year history. These assistance mechanisms have successfully achieved their goals in each program stage. Currently, the two active cooperative agreements, ENVISION and END in Africa, are on track to achieve their program goals supporting 26 countries globally. This program will continue to support the

milestones under the *acceleration stage* and also embark on supporting the *documentation and sustainability stage*.

Stage	**Program**	**Key Successes**
Proof of Concept	NTD Control Program FY2006-FY2011	Proof of principle achieved in initial 5 countries; expanded to 13 by the end of the program. The program provided over 594 million treatments to over 260 million people and leveraged $3.1 billion in donated drugs.
Expansion and Acceleration	End in Asia FY2011-FY2015	END in Asia provided support to 6 countries in Asia and focused on strengthening the capacity of national NTD programs by providing program implementation support, capacity building for improved supervision and management at the local level, and stronger communications and surveillance support.
	End in Africa FY2011-FY2016 (Extended through FY2018)	Scaled-up direct support to six countries' national NTD programs in West Africa on-track to achieve WHO's 2020 goals of elimination and control targeting 51.4 million people with mass drug administration for LF, trachoma, onchocerciasis, schistosomiasis, and soil-transmitted helminths.
	ENVISION FY2011-FY2016 (Extended through FY2019)	Provides technical assistance to 19 countries globally to implement successful national NTD control and elimination programs. ENVISION has mapped 1,387 districts and provided 61,315,173 treatments for NTDs. ENVISION continued support for END in Asia countries after that program ended.
	Onchocerciasis Elimination Program for the Americas FY2012-FY2017 (Extended through FY2020)	Provided technical assistance to Colombia, Ecuador, Mexico, and Guatemala to achieve verification of elimination of onchocerciasis. Currently ongoing, this project aims to achieve region-wide elimination in the Americas.

Evaluating the USAID NTD Program

After 10 years of programming, the USAID NTD program commissioned an external program evaluation to assess USAID's global leadership on NTDs, the value of the program's strategy and the progress of USAID-supported countries in meeting the WHO 2020 goals, and USAID's impact on improving countries' capacity to manage NTD programs. The evaluation began in May 2016 and was completed in March 2017. The final evaluation report is forthcoming and will be disseminated widely. On May 9th, 2017, USAID hosted over 50 public, private, and nonprofit organizations working or interested in NTDs in a daylong technical consultation meeting organized by USAID's NTD Division. At this meeting, USAID, in collaboration with the U.S. Centers for Disease Control and Prevention (CDC) and the World Health Organization, discussed the conclusions and recommendations from the latest evaluation of USAID's NTD Program. Participants were given the opportunity to discuss topics related the USAID's current NTD programming and USAID's contribution to WHO 2020 goals for NTD control and elimination. A summary report of that meeting is provided in Appendix B.

This evaluation was designed to be a multifaceted review and analysis of the program's extensive implementation and impact data. Evaluators visited selected USAID-supported countries and interviewed several key stakeholders including USAID staff, Ministry of Health staff, in-country partners, other USG partners, WHO, the Bill and Melinda Gates Foundation, United Kingdom's Department for International Development, and pharmaceutical and drug donation partners.

The evaluation found that USAID has been a strong global leader and that USAID investments in countries are crucial to helping to achieve the WHO 2020 NTD goals. USAID's emphasis on data has played a key role in promoting standardization of reporting, completing and/or updating disease mapping, consolidating coverage data, and using that data to improve program performance. USAID's support also catalyzed increased commitment from other donors, such as the UK government and private philanthropy.

The evaluation also found that USAID support has promoted efficiencies and has allowed countries to take increasing responsibility for their country programs. This was achieved by using existing service delivery platforms and issuing limited-amount, milestone-based awards called "Fixed Obligation Grants" (FOGs) to host-country governments and non-governmental organizations to provide sub-national technical and financial assistance. The evaluation found that FOGs have played a significant role in building sub-national capacity and increasing the sense of local ownership and accountability - especially at the district level, thus, strengthening country programs and local capacity. A key recommendation from the evaluation stressed that an emphasis on sub-national strengthening, which the proposed program intends to continue via FOGs, should continue and efforts to reach district, sub-district, and community personnel should increase. While FOGs have been replaced by Fixed Amount Awards (FAAs) under 2

CFR 200, it is anticipated that this approach to country ownership and capacity building will continue to be a significant part of the USAID NTD program.

Although the evaluation found that USAID's NTD Program has been very successful in many aspects, it also noted that coordination among other sectors such as nutrition, education, and water, sanitation and hygiene (WASH) has been limited. The evaluation recommended that efforts should be made to strengthen strategic partnerships with other sectors, as appropriate, in order to improve delivery strategies and secure and sustain current programmatic gains.

Additionally, the evaluation noted that NTD endemic countries lacked sufficient opportunities to convene, share challenges and best practices and to work together on common program issues. In response to this concern, USAID intends to group countries in this announcement that share regional and/or program commonalities that would benefit from increased peer-to-peer learning.

A central theme of this program evaluation was the concept of *mainstreaming*, which refers to the structural adoption of NTDs into national health systems. To create sustainable platforms for control diseases and post-validation surveillance, NTDs will need to be mainstreamed specifically through incorporation of NTDs into national planning, financing, and overall health systems, communication of successes, and more cross-sector collaboration. This is one of the core elements that CEP-NTDs will incorporate to ensure the sustainability of USAID's investments.

Relationship to other Donor Programs and Partners

Other Donor Programs

As noted earlier, this program is a tremendously successful private-public partnership. Each year pharmaceuticals companies donate billions of dollars' worth of pharmaceuticals to national NTD programs. Using WHO guidelines, these drugs can be accessed by countries if data are provided demonstrating disease burden and if the available resources and capacity are in place to distribute the drugs and monitor progress in country. USAID resources are prioritized to support countries to ensure that these conditions are met, effectively utilizing over $4 billion in donated drugs in 2016 alone. USAID's NTD Program works closely with the following six companies to access their respective pharmaceuticals:

- GSK – Albendazole
- Merck & Co. Inc. – Ivermectin
- Pfizer – Zithromax
- Johnson & Johnson – Mebendazole
- Merck Serono – Praziquantel
- Eisai – Diethylcarbamazine citrate

Globally, about 80 percent of donor funds supporting the implementation of integrated NTD programs is provided by three organizations: USAID, DFID, and the Ending Neglected Diseases Fund (END Fund), a private not-for-profit organization that aligns donations from private

philanthropy to meet global needs for NTDs. USAID is the largest of the three donors and works very closely with both organizations.

Similar to USAID, DFID has focused its resources on supporting countries to implement NTD programs. USAID and DFID's NTD colleagues work closely to complement and leverage existing resources, and help shape and advance a common agenda that directly supports the WHO 2020 goals for NTD elimination and control. Together, USAID and DFID present a strong, unified voice at global and regional technical and policy forums, and this strategy has proven effective in helping to accelerate global progress in the fight against NTDs. Also, USAID and DFID share implementation investments in many countries; therefore, program leadership and technical teams work together in-country and from headquarters to maximize each organization's strengths and to avoid conflicting and duplicative efforts. Collectively USAID and DFID have supported over 40 countries for these seven diseases. The UK government also makes investments in Guinea Worm and Leishmaniasis.

The END Fund is a newer and increasingly significant donor, attracting a wide range of private philanthropies. Over the past five years, the END Fund has raised approximately $50 million for NTDs and looks to increase this contribution as it begins its next 5-year campaign. The END Fund complements USAID and DFID investments by filling strategic program gaps at the country level. The END Fund's flexibility has been an asset when political instability has resulted in temporary suspension of USAID support, keeping crucial NTD programs operating and adherent to WHO guidelines, while protecting USAID's investment and preserving continuous cycles of mass drug administration to prevent disease recrudescence.

The USAID NTD program also maintains a close relationship with the Bill and Melinda Gates Foundation (BMGF). The BMGF primarily focuses on research for new drug regimens, diagnostic tools, and elimination strategies across a range of NTDs, thus complementing USAID's program implementation strengths. USAID and BMGF work together via a Global Development Alliance (GDA) that funds the Coalition for Operational Research for NTDs, dedicated to solving implementation problems to achieving WHO's 2020 goals. In 2017, DFID joined the Coalition with a $10 million investment. The BMGF and DFID, along with USAID, have been instrumental in providing supplemental resources to support WHO headquarters and regional offices in their promotion of the 2020 global control and elimination goals. The BMGF uses their convening power to bring key stakeholders together to discuss and address gaps in commitments for NTDs and the organization's co-founders, Bill and Melinda Gates, have used their voices to raise awareness and advocate for NTDs at the highest levels of government and industry. For example, Bill Gates was essential in launching the global advocacy effort, Uniting to Combat NTDs, where USAID and DFID currently co-chair the Donor Working Group.

Other USAID-Supported Programs

Although not directly involved in PCT implementation, USAID supports the following additional projects that contribute to the WHO 2020 NTD goals. It is expected that CEP-NTD will work closely with these projects to help USAID maintain a focused and cohesive program.

Morbidity Management and Disease Prevention Program: Led by Helen Keller International, the purpose of the MMDP program is to develop tools and best practices to strengthen national ownership and capacity within a select number of African countries to scale up the provision of quality services for the management of morbidity, disability and disfigurement related to trachoma and lymphatic filariasis, in a manner that will help to meet elimination targets.

The Coalition for Operational Research on Neglected Tropical Diseases (COR-NTD) program is led by The NTD Support Center, Task Force for Global Health. The Coalition helps define and research important questions hindering the successful implementation of NTD programs and progress towards control and elimination goals; aims to strengthen linkages among partners by engaging researchers, country-level program staff, implementation partners, and the donor community; and will link program questions with researchers, building capacity in the regions and accelerating consensus for key questions.

Additionally, through another anticipated mechanism, USAID intends to support an NTD "data hub" that will work closely with the CEP-NTD program implementer(s) and serve as the central point for all of the data collected between the PCT implementation programs. It is intended to support USAID's program by providing complex data analyses as needed for programming, provide a platform to facilitate access to and use of data, generate a variety of reports and presentations for key stakeholders, and help frame operational research questions that are needed to target issues or respond to pressing questions in the data.

Other Global Partners

USAID works in close coordination and partnership with the World Health Organization to accelerate the progress towards WHO and USAID NTD goals by strengthening the global capacity for the implementation of NTD programs. This is accomplished through coordinating with the WHO in the development of normative guidelines in program implementation, monitoring, and evaluation; supporting the scale-up and scale-down of mass drug administration; and ensuring the coordinated procurement, availability, and drug safety monitoring of quality-assured NTD medicines.

USAID also works in partnership with the U.S. Centers for Disease Control and Prevention. CDC NTD experts help solve diagnostic, surveillance, lab capacity and other technical issues that are rapidly emerging as countries transition from scale-up of mass drug administration to evaluating the break of transmission of lymphatic filariasis, trachoma, and in some cases, onchocerciasis. CDC also supports USAID with development of practical, low-cost diagnostics

and epidemiologic survey tools to help countries monitor control of other NTDs (i.e., schistosomiasis, soil transmitted helminthiasis).

Within USAID, there are several opportunities to work across sectors to help countries establish long-term, cost-effective NTD control programs (e.g., soil transmitted helminthiasis, schistosomiasis). CEP-NTD is intended to complement other activities within the Bureau for Global Health, the Bureau for Economic Growth, Education and Environment, as well as within USAID Missions. The NTD program recognizes that sustaining gains in *protecting communities from infectious diseases* will require cross-sector collaboration, particularly with Nutrition, WASH, and Education. By working closely, USAID can leverage cross-sector technical leadership, diverse partnerships, non-traditional public health platforms, and unique skills, resources, and perspectives. For example, schools are often used for NTD mass drug administration campaigns and are likely the best long-term platforms for sustainable de-worming programs, though not without limitations. Through CEP-NTDs, the NTD Program will work with the education sector to achieve widespread improvements to health and learning outcomes, capitalizing on the benefits of working in schools to deliver de-worming, nutrition, and WASH interventions.

Over the next five years, USAID and its implementing partners will continue to strengthen existing partnerships to further the WHO NTD elimination and control goals and the Agency intends to use its global leadership to engage new partners and catalyze additional funding to strategically support gaps in NTD support for the diseases in the USAID portfolio.

Core Principles of the USAID NTD Program

The core principles that will guide implementation of the CEP-NTD include the following:

1) The governments of disease-endemic countries are the owners and leaders of their national NTD control and elimination programs. The Program will stimulate increased government commitment for NTDs within disease-endemic countries and will support government leadership in the implementation of expanded integrated programs.
2) The Program will complement and not replace government, community or other external funding. The Program will only support countries that have documented financial need for support. USG will actively coordinate with other bilateral donors and international agencies to ensure the complementarity and leveraging of USG resources at global and country level.
3) It is anticipated that approximately 80 percent of the Program's funding will support activities directly related to provision of preventive chemotherapy (including program monitoring and evaluation) in disease-endemic countries.[2] High priority is placed on

[2] The target diseases are only those amenable to control through MDA, including trachoma, schistosomiasis, onchocerciasis, soil-transmitted helminthes, and lymphatic filariasis.

helping countries to obtain high MDA coverage. Sustained surveillance capacity is also important.

4) The Program will prioritize countries in Africa and Asia with prevalence of at least three overlapping NTD disease burdens (for the purposes of prioritization, soil-transmitted helminthiasis will be considered as one disease). In Latin America, a more targeted approach responding to disease foci will be employed. The Program's primary focus is disease elimination as a public health problem, where feasible, with a secondary focus on building capacity to sustain rigorous platforms for the control diseases.
5) The Program will work closely with the pharmaceutical industry to expand existing and establish new public-private partnerships that facilitate access to an affordable, quality-assured drug supply in support of preventive chemotherapy implementation.
6) The Program will, where there is opportunity, leverage and complement the existing resources of other USG programs, such as the President's Malaria Initiative (PMI), basic education, water, sanitation, and hygiene, and maternal and child health. This is envisioned to be accomplished through the development of coordinated country-level work plans in countries where USG-supported NTD control programs overlap with programs in other development sectors.
7) To the maximum extent possible, technical capacity for conducting NTD program activities should be anchored in existing, local and regional organizations and institutions (e.g., governments, universities and other learning institutions, non-government organizations).

Program Challenges

As 2020 approaches, USAID recognizes that supported countries face several challenges for meeting WHO NTD elimination and control goals. Implementing partners must be immediately prepared to help countries meet critical, time-bound elimination milestones and resolve program challenges for treating communities and documenting success. USAID is interested in partnering with organizations that demonstrate a deep understanding of these challenges and can propose innovative approaches to solving them as well as anticipating and addressing other key program challenges.

For example, LF and trachoma require multiple, contiguous years of treatment at minimum population coverage levels in order to proceed to impact evaluation (that determines whether or not a community no longer needs treatment). If a community misses a year of treatment, then much of the USAID investment of previous years is lost and those rounds of treatment must be repeated. Several of the countries currently supported by USAID are in the middle of such treatment rounds and will remain so at the anticipated time of this award(s).

Regardless of the disease, coverage levels are likely the most important factor in ensuring that the community treatment is effective. While progress under the USAID NTD program and globally have been substantial, there remains a significant number of communities where

coverage rates fall below the WHO minimum requirements. There are several reasons surmised for these shortcomings to include (but not limited to) dynamic cross-border movement of populations, poor denominator data, missed minority communities, mistrust of NTD drugs and fear of severe adverse events. These challenges must be quickly understood and effectively addressed in order for countries to meet WHO 2020 goals.

Nested within the issue of "MDA coverage" is the challenge of compliance. In many countries and communities, MDA supervision includes direct observation of community members ingesting the NTD medicines. However, in some countries and communities, community members refuse to ingest the medicines in front of the health workers and/or community drug distributors or to ingest them at all. Coverage surveys, implemented soon after the MDA, ask whether people received the drugs and also if they took them. Recently questions have been added to help us understand why people do not or will not ingest the drugs. Responses have included fear of side effects, perception by the individual that she/he is not at risk of the disease, forgetting, perception that the medicine does not work, etc. There is a need to find effective, low-cost, and relatively quick ways to understand and solve these compliance problems.

The vast portfolio of USAID-supported countries - effectively the largest NTD implementation program in the world - presents a unique opportunity to learn lessons from individual country experiences and then to adapt them to other countries with similar challenges. However, given that MDA usually occurs only once a year and for a short period (e.g., 4-10 days), this learning process has to be quick, efficient, and effective.

High quality monitoring and evaluation and data are foundational to a country's ability to meet WHO NTD elimination and control goals. Integrating up to five disease programs within a single country has been challenging, and bringing the data together consistently in a rigorous, standardized format continues to be a challenge for some countries. Largely through USAID support, the WHO developed and rolled out the Integrated NTD database in 2014, but many countries were slow to adopt it – often continuing to rely on siloed, and often unsecured data systems (e.g., disease-specific spreadsheets, paper-based records, locally developed databases). Where countries do have strong M&E and data systems, key program activities, such as completion of ordering forms for donated drugs and documentation of success for elimination and control, have been far easier. In addition to slow adoption of the integrated database, Ministry of Health staff often experience substantial personnel turnover, which makes M&E continuity difficult. Furthermore, NTD program data often sits outside of National Health Management Information systems (such as DHIS2), and this separation creates challenges for ensuring that NTD program activity is visible, sustainable, and prioritized along with other disease programs in the health system.

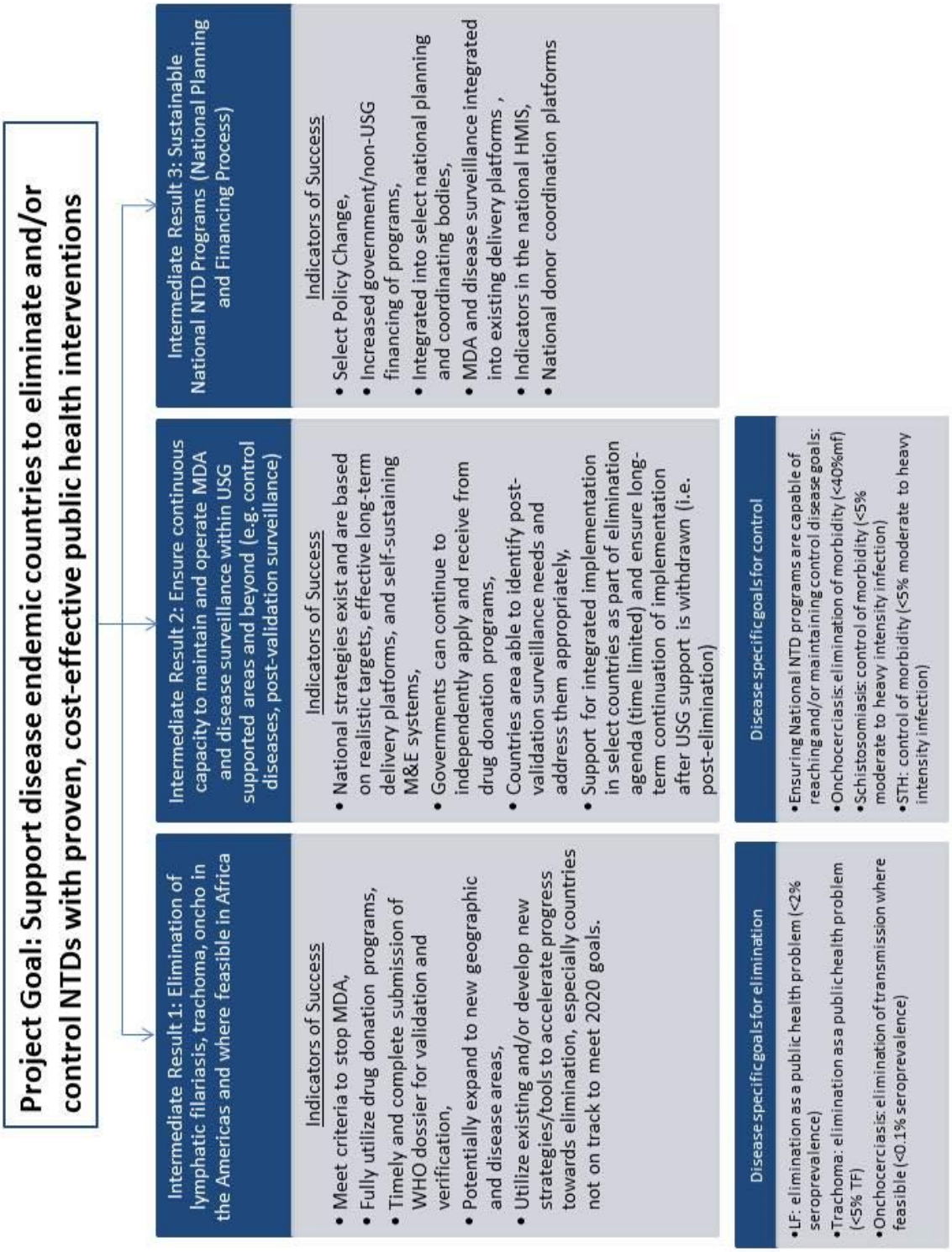
Programs that address diseases for which there is significant mortality, and for which there are relatively large donor and domestic budgets, are often the priority focus of many Ministries of Health. Thus, due to their comparatively low mortality, NTDs and the country programs that

seek to address them are often viewed as being external or on the periphery of the core national health system. This presents a special challenge to countries that have been supported by USAID to address both "elimination" and "control" NTDs. As a country program makes continued progress in eliminating diseases such as LF and trachoma as public health problems, they may realize that there is insufficient attention and support from their own leadership to help them sustain activities for "control" NTDs, such as soil transmitted helminthiasis, schistosomiasis, and in some cases, onchocerciasis. Bringing the NTD programs into the larger health system, "mainstreaming," may help ensure that NTD program indicators are established and monitored along with other national health indicators, that the NTD program functions would be integrated into the workforce, and that funding could be allocated within the national budget to support NTD-specific activities. This national support, coupled with the availability of drug donations, make NTD programs an inexpensive and cost effective investment for many countries – and one which produces clear, meaningful health outcomes.

ABBREVIATIONS AND ACRONYMS

AOR	Agreement Officer's Representative
BMGF	Bill and Melinda Gates Foundation
CDC	U.S. Centers for Disease Control and Prevention
CFR	Code of Federal Regulations
DFID	U.K. Department for International Development
FAA	Fixed Amount Award
FAR	Federal Acquisition Regulation
FOG	Fixed Obligation Grant
GDA	Global Development Alliance
GH	Global Health Bureau (USAID)
IEC	Information, Education, and Communication
LF	Lymphatic Filariasis
M&E	Monitoring and Evaluation
NGO	Nongovernmental Organization
NTDs	Neglected Tropical Diseases
OEPA	Onchocerciasis Elimination Program of the Americas
PCT	Preventive Chemotherapy
PMI	President's Malaria Initiative
SDG	Sustainable Development Goal(s)
STH	Soil Transmitted Helminths
TEC	Technical Evaluation Committee
USG	United States Government
USAID	U.S. Agency for International Development
WASH	Water, Sanitation, and Hygiene
WHO	World Health Organization

Appendix A. NTD Program Results Framework



Appendix B. Technical Consultation Executive Summary

USAID NEGLECTED TROPICAL DISEASES ("NTDS") PROGRAM

TECHNICAL CONSULTATION MEETING - MAY 9, 2017

EXECUTIVE SUMMARY

INTRODUCTION

On May 9th, 2017, the United States Agency for International Development (USAID) hosted over 50 public, private, and nonprofit organizations working or interested in neglected tropical diseases (NTDs) in a daylong technical consultation meeting organized by USAID's NTD Division. At this meeting, USAID, in collaboration with the U.S. Centers for Disease Control and Prevention (CDC) and the World Health Organization (WHO), discussed the conclusions and recommendations from the latest evaluation of USAID's NTD Program. Participants were given the opportunity to discuss topics related the USAID's current NTD programming and USAID's contribution to WHO 2020 goals for NTD control and elimination.

The consultation was divided into two parts. The first part was composed of a series of plenary presentations and discussions which were provided to help participants understand the five NTDs supported by USAID. Presentations from WHO and USAID outlined the global context as well as USAID efforts and results to-date, including findings from the USAID NTD Program Performance Evaluation. The second part of the consultation consisted of five parallel breakout sessions: 1) Sustainable Surveillance & Monitoring and Evaluation; 2) Program Implementation; 3) Integration of Control Platforms; 4) Mainstreaming; and 5) Working with USAID. These breakout groups were designed to facilitate a more in-depth conversation around some of the key highlights from the program evaluation and to get ideas on how USAID might improve progress towards reaching WHO 2020 targets.

OVERVIEW

USAID NTD PROGRAM OVERVIEW

USAID is the lead U.S. Government agency that works to end extreme global poverty and enable resilient, democratic societies to realize their potential. USAID's effort to tackle neglected tropical diseases (NTDs) contributes towards this poverty elimination goal.

Since 2006, the U.S. Congress has demonstrated bipartisan support for the USAID NTD Program. Initially focused on 5 countries, the program has marshalled resources to expand its geographic scope

and scale up access to critical health interventions across the globe. Over the past ten years, the program has expanded to support 31 countries in Africa, Asia and Latin America. To date, the U.S. government has allocated $686 million to the USAID NTD Program.

The USAID NTD Program targets the most prevalent neglected tropical diseases that have proven health interventions, including: lymphatic filariasis, trachoma, schistosomiasis, onchocerciasis, and three soil-transmitted helminths (whipworm, hookworm, roundworm).

Drawing upon over a decade of experience, USAID invests in areas that have the greatest potential to achieve the WHO 2020 goals for NTD elimination and control. USAID supports countries financially and technically to conduct disease mapping, implement large-scale treatment programs and measure the impact of programs. Additionally, USAID targets support in key areas that are critical in the global fight against NTDs: developing training tools to manage or correct the disability associated with trachoma and lymphatic filariasis; conducting operational research and developing new diagnostics, tools and drugs.

USAID works hand in hand with partners at the national, regional and global level to support national NTD programs. The program's success is underpinned by a dynamic public-private partnership with the pharmaceutical industry, enabling USAID to carry out the largest integrated NTD program in the world and ensuring that donated treatments reach those in need.

NTD Program Evaluation Overview

The USAID NTD Program performance evaluation was conducted in 2016. The purpose of the evaluation was to determine whether the NTD portfolio countries are on track to meet the WHO 2020 goals and specify what may still be required in order to achieve these milestones. It was based on a careful review of program documents and data, scholarly NTD literature, a survey, and key informant interviews. The evaluation centered around these four questions:

1) Global Leadership: How have the USAID NTD Program and implementing partners influenced global policy and best practices?
2) Program Implementation Strategy: Is the USAID NTD Program's current strategy the best approach for achieving 2020 goals at a country level?
3) Capacity Building/Country Ownership: Has the USAID NTD Program built country capacity and country ownership of the program?
4) Progress Towards Achieving Elimination: Are USAID supported countries on track to achieve the WHO NTD 2020 elimination and control goals for the diseases supported in the program?

Additionally, an interview guide was utilized for in-depth key informant interviews and a 22-question, three-part survey with both closed and open-ended responses was sent to a list of emails for 202 government, NGO and donor NTD program staff based in 21 countries. Field work was carried out in August and September of 2016 and consisted of visits to eight countries, seven of which are endemic for NTDs. Extensive in-person and telephone interviews were carried out with key stakeholders, non-governmental organizations (NGOs), and various technical experts (153 persons total).

SIGNIFICANT THEMES

The NTD Program Evaluation concluded the following general findings across the four objectives *of* 1) Mainstreaming; 2) Collaboration; 3) Capacity Building/Country Ownership; and 4) Progress towards Achieving Elimination.

From a global perspective, USAID's involvement in the field of NTDs has had a "transformational" effect on program implementation. The USAID NTD program introduced a management discipline and program transparency to national activities, while at the same time greatly expanding the available resources for supporting activities, such as advocacy and operations research. The program has brought together several individual "disease control" programs within ministries and encouraged an integrated approach. Though challenging and varied across countries, this approach has brought much needed ministry-level visibility to the programs and assisted to position most countries on track to meet the WHO 2020 disease elimination targets. Because of these successes, USAID maintains a strong leadership in the influence of global policies and has played a key role in strengthening country capacity, ownership of mass drug administration (MDA), as well as other related program activities, such as data collection and use, disease mapping, and disease impact assessments. Regionally and in-country, the Agency continues to lead the direction for current and future NTD activities by working with global partners to align contributions for NTD management, supporting local NGO's and fostering a platform for collaboration efforts.

EVALUATION KEY OUTCOMES AND RECOMMENDATIONS

A number of key outcomes and specific recommendations emerged from the NTD Program Evaluation Presentation:

COMMUNICATION IMPROVEMENTS: Communicating programmatic successes is important for the Agency. The USAID NTD program has had limited communication with partners outside the immediate sphere. Ministries of Health should focus on communicating their success and use their influence to raise resources, build partnerships and strengthen capacity. In addition to improving communications between countries, implementing partners, and the Agency, USAID should continue to assist countries in strengthening their ability to communicate progress and best practices both nationally and internationally and within the broader health and development community.

COLLABORATION & MAINSTREAMING IMPROVEMENTS: Incorporating national public health systems is imperative to achieve long-term NTD elimination, support and sustainability. More effort is needed to promote the support of existing partnerships, quality and routine data, annual work planning and advocacy. More consideration and emphasis on alternative approaches that include district and community level players is required. The USAID NTD Program should continue to work on fostering partnerships with other sectors, such as Education, Water, Sanitation and Hygiene ("WASH"), Maternal & Child Health ("MCH"), Malaria, Central Public Health Labs, etc.

COUNTRY OWNERSHIP AND CAPACITY IMPROVEMENTS: One of USAID's key objectives is to foster sub-national and national capacity building, assist in mainstreaming NTDs within the public health system and sustaining success after elimination. USAID should continue efforts to strengthen districts,

sub-districts, and community personnel. One way to achieve this is by increasing supervisory capacity; this will improve outcomes and may facilitate greater national and sub-national coordination.

MORBIDITY IMPROVEMENTS: Morbidity management and control continues to be a challenge globally. Funding and support for morbidity control remains limited, but it is an increasing concern of national NTD Programs. USAID should work on assisting in leveraging available resources through collaboration with WHO and partners.

KEY OUTCOMES FROM THE TECHNICAL CONSULTATION:

The technical consultation plenary session presentations were each followed by an opportunity for questions and feedback. While most questions from participants were requests for clarification of various technical aspects of the NTD program, there were some feedback comments. For example, one participant raised concerns about a potential reduction in ministry of health capacity to carry out program activities in some countries due to the closing or tremendous scale-down of polio programs (several countries rely on this platform for MDA). Another participant flagged the challenge of using school-based treatment platforms in countries/communities where many children do not attend school or attend regularly. It was also noted that country ownership should include an increased financial commitment by countries to operate NTD programs (thus, relying less on donor funds). This latter point will be especially important as countries reach WHO requirements for elimination status of some diseases while still needing to maintain long-term control programs for other diseases.

The breakout sessions that followed the plenary were organized based on areas where the USAID NTD program staff believed a deeper discussion, exchange of ideas, and other feedback would be useful in considering potential future programs. Some participants were asked to join specific groups based on their known areas of expertise, skills, and experience. The rest of the participants were invited to choose from among the breakout groups. Key points from each themed group are included below:

1) SUSTAINABLE SURVEILLANCE AND MONITORING AND EVALUATION:

Description: As NTD programs are approaching elimination for lymphatic filariasis and trachoma, control diseases (STH/SCH/ONCHO) will require long term sustainable drug delivery platforms and M&E systems that are integrated within the national health system. How can NTD programs be strengthened to sustain long term the monitoring and evaluation needs for both elimination and control diseases?

Key Outcomes:

- Special Program for Research and Training in Tropical Disease (TDR), in collaboration with WHO NTDs, needs to explore training opportunities that strengthen county capabilities for disease surveillance and M&E. Participants discussed the possibility of making a "lighter version" of some of the more complex tools so they are easier to understand and update. Carrying out disease transmission/epidemiology training down to the district level could be worthwhile.
- There is a clear need for district level staff to know how and where to access information and tools (e.g., from central Ministry of Health (MOH), implementing partners, WHO) This need is increasingly important as the programs stop MDA and need to plan and implement surveillance

activities and for longer term activities after elimination is achieved. This need for easy access to information also could adjunctly benefit country programs' morbidity management.

- Also mentioned was security and stability of country program NTD data. Some programs are not securely storing the data (e.g. cloud, network) or routinely completing back-up of data. Data that sits on desktop and laptop hard drives is much more likely to be lost.
- USAID's NTD program should learn from the deep experience of malaria programs and potentially bring NTDs into the HMIS/DHIS (the health information management system that many Ministries of Health are using). Access to real-time data for decision making could streamline processes, reduce costs of parallel systems and help move programs towards long term sustainability.
- USAID's NTD program should continue to follow the multiplex and other more advanced laboratory tool developments which are now incorporating vaccine-preventable diseases and NTDs. These platforms have the real potential to save on cost due to pooling strategies, decreased labor and multiple detection capabilities from single samples. If these platforms are regionally situated there could be significant opportunities to take advantage and maximize the impact.

2) PROGRAM IMPLEMENTATION:

Description: The USAID "formula" for NTD program implementation has been largely successful as is demonstrated by the high pass rate of disease specific assessments. However, as more countries experience success in treating NTDs, it is clear that more complicated challenges in some sub-national areas (e.g., districts) require either a different approach or a higher concentration of attention and effort under the current approach. What ideas, approaches, tools and other resources can help countries meet these challenges?

Key Outcomes:

- The USAID NTD Program should learn from other public health programs with similar challenges. For example, since 2002, the polio and immunizations programs in the Africa region have been using a "micro-planning" process down to the district level. This process engages local government officials in identifying hard-to-reach populations at a rather granular level. There are plans to extend this planning process down to the facility level where health workers are more likely to know the specific homes, workplaces, practices and issues of hard-to-reach populations.
- Increasing qualitative research was suggested as a way to gain insight into reasons why communities are missed during MDA or why community members do not comply with taking medicines. One meeting participant noted engaging local universities in this type of research is a quick and effective way to generate more comprehensive data on missed populations and MDA program compliance.
- Another participant suggested that USAID collaborate with other programs (even outside of health or development sector) for supplemental information and/or experiences to help improve MDA planning and implementation. The benefits of having a common data platform or established peer-peer network for sharing data and discussing challenges and best practices was also noted.

- In terms of capacity strengthening, the NTD program should explore ways to improve training practices and the sustainability of those practices after USAID support ends. Improvements should include efficient and effective methods of feedback on training (e.g., cell phone surveys).
    - Currently, the majority of annual training for MDA is done on a large scale (often reaching tens of thousands of people in a single country) and some countries view this training process as unsustainable without donor funding. The current method for large-scale training is to use a series of "train the trainer" ladders which tends to result in a degradation of quality with each step. Also, there is a need for good quality assurance on trainings as well as a system of support for trainers and trainees.
    - At the national, and sometimes sub-national level, there is a lot of staff turnover (e.g., M&E, data collection and management). Currently, the NTD programs sit outside of the larger public health systems, so training for some key functions are not integrated into the Ministry's internal program structure. This issue is cross-linked to "mainstreaming."
- Some participants noted, that while morbidity management is not a part of this discussion, countries still need help. Some aspects of morbidity, such as estimating patient burden, availability and quality of morbidity services, are required for countries to complete WHO dossiers.
- Countries need more help with using program data - especially for advocacy and decision-making.

3) INTEGRATION OF CONTROL PLATFORMS:

Description: Support for schistosomiasis (SCH) and soil transmitted helminths (STH) MDA and monitoring and evaluation under the USAID NTD program have been ancillary benefits of the expanded elimination platform (LF, trachoma, onchocerciasis). The USAID NTD program is focused on end points which currently are not detailed in global guidelines for SCH and STH. As a result, countries that achieve their elimination goals and begin to scale down MDA for the elimination diseases, are at risk of losing support for the platforms and funding on which SCH and STH now stand. Therefore, the a key challenge that must be addressed in order to sustain the gains made under the USAID NTD program is to identify what sustainable community or service platforms can be leveraged to provide continued drug distribution for control diseases?

Key Outcomes:

STH and SCH have benefited from integrated MDA with LF, onchocerciasis, and trachoma. Ideally, as these diseases with elimination goals reach their stop MDA objectives, STH and SCH programs would continue through the integration of STH/SCH MDA into other health platforms. The window of opportunity to continue to take advantage of the drug donation programs (which make deworming incredibly cost effective) is narrowing as elimination programs scale down. The discussions included identifying the following key activities that would be essential to the development of a sustainable STH/SCH platform as well as taking into account USAID's comparative advantages. The major key activities identified are:

- High level diplomacy/dialogue is needed to raise the visibility of the SCH/STH program to increase interest and strengthen political will in support of integrating control diseases into alternative platforms that are likely to have long-term viability.

- It is especially important to attract cross-sectoral collaboration as integrating STH/SCH into other health platforms requires buy-in across ministries and technical communities (WASH, Education, Maternal and Child Health, etc.)
- Ultimately the aim of this effort is to encourage change and/or updates national policy that supports or mandates the integration of STH/SCH MDA into existing sustainable platforms.

- Communication: Communication of the successes and impacts of the program, especially in regards to STH and SCH, has been generally weak under the USAID program. Increased focus on strengthening communication on program successes to date, the benefits of integrating STH/SCH control/treatment into other health platforms to maintain progress, and the sustainability of these deworming programs is needed.
  - A key message to reinforce is that STH/SCH deworming programs have been very successful and that deworming contributes to other cross-sectoral goals and overall country development goals.
  - Successful communication will require understanding other sector/service delivery platform goals and how STH/SCH would contribute to accelerating progress towards those sector specific goals as well as the overall development goals in a country.
- Support for Cross Sectoral Coordination: A robust and sustainable STH/SCH program would ultimately include a behavior change and Water, Sanitation, and Hygiene component, and therefore, would require multisectoral buy-in. Hence, once there is interest from other sectors, support for coordinating bodies across sectors/ministries is crucial during the initial stages of policy and program development.
- Landscaping/Situational Analysis: To support strengthening high level diplomacy and communication, a country specific understanding of the programmatic, epidemiological, and cross sectoral/partner landscape is essential. This process also includes understanding the opportunities and avenues available through national governments for domestic resource mobilization. For example, the Philippines deworming program identified key stakeholders within the ministry and created an opportunity for program support through the national tax on tobacco and alcohol.

4) MAINSTREAMING:

Description: What capacities, strategies and resources should be considered in helping countries to merge relatively isolated country NTD programs into the broader health systems and efforts to increase domestic financing for health (e.g., Universal Health Coverage)

Key Outcomes:

- USAID should consider re-defining its support relationship with some countries such that host country NTD budget becomes standard practice. For example, the memorandum of understanding **(**MOU) with the host country could require some amount of co-investment by the government in order to receive USAID funding support. This practice has been successful in countries such as Sudan and Nigeria.
- Ensuring that deworming is part of a country's minimum package of health services is a good first step to getting long-term NTD control activities into the national health budget.

- Given that there is a lot of competition for health dollars within governments (e.g., Malaria, HIV, MCH), it is important to help NTD programs communicate to Ministries of Health and Finance the big social returns for low cost investments in NTD control - despite the low rate of mortality caused by NTDs. Additionally, existing infrastructure for delivery and integrated treatment methods help make NTD control an attractive investment.
- Most country NTD program managers are consumed with the requirements of managing a long list of neglected diseases (beyond the five supported by USAID). They need assistance in identifying host government priorities, the budget cycle and timing of financial commitments to priorities, and how to influence those priorities by strategically communicating the need for NTD program support and the benefits of investing in the NTD program.

5) WORKING WITH USAID:

Description: USAID seeks to tap the creativity, energy, and innovative ideas of individuals and organizations around the world to discover new ways to tackle global challenges. In this breakout session, USAID sought ideas, recommendations, and feedback on the different ways and modalities of working with the Agency. What are the strengths and challenges of different procurement mechanisms, ways of collecting data, reporting requirements, and implementation experience as is related to Neglected Tropical Diseases programming?

Key Outcomes:

- The USAID program should work towards economies of scale – recognizing that efficiency allows more MDA and related activities to be funded.
- A decreased management burden is desired as the administrative requirements divert technical staff members from doing technical work.
- Participants noted that more transparency across the portfolio of countries is very important. Having standardized, centralized data available for regular review among partners helps the teams improve by learning from each other. Likewise, transparency also makes it easier to learn lessons on implementation from across the portfolio and apply to countries with challenges.

CONCLUSIONS AND NEXT STEPS

Overall, this technical consultation brought together a broad range of stakeholders with organizational and technical perspectives to review the USAID NTD Program's work, progress, and challenges. Also, it provided a forum for providing feedback and suggestions to further advance USAID's NTD program. Participants suggested areas of improvements, provided ideas for program structure, and ways that USAID could respond to the recommendations from the 2017 program evaluation, in order to support countries to accelerate and meet WHO 2020 NTD control and elimination goals. USAID will take these comments and ideas into consideration as the NTD program moves forward.