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The U.S. Government and Global Neglected Tropical Diseases

Overview

More than a billion people – one-sixth of the world's population – are infected with one or more NTDs, an additional two billion are at risk, and each year, half a million people die as a result.[1] NTDs have low mortality but high morbidity rates and are the fourth most devastating group of communicable diseases behind lower respiratory infections, HIV, and diarrheal diseases – ranking higher than either malaria or tuberculosis.[2]

NTDs have only recently garnered greater international attention from the U.S. government (USG) and other global donors, spurred on by growing recognition of their potential threat to the achievement of the Millennium Development Goals (MDGs) by 2015.[3] In addition, the development and expansion of an integrated NTD treatment approach capitalized on the availability of safe and effective treatments for the most prevalent NTDs.

> **Neglected Tropical Diseases (NTDs):** A group of parasitic, bacterial, and viral infectious diseases that primarily affect the most impoverished and vulnerable populations in the world and, as such, have received scant attention until recently.[4]

Over the past ten years, the USG has become more involved in global NTDs. Since the launch of the first USG NTD program in 2006, its efforts have expanded to a greater number of countries and provided more than a billion NTD treatments to almost a half a billion people. More recently, the USG has affirmed its support for global NTD goals, including eradicating, eliminating, and controlling several NTDs.[5]

Current Global Snapshot

NTDs are grouped together due to their often chronic, disfiguring, and stigmatizing impact; their close association with poverty; and their geographic overlap. While there are numerous NTDs in the world, the World Health Organization (WHO) has highlighted 17 that particularly impact poor, politically marginalized populations; cause significant morbidity and/or mortality; are neglected by research; and can be controlled using effective methods.[6] Infection with an NTD may result in severe disability, disfigurement, blindness, and malnutrition, and individuals are often infected with multiple NTDs simultaneously. The health impact of NTDs negatively affects economic development, hampers educational achievement and cognitive development, and reduces agricultural productivity and food security.[7]

Global Status

Endemic to almost 150 countries, NTDs span the globe.[8] However, the majority of the NTD burden is concentrated in low- and middle-income countries in Africa, Asia, and Latin America.[9]

People living in rural areas as well as urban slums are among the most affected, since lack of access to clean water, health services, adequate housing, and good sanitation contribute to NTDs' prevalence and impact. Women and children are most at risk of infection, since they are more exposed to NTDs and more often face barriers to accessing treatment, particularly those living in remote areas.[10] For example, young children are the principal reservoir of trachoma infection, and, due to the role of women as caretakers of children, there is an increased likelihood of being infected with trachoma multiple times. Women are 2 to 3 times more likely to be blinded by trachoma than men.[11]

Seven "tool-ready" NTDs (see Table 1) are responsible for the overwhelming majority of the NTD burden but can be controlled and even eliminated with low-cost and effective interventions. This subset of NTDs is increasingly the focus of donor efforts, including USAID's NTD Program.

Effective Interventions

A number of strategies have been successful in controlling and, in some areas, even eliminating certain NTDs. Although many interventions are relatively inexpensive, challenges persist in delivering tools and services to the most at-risk populations. Today, the recommended strategy is an integrated control approach targeting multiple NTDs simultaneously through mass drug administration (MDA), combined with community-level transmission control measures. This allows programs to reach more

Table 1: Seven NTDs Targeted by USAID's NTD Program[12]			
Disease	# of People Affected Each Year	# of Affected Countries	Causes
Soil-Transmitted Helminths (STH):	1,500 million+	112	Infection with worms transmitted through ingestion of or direct exposure to soil that is contaminated by human feces in which STH eggs are present.
Ascariasis *(roundworm)*	*819 million*	--	*Infection typically due to ingesting contaminated soil, food, or water*
Hookworm	*439 million*	--	*Infection typically due to walking barefoot on contaminated soil or ingesting larvae*
Trichuriasis *(whipworm)*	*465 million*	--	*Infection typically due to ingesting contaminated soil or food*
Lymphatic filariasis (elephantiasis)	120 million	73	Infection with worms transmitted by mosquitoes
Onchocerciasis (river blindness)	37 million	36	Infection with worms transmitted by black flies that breed near fast-moving rivers and streams
Schistosomiasis (snail fever)	249 million*	78	Infection with worms transmitted through contaminated freshwater inhabited by snails carrying the parasite
Trachoma	29 million+	51	Infection transmitted through direct or indirect contact with bacteria in an infected person's eye or nasal discharge (on hands/clothes or on the feet of flies)
NOTES: -- indicates the information in not available; *indicates number requiring preventive chemotherapy; + indicates active trachoma, trichiasis, and irreversible blindness due to trachoma.			

people and increase cost-efficiencies over tackling each disease separately.[13] MDA often uses the "rapid-impact package," which is a combination of four drugs used to prevent or treat the seven most prevalent NTDs for as little as $0.25-$0.50 per person per year.[14] The low cost of the rapid-impact package is partially due to donations of drug treatments from pharmaceutical companies, which have risen by more than 35% since 2011.[15] Additional measures such as promoting clean water, sanitation, and hygiene (WASH), and good veterinary public health also play critical roles in addressing the underlying causes of NTDs.[16]

Global Goals

As NTDs began to receive greater attention and global efforts have expanded over the past ten years, major global NTD goals have been set through:

- **The 2012 WHO *Roadmap for Implementation*,** which outlined targets and strategies for global NTD control, elimination, and eradication efforts from 2012 through 2020. Among its goals are the eradication of dracunculiasis (Guinea worm disease) by 2015 and yaws by 2020 and elimination of four NTDs – blinding trachoma, human African trypanosomiasis (sleeping sickness), leprosy, and lymphatic filariasis (LF) – by 2020.[17]
- **The *London Declaration on Neglected Tropical Diseases*,** which was endorsed by key public and private stakeholders in 2012 and laid out global NTD goals (affirming those in the *Roadmap*) and commitments. It aims to improve partner efforts to coordinate and collaborate across their respective efforts in order to help eradicate Guinea worm disease and, by 2020, to help to eliminate the four NTDs mentioned above (blinding trachoma, sleeping sickness, leprosy, and LF) and to control schistosomiasis, soil-transmitted helminths, Chagas disease, visceral leishmaniasis, and onchocerciasis.[18]

The U.S. Government's Response

Over the past ten years, U.S. attention to and funding for NTDs have increased markedly. Historically, the U.S. government's response to NTDs was relatively limited, focusing largely on research and surveillance conducted by the National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC), and the Department of Defense (DoD). In 2006, Congress first appropriated funds to the U.S. Agency for International Development (USAID) for integrated NTD control, after which the agency launched its NTD Program. In 2008, the USG announced expanded NTD efforts, building on USAID's NTD Program.[19] In 2012, the USG signed onto the *London Declaration*,[20] and more recently, the USG has adopted a longer term global health goal of protecting communities from infectious diseases and highlighted the important role of NTD efforts in achieving this goal.[21]

Structure and Approach

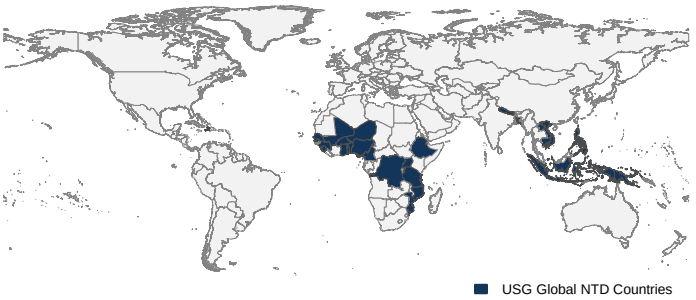
USAID serves as the lead implementing agency for U.S. NTD efforts. Several other agencies, including NIH, CDC, DoD, and the U.S. Food and Drug Administration (FDA), are also involved in responding to NTDs worldwide.

USAID's NTD Program.[22] USAID's NTD Program targets seven "tool-ready" NTDs that are particularly amenable to control due to the availability of effective drugs against these diseases (see Table 1). The program spans 25 countries, mostly in sub-Saharan Africa and Southeast Asia (see Figure 1), having been scaled up from five countries in 2006. Using interventions such as the rapid-impact package, the USG supports endemic countries in scaling up MDA and developing their capacity to manage NTD

control programs. The program's goals are to contribute to the elimination of onchocerciasis in the Americas by 2016 and the elimination of LF and blinding trachoma globally by 2020.

Figure 1

U.S. Government Global Neglected Tropical Diseases (NTDs) Countries, FY 2013



SOURCES: USAID, *Global Health Programs: Progress Report to Congress FY 2013*, 2014; USAID's NTD Program website, www.neglecteddiseases.gov.

Other USG NTD Efforts. Other USG agencies support research and development (R&D) activities related to and efforts focused on encouraging adoption of control tools for NTDs, including the seven targeted NTDs as well as others not yet considered "tool-ready" (Buruli ulcer, Chagas disease, dengue, human African trypanosomiasis, leishmaniasis).[23] NIH, CDC, and DoD support various NTD R&D efforts,[24] while the FDA administers the congressionally-authorized Tropical Disease Priority Review Program, which "provides for a voucher that is awarded at the time of approval of certain drugs that prevent or treat" an NTD. The voucher, which can subsequently "be redeemed for a priority review of an application for a drug for any indication submitted at a later time,"[25] is designed as an incentive for the private sector to invest in new NTD drug development.[26] Additionally, CDC provides technical assistance to countries and other partners, helps to develop guidelines for NTD control, and aids efforts to monitor and evaluate progress.[27]

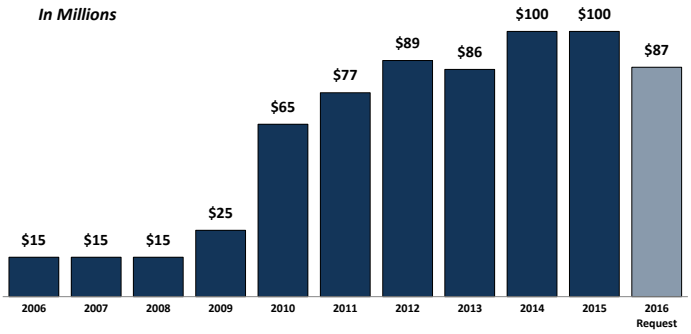
Multilateral and Other Efforts. USG NTD efforts are coordinated with a number of international partners (like WHO and private sector entities), regional strategies (like the *Regional Strategy on NTDs in the WHO African Region 2014-2020*), and funding mechanisms (like The END Fund).[28] For example, the pharmaceutical industry donates several NTD drugs to many of the countries that also receive USAID NTD support; USAID has estimated the value of these donations in U.S.-supported countries at more than $6.7 billion since 2006.[29]

U.S. Government Funding[30]

Total USG funding for NTDs increased from $15 million in FY 2006, which was the first year Congress appropriated funds for NTDs, to $100 million in FY 2015 (see Figure 2). The President's FY 2016 budget request included $87 million for NTDs. If approved by Congress, this would be a $13.5 million (14%) decrease from the FY 2015 enacted level. USG funding for NTDs is provided through the Global Health Programs (GHP) account at USAID.[31]

Figure 2

Neglected Tropical Diseases (NTDs), FY 2006-FY 2016 Request



NOTES: Includes NTD funding provided through USAID. Includes base and supplemental funding. FY13 includes the effects of sequestration. FY15 is based on funding provided in the "Consolidated and Further Appropriations Act, 2015" (P.L. 113-235) and is a preliminary estimate.
SOURCE: Kaiser Family Foundation analysis of data from the Office of Management and Budget, Agency Congressional Budget Justifications, Congressional Appropriations Bills, and U.S. Foreign Assistance Dashboard [website], available at: www.foreignassistance.gov.

Looking Ahead

Over the past decade, USG global NTD efforts and funding have expanded, as have those of other entities. Today, USG NTD efforts are an important part of the USG global health agenda. As global efforts focus on reducing the burden of NTDs among the world's poor, key issues and challenges for USG NTD efforts going forward include: sustaining and augmenting successes, such as expanding the availability of low-cost and effective interventions to control and even eliminate some NTDs; realizing further cost efficiency savings; securing additional donated drugs; strengthening countries' capacity to conduct intensified case detection and management; supporting improved monitoring and evaluation of global progress; addressing outstanding research challenges, including identifying cost-effective interventions for NTDs not yet "tool-ready;" further integrating NTD efforts with other USG global health programs, such as HIV/AIDS, TB, and malaria programs; and improving coordination among the USG and other donors and stakeholders.

[1] WHO, *Investing to Overcome the Global Impact of NTDs*, 2015.
[2] WHO, *Neglected Tropical Diseases: Hidden Successes, Emerging Opportunities*, 2009; USAID's NTD Program website, www.neglecteddiseases.gov.
[3] United Nations, *The Millennium Development Goals Report 2008*, Sept. 2008; Congressional Research Service (CRS), *Neglected Tropical Diseases: Background, Responses, and Issues for Congress*, Jan. 2011; Global Network "NTDs and the Millennium Development Goals," fact sheet, undated.
[4] WHO, *Neglected Tropical Diseases: Hidden Successes, Emerging Opportunities*, 2009; USAID's NTD Program website, www.neglecteddiseases.gov; Peter Hotez, et al., "Control of Neglected Tropical Diseases," *NEJM*, Vol. 357 (10), 2007; CDC, "Neglected Tropical Diseases," webpage, http://www.cdc.gov/globalhealth/ntd/.
[5] *The London Declaration on Neglected Tropical Diseases*, Jan. 30, 2012.

[6] WHO, *Working to Overcome the Global Impact of NTDs*, 2010. The 17 are: Buruli ulcer, Chagas disease, cysticercosis, dengue, dracunculiasis (Guinea worm disease), echinococcosis, foodborne trematode infections, human African trypanosomiasis (sleeping sickness), leishmaniasis, leprosy, lymphatic filariasis, onchocerciasis (river blindness), rabies, schistosomiasis, soil-transmitted helminths, trachoma, and yaws.
[7] Peter Hotez, et al., "Rescuing the bottom billion through control of neglected tropical diseases," Lancet, Vol. 373, 2009.
[8] WHO: "Neglected tropical diseases: diseases," webpage, http://www.who.int/neglected_diseases/diseases/en/; *Neglected Tropical Diseases: Hidden Successes, Emerging Opportunities*, 2009; *Investing to Overcome the Global Impact of NTDs*, 2015.
[9] WHO, *Neglected Tropical Diseases: Hidden Successes, Emerging Opportunities*, 2009; USAID's NTD Program website, www.neglecteddiseases.gov; WHO, *Investing to Overcome the Global Impact of NTDs*, 2015.
[10] WHO, *Investing to Overcome the Global Impact of NTDs*, 2015; WHO, *Neglected Tropical Diseases: Hidden Successes, Emerging Opportunities*, 2009; USAID's NTD Program website, www.neglecteddiseases.gov.
[11] WHO, "Blinding Trachoma," March 2015.
[12] WHO, *Neglected Tropical Diseases: Hidden Successes, Emerging Opportunities*, 2009; Peter Hotez, et al., "Control of Neglected Tropical Diseases," *NEJM*, Vol. 357 (10), 2007; WHO fact sheets: "Soil-transmitted helminth infections," April 2014; "Lymphatic filariasis," March 2014; "Schistosomiasis," February 2014; "Onchocerciasis," March 2015; "Blinding Trachoma," March 2015; WHO, The 17 NTDs – Summary webpage, http://www.who.int/neglected_diseases/diseases/summary/en/; WHO, *Investing to Overcome the Global Impact of NTDs*, 2015; Rachel Pollan, et al., "Global numbers of infection and disease burden of soil transmitted helminth infections in 2010," *Parasites & Vectors*, Vol. 7: 37, 2014.
[13] USAID, "Portfolio Review: Neglected Tropical Diseases," presentation, Feb. 17, 2011.
[14] Peter Hotez, et al., "Control of Neglected Tropical Diseases," *NEJM*, Vol. 357 (10), 2007; Mary Linehan, et al., "Integrated Implementation of Programs Targeting NTDs through Preventive Chemotherapy: Proving the Feasibility at National Scale," *AJTMH*, Vol. 84 (1), 2011; WHO, *Investing to Overcome the Global Impact of NTDs*, 2015.
[15] Peter Hotez, et al., "Control of Neglected Tropical Diseases," *NEJM*, Vol. 357 (10), 2007; Uniting to Combat NTDs, *Delivering on Promises and Driving Progress*, 2014.
[16] WHO, *Investing to Overcome the Global Impact of NTDs*, 2015; USAID's NTD Program website, www.neglecteddiseases.gov.
[17] WHO, *Accelerating Work to Overcome the Global Impact of Neglected Tropical Diseases: A Roadmap for Implementation*, 2012.
[18] *The London Declaration on Neglected Tropical Diseases*, Jan. 30, 2012. The *Roadmap* and the *Declaration* were subsequently acknowledged in 65th World Health Assembly, "Neglected tropical diseases," resolution 66.12, May 27, 2013.
[19] White House, "President Bush Announces New Global Initiative for Combating Neglected Tropical Diseases," press release, Feb. 20, 2008; USAID's NTD Program website, www.neglecteddiseases.gov; CRS, *Neglected Tropical Diseases: Background, Responses, and Issues for Congress*, Jan. 2011.
[20] *The London Declaration on Neglected Tropical Diseases*, Jan. 30, 2012.
[21] USG Global Health Programs website, www.ghi.gov; USAID, *Annual Progress Report to Congress: Global Health Programs FY 2013*, 2014.
[22] USAID, Neglected Tropical Diseases," webpage, http://www.usaid.gov/what-we-do/global-health/neglected-tropical-diseases; USAID's NTD Program website, www.neglecteddiseases.gov.
[23] WHO, "NTDs: Innovative and Intensified Disease Management," 2007.
[24] NIH/NIAID, "NIAID's Role in NTD Research," webpage, http://www.niaid.nih.gov/topics/tropicalDiseases/research/Pages/role.aspx; CDC, "Neglected Tropical Diseases: CDC's Role," webpage, http://www.cdc.gov/globalhealth/ntd/cdc_role/index.html; KFF, *The U.S. Department of Defense and Global Health: Infectious Disease Efforts*, 2013.
[25] FDA: Guidance for Industry: Neglected Tropical Diseases of the Developing World: Developing Drugs for Treatment or Prevention, July 2014; Guidance for Industry: Tropical Disease Priority Review Vouchers [draft], October 2008.
[26] Per Jesse L. Goodman, FDA Chief Scientist, "Working Together to Address the Challenges of Rare and Neglected Diseases," Testimony before the House Foreign Affairs Committee's Subcommittee on Africa, Global Health, Global Human Rights, and International Organizations, June 27, 2013, "FDA has long had in place a review system to ensure that the most critical medical products are reviewed on a priority basis. The goal for Priority Review applications for products that offer major advances in treatment, or provide a treatment when no adequate therapy exists, is to complete them within a six-month period, compared to the 10-month goal for standard review of other products. The Food and Drug Administration Amendments Act of 2007 (FDAAA) granted FDA the authority, beginning in 2009, to award Priority Review vouchers to a company that submits and, after review, receives marketing approval for certain products for one of 16 neglected 'tropical' diseases listed in the legislation. If transferred to apply to a blockbuster drug, the four months of earlier market access available when a Priority Review voucher is redeemed could, in some circumstances, be very valuable."
[27] CDC, "Neglected Tropical Diseases: CDC's Role," webpage, http://www.cdc.gov/globalhealth/ntd/cdc_role/index.html.
[28] USAID's NTD Program website, www.neglecteddiseases.gov; USAID, "Neglected Tropical Diseases," fact sheet, Sept. 18, 2012; WHO Regional Office for Africa (AFRO), *Regional Strategy on NTDs in the WHO African Region 2014-2020*, 2014; AFRO, *Regional Strategic Plan for Neglected Tropical Diseases in the African Region 2014–2020*, 2013; The END Fund, http://www.end.org/; Emily Toubali, "ENVISION Resumes Support for Mali's NTD Program," April 21, 2014, NTD Spotlight, http://www.ntdenvision.org/spotlight/envision_resumes_support_for_malis_ntd_program.
[29] Through FY 2013. USAID, *Annual Progress Report to Congress: Global Health Programs FY 2013*, 2014; USAID's NTD Program website, www.neglecteddiseases.gov; USAID, "Neglected Tropical Diseases," fact sheet, Sept. 18, 2012, http://www.usaid.gov/news-information/fact-sheets/neglected-tropical-diseases.
[30] KFF analysis of data from the Office of Management and Budget, Agency Congressional Budget Justifications, Congressional Appropriations Bills, and the U.S. Foreign Assistance Dashboard website, ForeignAssistance.gov.
[31] Represents specified funding for international NTD programs in the President's budget request, ForeignAssistance.gov, and Congressional appropriations bills. Additional support for international NTD programs is provided through research activities at CDC and NIH.