

Neglected Tropical Diseases (NTD)

Background

Over one billion people are infected with one or more of the 14 diseases defined by the World Health Organization (WHO) as neglected tropical diseases (NTDs).⁸² These are the most common infections in the 2.7 billion people living on less than \$2 a day.⁸³ Those affected are often marginalized and forgotten by governments, left to suffer in silence.

NTDs are diverse but all cause severe disability or death and bring a major economic burden on endemic countries. The successes achieved to date prove that the interventions are technically feasible, immediate, visibly powerful, and scalable when there is political will and financial resources dedicated to recognizing and responding to these diseases.

A comprehensive NTD response will require a significant increase in prevention and treatment resources – as well as dedicated research and development (R&D) for improved tools. The cost of the ongoing neglect of these diseases is tremendous. The prioritization of NTDs in the Global Health Initiative (GHI) presents a unique opportunity for an effective response.

US Investment in the Fight Against NTDs

In 2006, USAID began an integrated two-year, \$30 million NTD control program. This program concentrated on only five of the fourteen WHO identified NTDs.⁸⁴ In 2008, the Presidential Initiative for Neglected Tropical Diseases (NTD Initiative) was introduced, calling for a commitment of \$350 million over five years to NTDs. The White House budget request proposes \$70 million for NTDs in 2010. The NTD Initiative expanded the available funding and targeted number of countries to approximately 30 by 2013 but still targeted only five of the fourteen WHO identified NTDs.

The Most Neglected Diseases

The NTD Initiative currently excludes nine of the WHO recognized NTDs. Among these are the four diseases recognized by the WHO as the most neglected—leishmaniasis, human African trypanosomiasis (HAT or sleeping sickness), Chagas disease (American trypanosomiasis), and Buruli ulcer. All of these, save for Buruli ulcer, are often fatal if left untreated and have the highest rates of death of all of the NTDs.⁸⁵

These four diseases are largely left out of control and treatment programs because they are considered more difficult and costly; the available tools are limited; there has been negligible research; and there are less measurable results due to poor diagnostics and surveillance systems. The diseases are no less devastating for the individuals and countries affected. These barriers beg greater and more directed attention to an effective response to these diseases, not less.

- **Leishmaniasis**, including cutaneous (CL) or visceral (VL, or kala azar) is, after malaria, the most common parasitic killer. VL, the most severe form, is 100% fatal within 2 years if untreated.⁸⁶ There are a total estimated 12 million people infected currently with leishmaniasis, including 500,000 new cases annually of VL—over 90% in five countries.⁸⁷ VL is an increasingly common opportunistic infection for people living with HIV.⁸⁸ Liposomal amphotericin B is available as a highly effective treatment for VL, with a cure rate surpassing 90%.⁸⁹ However, the cost, distribution, and storage requirements, and administration of this life-saving medicine are factors that have restricted wider access.⁹⁰

- ***Sleeping sickness*** is a fatal parasitic disease in 36 countries in sub-Saharan Africa, with an estimated 70,000 annual cases and 60 million at risk.⁹¹ Developments using nifurtimox-eflornithine combination therapy (NECT) have proven that there is safer, more effective treatment compared to the existing standard of care—melarsoprol, which is painful and toxic.⁹² This new regimen should be implemented widely while efforts continue to develop appropriate tools for disease control, easy diagnosis, and an oral treatment at village level.
- ***Chagas*** is endemic in parts of Latin America and with up to 15 million cases worldwide, including 300,000 in the US, causing 14,000 deaths annually.⁹³ A meaningful response to Chagas requires implementation of screening and treatment programs using available tools (benznidazole and nifurtimox), and dedicated R&D for new diagnostics and treatments as the existing tools require complex and long regimens and do not have pediatric formulations.⁹⁴
- ***Buruli ulcer*** is the third most common mycobacterial disease and is in over 30 countries. Lack of treatment can cause irreversible deformity.⁹⁵ Effective and easy to administer treatments exist for the early stages, but are insufficiently available.⁹⁶

Targets

Within the GHI, the U.S. government should work to eliminate the 14 WHO recognized NTDs.⁹⁷ In particular, by 2014, the US government should have comprehensive initiatives in place in the main disease-endemic countries to treat leishmaniasis, sleeping sickness, Chagas, Buruli – diseases that affect over 30 million people – in addition to the nine other WHO-recognized NTDs, only five of which are currently included within the NTD Initiative.

Costs

To make progress in the fight against the NTDs *already identified* in the NTD Initiative, the US would need to invest \$1.2 billion as its “fair share” of the total global need over the duration of the GHI.⁹⁸ To expand on the number of diseases on which the US government provides funding—to include the diseases discussed above and the other WHO-identified NTDs, for instance—the U.S. would need to increase the NTD financial commitment beyond \$1.2 billion over six years.⁹⁹

A meaningful NTD initiative would require a comprehensive response to the 14 WHO recognized NTDs, including vector control and other forms of prevention; routine testing and diagnosis; treatment in health care systems, including increased access to available medicines and capacity for surgical or other interventions where necessary; surveillance and research and development.

The diseases specifically identified here as in need of further funding are treatable with political and financial commitments. Visceral leishmaniasis, for instance, can be treated with \$130-\$300 including cost of drugs, medical care and hospitalization.¹⁰⁰ Sleeping sickness, also inevitably fatal without adequate treatment, can be treated for between \$100 and \$600 per patient, depending on drug regimen and the costs of hospitalization.¹⁰¹ The cost of implementing the new recommended nifurtimox-eflornithine combination therapy (NECT) is \$345.¹⁰² Chagas can be treated at a cost of approximately \$120, relying on

partial drug donations.¹⁰³ For some interventions, cost savings can be pursued, but even these costs are not too high for lives saved.

Though saving lives by treating those infected today should be the priority, research and development (R&D) for the most neglected diseases is critical to provide the tools needed to eliminate these diseases. In 2007, only \$268 million worldwide was invested in R&D for the WHO-recognized NTDs.¹⁰⁴ U.S. government R&D spending for the four most neglected NTDs totaled only \$43 million, primarily on basic research.¹⁰⁵ Product development partnerships (PDPs) are proving to be an efficient alternative in the development of new tools adapted to patient needs.¹⁰⁶ Modest resources invested in needs-based approaches to R&D for NTD tools, can be targeted for the most impact.¹⁰⁷

Needed Policy Changes: Neglected Tropical Diseases

A key set of policy changes are needed to ensure that U.S. global neglected disease programs and the Global Health Initiative can be most effective:

Commit Resources

- The US government should commit at least \$1.2 billion over the 6-year GHI to implementing prevention, diagnosis, treatment, health systems strengthening, and disease surveillance efforts to address all 14 NTDs.

Encompass All WHO Identified Neglected Diseases

- Any US government supported comprehensive global health strategy must encompass the 14 WHO-recognized NTDs, including leishmaniasis, sleeping sickness, Chagas disease, and Buruli, four diseases identified by WHO as the most neglected.

Support Comprehensive Approach

- The US government should support a comprehensive initiative, including programs of early and accurate diagnosis and treatment, vector control, capacity building, and follow-up in endemic countries. The government should work with national programs and non-governmental organizations (NGOs).

Support Routine Testing and Diagnosis

- The US government should support routine testing and diagnosis at the primary care level in endemic areas, and where there is significant migration from endemic areas.

Identify Needs

- The US government should support better data collection through stronger national health information systems to determine the prevalence and incidence of NTDs, and R&D needs.

Encourage Drug Cost Reduction

- Where the high cost of patented drugs has been a barrier for affordable treatment access for drugs for neglected diseases, the US government must support the reduction of the prices of key drugs. This includes liposomal amphotericin B and sodium stibogluconate (SSG), important medications for the treatment of VL that are priced out of reach of poor countries.

Strengthen Research, Development, and Implementation

- The US government, especially the NIH and USAID, should support needs-based research, development and implementation of new and better tools that can meaningfully impact the global burden of NTDs. An additional \$7-10 million annually invested into NTD R&D would contribute significantly to bringing at least three new tools for the most deadly NTDs by 2014. The US government should also support new R&D incentives and funding mechanisms; and ensure that existing mechanisms, such as the FDA's priority review voucher (PRV) system, encompass the WHO's list of 14 NTDs.

Support Multilateral Efforts

- The US government should prioritize and address NTDs in delegations to international bodies, such as the UN, WHO, PAHO and the G8.