Stakeholders' Meeting: Presidential Initiative for Neglected Tropical Disease (NTD) Control

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Working Paper 4: *Country Selection*

Acronyms

ADB	Inter-American Development Bank
AIDS	acquired immunodeficiency syndrome
DFID	Department for International Development, United Kingdom
HIV	human immunodeficiency virus
MDA	mass drug administration
MoH	ministry of health
NTD	neglected tropical diseases
PCT	preventive chemotherapy
USAID	United States Agency for International Development
USG	United States Government
WHO	World Health Organization

Background

On February 20, 2008, President Bush challenged the world to reduce and eventually control and eliminate the burden of neglected tropical diseases (NTDs) as a major threat to health and economic growth in the developing world. The new Presidential Initiative for NTD Control ("the Initiative") calls for an increase in the United States' commitment to NTD control to $350 million over five years.

Selecting the countries that will benefit from the Initiative is complex and of critical importance. This paper highlights many of the considerations and options that may be explored. It is not anticipated that a single option is the 'right' option, but rather that a balanced mix of approaches to selecting countries will be needed to maximize the Initiative's public health impact.

I. Context for Selection of Countries

The Initiative seeks to make a major contribution to the worldwide effort to control the seven major neglected tropical diseases that can be targeted through mass drug administration (MDA): lymphatic filariasis (elephantiasis), schistosomiasis (snail fever), trachoma (eye infection), onchocerciasis (river blindness), and three soil-transmitted helminthes (hookworm, roundworm, and whipworm). The Initiative is global in scope and will target disease-endemic countries in Africa, Asia, and Latin America.

The overall targets of the Initiative include:

- Scaling-up integrated NTD control to 30 countries in Africa, Asia, and Latin America over five years
- Delivering 300 million integrated treatments to people in Africa, Asia, and Latin America over five years

Table 1. Plan for Country Scale-up 2009-2013

	2009	2010	2011	2012	2013
Number of countries	13	18	20	25	30

To date, nationwide coverage with integrated NTD programs has been achieved in only a handful of countries. The targets for the Initiative represent an ambitious scale-up of the integrated approach to MDA promoted by the World Health Organization (WHO) through its Preventive Chemotherapy (PCT) Strategy. If the targets are achieved, the Initiative will yield a 50% decline in the prevalence of several of the diseases and the potential for elimination of others in the countries reached.

Reaching the treatment target, in and of itself, would be noteworthy. However, with careful planning, the Initiative can do much more. For example, geographically planning for where the treatments are delivered may maximize the public health, poverty

reduction, and development impacts of the Initiative; e.g. targeting contiguous states to achieve sub-regional elimination, explicitly focusing on the poorest countries/areas, or prioritizing coverage where school enrollment is low to enable cognitive development, respectively. Furthermore, if used to strategically leverage and/or complement other funding, the Initiative's impact will obviously be extended. Proactively seeking to complement other activities that benefit from United States government (USG) funding, such as malaria control, improved water and sanitation, education, food and nutritional support, and HIV/AIDS prevention and control may both facilitate the attainment of the NTD treatment targets and enable a more comprehensive response to these diseases of poverty.

II. Focus of the Initiative

The funding called for by the Initiative[1] will represent a major increase in funding for integrated NTD control. However, it is widely recognized that the global financing gap for NTD control is well beyond the U.S. commitment of $350 million. Other important international investments, such as the long-standing support of drug donations from several pharmaceutical companies, and the more recently announced increased financial contributions from the United Kingdom's Department for International Development (DFID) and the Bill & Melinda Gates Foundation, are helping to close the financing gaps that remain to address the country and regional-level needs identified for NTD control. Nonetheless, country investments remain the most important source of funding for sustained NTD control and the Initiative aims to encourage more of them. The Initiative risks spreading its funding too thin if it engages in too many activities. The focus of other donor financing must be considered to ensure complementarity and to maximize leveraging potential.

The Initiative's mandate is to ensure efficient and sustained mass drug administration. Key strategies are to::

- Support and stimulate increased government commitment for NTDs within disease-endemic countries
- Dedicate at least 80% of the Initiative's funding for country implementation for direct support of MDA in disease-endemic countries.[2]. This principle has been achieved in the 2 years of implementation of the current USAID-funded NTD program that is operational in 8 countries.
- Expand public-private partnerships to facilitate access to an affordable drug supply and in support of MDA implementation
- Stimulate innovative financing mechanisms to leverage the Initiative's funding

[1] The U.S. Congress will need to appropriate funding for the Initiative on an annual basis in order to fully fund the Initiative.
[2] The target diseases are only those amenable to control through MDA, including trachoma, schistosomiasis, onchocerciasis, soil-transmitted helminthes, and lymphatic filariasis

It is recognized that integrated MDA is one of a number of interventions that require attention and donor resources for the control of NTDs. The Initiative is not designed to fund interventions beyond support for integrated MDA. It is expected that other donors, country resources, private-sector support, and other relevant USAID and USG-funded programs will help fill remaining gaps as global support for NTD control increases.

III. Core Principles

It is important that several core principles that will guide implementation of the Initiative be agreed upon. Listed below are proposed core principles.

1. Implementing partners funded by the Initiative will work only in support of national NTD program goals and strategies under the Ministry of Health's (MoH) leadership in national NTD control.
2. The Initiative will only support countries that have demonstrated Government commitment to integrated control of NTDs, through commitment to sustain and/or increase national financing and to actively plan for, seek and coordinate the delivery of drug donations for NTD control.
3. The Initiative will not replace government, community or other external funding.
4. The Initiative will only support countries that have documented financial need for support (for example, an analysis of existing and potential financial resources among partners/donors in country and identified gaps in resources for NTD control).
5. The Initiative will prioritize countries with prevalence of at least two overlapping NTD disease burdens (for the purposes of prioritization, STH will be considered as one disease).

IV. U.S. Government Funding for the Initiative

USG development resources work with national governments in support of national government efforts. A core principle for USG funding is to work within a national plan in a given country and to support the objectives of that plan. USAID is a very flexible organization that provides funding through a variety of avenues, including direct government funding when appropriate. With regard to the Initiative, USAID will provide financial support through a number of different mechanisms designed to efficiently and effectively roll out funding. Funding recipients will be selected through a competitive process.

Focus area 1: Ensuring efficient and sustained mass drug administration

The following sections describe three tiers or groupings of countries that could be used as an approach to country selection. Also outlined in these sections are potential weighting criteria to consider for selecting countries from the various tiers.

Tier 1: Demand – Driven Approach (Expanding MDAs)

The current USAID-supported project for NTD Control has adopted a demand-driven approach to the expansion of countries benefiting from current USG funding. NTD control partners working in disease endemic countries that meet eligibility requirements can apply for funding to support MoH efforts to provide integrated MDA.

To be eligible for a grant under the current project, the applicant must demonstrate that the proposed target country has an NTD control focal point in the relevant ministry (usually the MoH) and has an existing National NTD Control Strategy. Countries that meet these requirements often have existing NTD Control Programs that are reaching a portion of the target population, but are lacking some critical funding or technical assistance that is impeding full implementation of an integrated approach. In these countries, the goal of the project is to integrate and scale-up delivery of PCT for the targeted NTDs.

Under this approach, the USAID-supported NTD Control project has been able to deliver over 36 million treatments for the first round of MDA in the project's first five countries (Burkina Faso, Ghana, Mali, Niger, and Uganda). A similar demand-driven approach may be appropriate for country selection under the Initiative.

Countries eligible for this tier of funding may already have many of the policies and systems in place to support integrated NTD control and are in a position to scale-up relatively quickly. Eligible countries will have:

- Existing national policy and multi-year plan consistent with WHO guidelines
- Focal point for the integrated approach to addressing the 7 targeted NTDs
- Government plan to sustain and/or increase national financing for NTD control
- Government willingness to actively plan for, seek and coordinate the delivery of drug donations for NTD control
- Prevalence of at least 2 overlapping NTD disease burdens (for the purposes of prioritization, STH will be considered as one disease)
- Documented financial need for support (for example, an analysis of existing and potential financial resources among partners/donors in country and identified gaps in resources for NTD control)

Goal in tier 1 countries: To integrate and scale-up delivery of PCT for targeted NTDs

There are likely to be many countries that meet the criteria above that will be eligible for support under tier 1. As outlined in section IV above, USAID will use a competitive process to select funding recipients. Criteria for prioritizing countries for support will include factors such as epidemiology, political commitment, feasibility, and financial need. Weighting of such factors is described in the below section titled "Tiers 1-3 Weighting criteria within each tier."

Tier 2: Need – Driven Approach (Introducing MDAs)

Focusing only on the countries that would be eligible for support under tier 1 would result in the neglect of many countries with pressing epidemiological and development needs. Some countries may recognize the need to prioritize integrated NTD control, but are not yet prepared to begin to integrate and scale-up delivery of PCT. For example, while countries new to the integrated approach to NTD control may benefit from strong disease-specific programs, they may not have developed a national plan for the strengthening of NTD control overall. Similarly, they may not have inventoried the available resources – human, organizational and financial – that exist in governmental and partner agencies across the country, let alone plan how these resources could best be networked for integrated NTD control. Such countries may require focused technical assistance before proceeding with implementation of integrated NTD control.

Countries eligible for this tier of funding may not yet have all the needed policies and systems in place to support integrated NTD control and are not in a position to scale-up until these issues are addressed. Eligible countries *will* have:

- Government willingness to develop a national policy and multi-year plan consistent with WHO guidelines, and the appointment of a focal point for the integrated approach to addressing at least the 7 targeted NTDs
- Government willingness to actively plan for, seek and coordinate the delivery of drug donations for NTD control
- Prevalence of at least 2 overlapping NTD disease burdens (for the purposes of prioritization, STH will be considered as one disease)
- Willingness to undertake an analysis of existing and potential financial resources among partners/donors in country to identify gaps in resources for NTD control

Goal in tier 2 countries: To develop the policies and systems to integrate and scale-up delivery of PCT for the targeted NTDs

There are likely to be many countries that meet the criteria above that will be eligible for support under tier 2. Under tier 2, some countries may be identified for support based on

epidemiology or other public health criteria, humanitarian reasons, and financial need. More detail on weighting of criteria is described below.

Tier 3: Preparedness (Preparing for MDAs)

Some countries may be at a disadvantage when it comes to competing for funding through the demand-driven approach or consideration through a needs-driven approach due to gaps in information and strategic planning. For example, in many countries there exist data on prevalence of some or all NTDs, but there is a need to use the data to coordinate partners in country, make critical decisions about an integrated response, and/or develop a national plan. In many countries, only case reporting data exists to suggest the prevalence of some or all of the targeted NTDs. In such countries, the magnitude and geographical details of prevalence have not been mapped sufficiently to provide the evidence needed for safe and effective community-level programming of integrated MDA. At the national level, these countries are unable to accurately forecast drug or financial requirements for reaching their at-risk populations.

It is anticipated that support of all countries with needs such as those mentioned above would consume a disproportionate amount of the Initiative's budget and may constrain the Initiative's impact given available resources. Supporting all of these countries is financially untenable, yet leaving behind all of these countries is ethically unacceptable and programmatically unsound.

For countries with solid government commitment to integrated NTD control but limited financing to prepare the foundation, the Initiative could represent the only immediate option to begin the process of introducing integrated MDA nationwide. Countries supported under this tier are countries that need financial and/or technical assistance to prepare for an integrated NTD control program. They will have demonstrated a discrete need that can be met with a short-term infusion of resources. For example, a country in need of evidence to support integrated MDA may be eligible for short-term funding to support prevalence mapping.

Countries eligible for this tier of funding *will* have:

- Documented a specific need that is impeding the development of the policies and systems to integrate and scale-up delivery of PCT for the targeted NTDs
- Willingness to develop a national policy and multi-year plan consistent with WHO guidelines, and the appointment of a focal point for the integrated approach to addressing at least the 7 targeted NTDs
- Government plan to sustain and/or increase national financing for NTD control
- Government willingness to actively plan for, seek and coordinate the delivery of drug donations for NTD control
- Suspected high burden of at least 2 NTDs (for the purposes of prioritization, STH will be considered as one disease)

- Willingness to undertake an analysis of existing and potential financial resources among partners/donors in country to identify gaps in resources for NTD control

Countries eligible under tier 3 are not likely to contribute significantly to the treatment targets of the Initiative in the short-term. They may, however, contribute to other indicators that will be developed to track the progress of the Initiative. Countries in this tier may also benefit the long-term aims of the Initiative by increasing the number of eligible/applicant countries under tiers 2 or 1.

Goal in tier 3 countries: To address specific needs that are impeding the development of the policies and systems to integrate and scale-up delivery of PCT for the targeted NTDs

There are likely to be many countries that meet the criteria above that will be eligible for support under tier 3. As outlined in section IV above, USAID will use a competitive process to select funding recipients. Criteria for prioritizing countries for support will include factors such as presumed epidemiology, political commitment, feasibility, and financial need.

Tiers 1-3: Weighting criteria within each tier

To maximize the global public health impact of the Initiative, a mix of approaches to select countries from among the various tiers will be needed. Within each tier, as noted above, countries may be selected based on criteria such as epidemiology, financial need, political commitment, and feasibility. These criteria are not dichotomous; i.e. there exists a range within each criterion, with trade-offs associated with giving priority to any given point along the range. This is most relevant for the criteria of epidemiology and financial need. Further consideration of these criteria may enable weighting or prioritizing aspects of the criteria. Some of the considerations and trade-offs for 3 criteria are described below.

a. Financial Need

USG funding will contribute to filling financing gaps at the country level, thereby overcoming a major constraint to controlling and possibly eliminating selected NTDs. Among the core principles of the Initiative are a documented financial need for support and an explicit commitment by governments to sustain support to NTD control, recognizing that the Initiative should not replace government, community or other external funding. The existence and magnitude of financing gaps should be weighed and should contribute to the selection of countries.

There are three distinct options that may be worth considering. The first is that of the 'low hanging fruit', or countries that have secured funding for the majority of their activities but are lacking some critical funding that is impeding full implementation of an integrated approach. Such a country may, for example, have secured all of the necessary drugs through donations, and trained community volunteers through its health and

education sectors, but lack funds to transport the drugs to the community level. A small investment in drug transport/distribution could make the difference between a nationwide integrated MDA campaign and nothing. These small investments would certainly contribute to the treatment target objectives. However, focusing only on the low hanging fruit may result in the neglect of countries with more pressing epidemiological needs or development opportunities.

A second option is to focus on countries with the greatest financial need. For countries with solid government commitment to integrated NTD control but limited financing, the Initiative could represent the only immediate option to introduce integrated MDA nationwide. Much greater attribution of the success in NTD control in the country could be applied to the Initiative if this were an implicit aim. However, these countries would consume a disproportionate amount of the Initiative's budget and may constrain the ability to achieve the treatment targets given available resources. Likely, these countries will also be those that have delays for other development indicators, such as reductions in the prevalence of poverty and school enrollment. The gains of investing in these countries may be seen in other measures of the Initiative's impact in addition to the contribution to treatment targets.

A third alternative is for the Initiative to invest at the level needed in individual countries, but with selection of a country being based on criteria other than the magnitude of the financing gap. Humanitarian and public health rationale may suggest that the level of financing need should not be a consideration in the selection of countries. Some of the other criteria are discussed below.

b. <u>Epidemiology</u>

WHO estimates that over 80% of the global burden of the targeted NTDs occurs in 30 countries globally. Since it is widely recognized that the global financing gap for NTD control is well beyond the committed $350 million, the Initiative risks spreading its funding too thin if it engages in too many countries or in countries that don't contribute significantly to the global burden. An emphasis on this sub-set of the highest burden countries may help to focus the Initiative such that it can have the greatest impact on reducing the global burden of NTDs. This sub-set of countries could be used to minimize the list of countries eligible to participate in the Initiative, while still allowing for other criteria to be considered. Similarly, the list of eligible countries could be limited to the countries with prevalence rates at or above a pre-determined level, or only countries with 3 or more overlapping disease burdens.

Taking a longer term, global vantage point, the Initiative may best contribute to sustained reductions in prevalence through a sub-regional approach rather than a country-specific approach. Through a sub-regional approach, MDAs in contiguous states are supported. This may reduce cross-border transmission and support more rapid and sustainable prevalence reductions regionally or globally. If this approach is prioritized, the trade-off is the potentially limited short-term reach and impact of the Initiative. The costs of this approach may be considerable relative to the numbers of people treated as sub-regions

may consist of numerous countries with small populations. In addition, the management expenses of establishing operations in each country consume considerable human and financial resources.

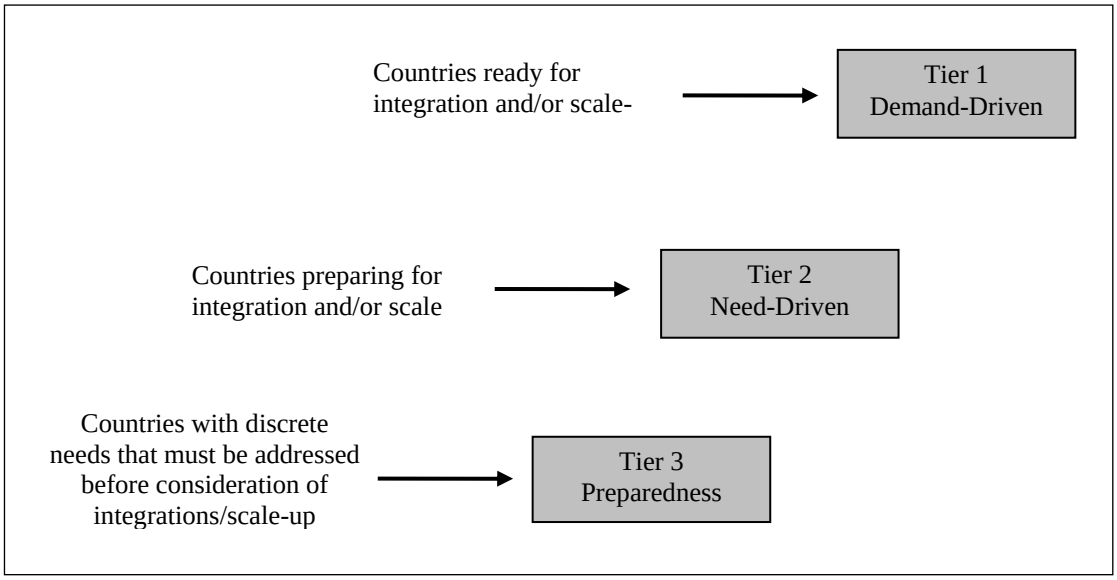
Beyond delivering treatments, the Initiative aims to reduce the prevalence of, and possibly eliminate, some of the NTDs. Elimination aims may suggest another option for prioritization based on the epidemiology of the targeted NTDs. For instance, onchocerciasis and lymphatic filariasis have elimination targets within the next decade. As the Initiative progresses, an increased focus on reducing prevalence and eliminating some of the diseases will likely emerge. In this sense, some consideration of the potential to eliminate a sub-set of the NTDs in some countries or regions may guide investment decisions.

c. Regional approaches / regional specificity

As a global initiative, the specificity and opportunities of each region will need to be considered independently as well as contributing to the overall plan to reach global targets. The epidemiological and financial criteria will likely influence the relative allocation of resources across Asia, Africa and Latin America. However, there may be utility in assigning different weights to the criteria by region to ensure that the needs and opportunities of each region are comparable. For example, if the prevalence rate is the only epidemiological consideration in a global priority-setting exercise, a large proportion of funding will likely go to Africa while opportunities to eliminate some diseases in Latin America in the coming years may be lost. Specific funding levels or proportions to each region may need to be established to enable appropriate priority-setting within and between regions.

Within the tiers described above, there may be opportunities to pursue multi-country approaches. These may yield important efficiency gains for the Initiative if, for example, a single technical assistance partner were able to work with the governments of various countries and could streamline project management. The trade-off would come if the package of countries included some of lower priority, based on other criteria, and therefore would absorb Initiative resources outside of established priorities.

Schematic: Three-tier approach to country selection



Focus area 2: Stimulating innovative financing mechanisms and public-private partnerships

Further options for country selection

The Initiative presents a unique opportunity to stimulate innovative financing mechanisms and public-private partnerships that will ultimately extend the reach and impact of the Initiative. One obvious partnership is the on-going relationship with pharmaceutical partners for drug donations and subsidized purchases. The options to further enhance these partnerships are explored in Working Paper 1: Provision of Essential Medicines for Preventive Chemotherapy for NTDs. Based on the current USAID-funded project and assuming current global funding sources for drugs, it is estimated that the proportion of funding that will be allocated to ensuring an adequate drug supply will likely be 15-20% of the overall budget of the Initiative. Any efficiencies gained in this area can be applied directly to countries for MDA implementation.

USAID is pursuing other opportunities to strategically leverage and/or complement other sources of funding for NTD control. An option being explored with the Inter-American Development Bank (IDB), for example, is the potential to offer matching funds through a Trust Fund being developed by the IDB and the Pan American Health Organization (PAHO). . The Trust Fund would provide challenge grants for the scale-up of MDAs to a particular district or region in Latin America and the Caribbean. These performance-based' grants would provide matching funds to meet mutually agreed upon target coverage rates over a period of five years. After the first disbursement, subsequent payments would be made based on a strict data quality audit to assess the number of

people covered by MDA and the quality of the reporting system. In addition to supporting the scale-up of MDA, this Fund seeks to provide resources for improving health information systems and intersectoral action- two activities that are known to be critical to decreasing the incidence and prevalence of NTDs. Because the decision has been made to focus USAID's initiative on MDA, liaising with the IDB/PAHO provides an opportunity to support a comprehensive approach to combating NTDs while maintaining our strategic focus.

Finally, USAID is pursuing a more comprehensive response to NTD control by leveraging existing USG initiatives such as the Basic Education Initiative, the President's Malaria Initiative, and the President's Emergency Plan for AIDS Relief. These initiatives have pre-selected countries in which they operate. The opportunity to plan jointly and to leverage funds may suggest that some order of priority should be given to countries where this potential exists, with requirements that this be an explicit aim of the country program.

V. Graduation/Exit Strategy

As countries make significant progress in NTD control, treatment will result in elimination or reduction of disease burden. Once this occurs, continued MDA may no longer be necessary and resources will need to be reallocated to other diseases or countries at greater risk. Thus, there is a need to develop a strategy for ending MDA where elimination targets have been achieved and/or transitioning away from MDA to more targeted treatment where transmission continues (for example, due to cross-border infection or migration of vectors or infected humans). Such guidance will be very timely in the short-term for several countries nearing elimination, particularly of lymphatic filariasis, allowing them to develop models for graduation that will guide countries nearing elimination in the longer-term.

VI. Conclusion

Defining country selection criteria and how such criteria are ranked is of necessity for ensuring transparency. Moreover, defining appropriate selection criteria is of vital importance for ensuring that the Initiative maximizes its public health impact.

As laid out in this working paper, there are a number of issues to be considered in the selection of countries. In the near-term, USAID will collect input from the Initiative's stakeholders, including local governments, members of the international donor community, local NGOs, and other USG agencies. Such input will be utilized to inform the way forward for addressing country selection issues and ultimately, for developing clear guidance for the Initiative.