

# **Presidential Initiative for Neglected Tropical Disease Control October 20-21, 2008 Stakeholders' Meeting Executive Summary**

## **Introduction**

On February 20, 2008, President Bush announced the Presidential Initiative for Control of Neglected Tropical Diseases (NTDs). The Initiative will make a total of \$350 million available over five years to provide integrated treatment to 300 million people in Africa, Asia, and Latin America and will target seven major NTDs: lymphatic filariasis (elephantiasis), schistosomiasis (snail fever), trachoma (eye infection), onchocerciasis (river blindness), and three soil-transmitted helminthes (hookworm, roundworm, whipworm). The Initiative will build on USAID's existing NTD Control Program.

In preparation for implementation of the Initiative, USAID convened a key stakeholders meeting on October 20-21, 2008 in Washington D.C. The meeting was co-hosted by USAID, the World Health Organization (WHO), and the U.S. Centers for Disease Control and Prevention (CDC). Participants included representatives from U.S. Government agencies, Ministries of Health of disease endemic countries, pharmaceutical partners, the NTD scientific community, NGO implementation partners, and other donor partners.

The following provides an overview of the meeting, a summary of significant issues discussed, and a description of key outcomes and next steps.

## **Overview**

The meeting focused on issues pertaining to four technical areas that will be critical to the successful implementation of the Initiative, including: 1) monitoring and evaluation for integrated control programs; 2) drug supply and delivery; 3) operational research for improving implementation of mass drug administration (MDA); 4) selecting countries for inclusion in the Initiative. A working paper for each of these areas was distributed to participants prior to the meeting. These working papers provided the basis for meeting break-out sessions, during which participants offered a number of ideas and suggestions.

## **Significant Issues Discussed**

Significant issues were raised and suggestions offered pertaining to each of the four technical areas. Key discussions included:

**Monitoring and evaluation:** Participants indicated that the global adoption of a standardized monitoring and evaluation (M&E) system is of immediate priority, though it was acknowledged that several issues must still be addressed before such a package is ready. Specifically, participants requested tools for programs to easily calculate treatment coverage, guidelines for standardizing indicator numerators and denominators, development of integrated indicators, assistance for monitoring severe adverse events, and plans to address scaling down or ending mass drug administration when elimination has been reached or is foreseen. There was general agreement that tools for M&E should

be simple and cost-effective and that M&E should be adequately planned for in national Plans of Action.

**Drug supply and delivery:** Representatives from disease-endemic countries indicated that the provision of tools and training for drug forecasting was of utmost importance. Pharmaceutical partners similarly called for better global forecasting of the demand for donating and purchased drugs. Participants requested that the Initiative, with WHO, ensure the provision of technical assistance to countries for drug forecasting. They suggested that the Initiative work with pharmaceutical partners to standardize drug packaging to facilitate drug differentiation and appropriate dosage. Participants also recommended that country applicants for funding to the Initiative communicate as early as possible with drug donation programs and procurement vehicles to ensure timely programming of drug needs into suppliers' forecasts. Additionally, they recommended that the Initiative's application process encourage sharing of drug procurement and delivery information with all applicants.

**Operational research for improving implementation of MDA:** Participants identified several important operational research questions to be considered by the Initiative in support of the most efficient means to achieve widescale MDA for NTD control. It was highlighted in this discussion that operational research needs and priorities may change as programs evolve and that there is an unparalleled opportunity to evaluate and refine different tools (e.g., validation methodologies) within the scope of the Initiative. It was also recognized that there are operational research needs beyond the scope of the Initiative that should be prioritized by other donors and members of the broader NTD community, such as development of new sensitive and specific diagnostic tools. It was proposed that CDC, in collaboration with USAID, WHO and the Bill and Melinda Gates Foundation, will define an appropriate complementary research agenda that capitalizes on ongoing research and addresses the priorities of the Initiative

**Selecting countries for inclusion in the Initiative:** Participants highlighted the need to explore various mechanisms to select countries, particularly noting that many countries are in nascent stages of the development of integrated programs and will require considerable technical assistance for mapping and strategic planning before being able to compete for funding. Dialogue over programmatic sustainability was a key component of the country selection sessions, including the necessity of government commitment, the need for costing and impact data to assess sustainability of existing or expanded NTD control programs, and the need for exit strategy plans.

#### **Key Outcomes and Next Steps**

A number of key outcomes and follow-up steps emerged from the meeting:

- USAID will continue to work with pharmaceutical partners to improve demand forecasting, enhance coordination with drug donation programs, provide support to countries for logistics, and jointly tackle severe adverse event reporting issues

- USAID will continue to explore issues pertaining to sustainability, including culling lessons learned from community programs, and potentially bringing together a task force to offer recommendations
- USAID will process ideas shared pertaining to the selection of countries for inclusion in the Initiative. As soon as selection criteria are solidified, USAID will share this information with countries through USAID and WHO communication channels. Countries and other meeting participants may be asked to comment on USAID's eventual strategy for selecting countries
- WHO will host two follow-up task forces, one on monitoring and evaluation and another on drug supply and delivery
- WHO will convene the next Global NTD partners meeting in December 2009
- CDC, in collaboration with USAID, WHO and the Bill and Melinda Gates Foundation, will define an appropriate complementary research agenda that capitalizes on ongoing research and addresses the priorities of the Initiative
- The NTD community will explore other areas of integration (e.g. water and sanitation) and will highlight to external groups the benefits of NTD control to other areas of development

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## **Introduction**

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This document provides a summary of the key questions raised and issues addressed during the meeting. The summary is organized according to the meeting agenda and is divided into two main sections, the first of which provides a brief description of opening remarks, updates shared, and an overview of the Initiative, and the second of which provides a more detailed report on the four technical areas that structured the meeting: monitoring and evaluation (M&E), drug supply and delivery, operational research, and country selection.

## **Section One: Opening Remarks, Updates, and Overview of the Initiative**

During day one of the meeting, a number of organizations presented opening remarks and updates. Additionally, CDC and WHO provided an overview of the diseases and USAID provided an overview of the Initiative. These presentations can be viewed on the USAID website at [www.usaid.gov/our\\_work/global\\_health/id/ntd\\_meeting.html](http://www.usaid.gov/our_work/global_health/id/ntd_meeting.html). Highlights of the presentations are included below.

### **Opening Remarks**

Kent Hill (Assistant Administrator for Global Health, USAID), Hiroki Nakatani (Assistant Director-General - HIV/AIDS, TB, Malaria and Neglected Tropical Diseases, WHO), Mark Eberhard (Director of the Division of Parasitic Diseases, CDC), Uche Amazigo (Director, African Programme for Onchocerciasis Control (APOC)), and Tim Rieser (Senior Foreign Policy Aide, US Senate) made welcoming remarks. Key points included:

- Kent Hill underscored the commitment of USAID to the effective implementation of this Initiative and USAID's appreciation to the partners represented at the meeting. He also announced the expansion of USAID NTD funding to two additional countries—Bangladesh and Nepal
- Hiroki Nakatani delivered an opening address on behalf of Dr. Margaret Chan, Director-General of WHO, stating “The US Presidential Initiative is a huge boost to [NTD] control that will be met with open arms.”
- Mark Eberhard noted that the collaboration of USAID and CDC on the fight to control NTDs has been a model for inter-agency collaboration
- Uche Amazigo described many challenges and opportunities facing countries in implementing the Initiative. She also stressed the need to stimulate and sustain local government commitment through such avenues as in-country financing mechanisms and identification of NTD integration strategies to promote intersectoral approaches
- Tim Rieser explained that the best way to ensure continued Congressional funding for NTD control is to be good stewards of funding, to produce results, and to collect and report data to validate results.

### Updates

The Bill and Melinda Gates Foundation and Global Network for NTD Control (GNNTDC) provided updates on their NTD work:

- The Gates Foundation is investing in new tools (drugs, vaccines, diagnostics) and in better use of existing tools (operations research). A few items currently under consideration for funding are a new schistosomiasis diagnostic tool, operations research on NTD treatment integration, and research on Azithromycin treatment impact. The Foundation recently approved a five year strategy for NTD control and is committed to building partnerships and coordinating with other donors.
- GNNTDC continues to advocate for NTD control, and to mobilize and leverage resources for NTD control.

### Overview of the President's Initiative

Christy Hanson of USAID presented an overview of the Initiative, the main points of which were:

- In February 2008, President Bush announced a new, \$350 million, five-year initiative to control in an integrated manner, the seven NTDs that can be addressed through mass drug administration
- The Initiative will begin in fiscal year 2009 and end in fiscal year 2013 and will build on USAID's existing integrated NTD program
- USAID's existing integrated NTD program is budgeted at \$15 million/year and operates in 10 countries (Burkina Faso, Ghana, Niger, Mali, Uganda, Haiti, Sierra Leone, southern Sudan, Nepal, and Bangladesh) and in 2007 delivered 36 million treatments

- Under the Initiative, NTD control will scale-up to 30 countries by 2013 and will deliver integrated treatments to 300 million people in Africa, Asia, and Latin America
- Expansion countries have not yet been selected, and criteria for country selection will be established with collaboration from the global stakeholder group
- 80% of programmatic funding will go directly to mass drug administration
- Additional funding to provide treatments to a greater number of people has been committed by the G8, Great Britain, and the Gates Foundation. Pharmaceutical companies have offered to donate many necessary drugs and/or provide them at reduced cost.

### **Section Two: Technical Considerations**

The meeting was primarily structured around four key technical areas: 1) monitoring and evaluation for integrated control programs; 2) drug supply and delivery; 3) operational research for improving implementation of mass drug administration (MDA); 4) selecting countries for inclusion in the Initiative. A working paper for each of these areas was written and distributed to participants prior to the meeting. During the meeting, these working papers formed the basis for discussions during break-out sessions, from which participants offered a number of ideas and suggestions. This section outlines some of the key recommendations emerging from the meeting.

#### **Monitoring and Evaluation**

Participants were asked to focus their discussion and recommendations on four questions:

- **Question:** What is your vision for M&E from the country level?  
**Answer:** M&E plans should be simple and cost effective. Plans should build on what is available, be designed with the active input of users/communities, and include capacity building for local M&E staff. Plans should also be properly funded with a percentage of country program budgets dedicated to M&E. For ongoing programs, M&E plans should address scaling down or ending (elements of) mass drug administration in a changing endemic situation. A single data management system should be established to help ensure collection of quality data. Finally, information collected during monitoring should be applied by programs to improve program implementation.
- **Question:** Do you agree with the basic M&E package as presented in the paper?  
**Answer:** Implementation of a basic M&E system is the immediate priority though several issues must still be addressed. For example, there is a need for tools to help programs calculate coverage and other performance indicators automatically and a desire for a single summary measure which could be used for both advocacy and programmatic purposes. Guidelines for M&E should be clear on indicator numerators and denominators. In particular, these guidelines should indicate whether population data should be derived from registered data or from the

population census. (The WHO manual recommends registered data to calculate program coverage and national census data for epidemiological coverage.) Operational research should focus on developing new indicators to guide districts on how to adapt their implementation strategies. M&E tools should include tools for validating reported coverage, however, the level at which those tools should be used (national level or peripheral level or both) must be decided upon.

- Question: How should we measure other health and development outcomes and impact (e.g. school enrollment, poverty reduction, financial sustainability, etc) and who should be responsible for measurement?

Answer: A few indicators to measure the impact of all NTD programs on other health and development indicators (e.g. school enrollment) should be defined. However, this type of monitoring is complex and beyond the scope of basic M&E. Such data should be collected through national surveys such as DHS or through specific studies.

- Question: Are there any other issues that need to be considered?

Answer: The use of community self-monitoring ought to be considered. It allows for community feedback to check data reported by the health system. Advantages include increased community ownership and health systems strengthening. This approach does, however, have several limitations, including resource constraints due to need for extra funding for additional community activities, and potential reporting bias by communities to their advantage. Since the information provided through community self-monitoring might not be adequate to provide the empirical data needed for decision making at the national level and advocacy at the international level, community and health systems could and should be involved in evaluating each other. A working group on M&E will be convened by WHO to further discuss issues outlined above.

### Drug Supply and Delivery

Participants were asked to focus their discussion and recommendations on four questions:

- Question: In addition to the challenges and avenues outlined in the paper, what else do we need to consider in addressing potential drug constraints that may emerge during the Initiative?

Answer: First, the Initiative should consider assisting countries with mapping to facilitate accurate forecasting and to more precisely identify endemic districts for each NTD. Second, consistent presentation of products and sufficient education is needed to ensure that implementing programs can distinguish each drug and its appropriate dosage. For example, a poster with images of the drug and its packaging along with dosage and other details may help with presentation of multiple interventions. Similarly, color coded and/or standardized packaging across NTDs with corresponding dose poles would help ensure safe and accurate administration of PCT. Such standardized packaging would need to be field

tested before being implemented. Third, the Initiative should be prepared to invest in proper monitoring and assistance in countries where capacity for monitoring severe adverse events is limited. Fourth, recognizing that the maximum production potential for each product and subsequent active pharmaceutical ingredient (API) needs to be determined, the Initiative can consider subsidizing costs for the API to help companies increase production if needed. Additionally, in cases where a long-term/indefinite drug donation has not been made, discussions are needed to determine how affordable drugs can be procured to sustain the programs. Finally, the Initiative should consider the possibility for elimination of diseases where feasible, which will require high levels of sustained coverage. In these cases, the Initiative may consider focusing on rapidly increasing the number of people treated rather than increasing the number of countries.

- Question: What are options for improving drug forecasting? Are there lessons from other public health areas that could be used?

Answer: Countries with limited capacity would benefit from forecasting technical assistance from WHO. Treatment target populations can be based on national census data projected to the year in consideration, following WHO guidelines. This census data should be available at both national and district level. Lessons and best practices on drug supply and delivery may be learned from immunization programs that have been operating in resource poor countries for many years.

- Question: What are the most feasible and impactful things the Initiative should do to ensure an affordable drug supply and facilitate drug procurement by countries?

Answer: The Initiative/USAID in collaboration with partners can evaluate the conditions for country-specific importation for donated drugs and, in countries where excess costs for shipping/storage cannot be absorbed, consider allocating funds for shipping and/or storage. A working group on drug supply and delivery will be convened by WHO to more accurately estimate drug needs during the Initiative and to address constraints that may arise. Research-driven, commercial, and procurement companies should be invited to participate and the working group should collaborate with the Initiative's M&E working group. The first meeting is proposed by WHO to convene in February 2009.

- Question: Are there other drug issues that may constrain rollout of the Initiative?

Answer: Countries need to be aware of the shelf life of each drug and avoid requesting drugs for a timeline that isn't feasible. Pharmaceutical companies may wish to consider stability testing to extend shelf life and humidity testing to address storage issues. This is a long-term issue and may take several years to fully implement. To mitigate increased demands on drug supply and to facilitate accurate forecasting, countries may need to adjust their rate of scale up, and the Initiative should allow for this possibility. Country applicants for funding to the Initiative should communicate as early as possible with drug companies and procurement vehicles to ensure timely programming of drug needs into suppliers'

forecasts. The Initiative's application process should encourage sharing of drug procurement and delivery information with all applicants.

### Operational Research

Participants were asked to focus their discussion and recommendations on three questions:

- Question: Identify any other operational research issues that should be considered for the Initiative.

Answer: Several important issues include: Harmonization of existing disease-specific guidelines to facilitate integration; Evaluation of new diagnostic tools; Inclusion of a social science research agenda, especially for social mobilization research.

- Question: Prioritize the operational research that should be addressed under the Initiative, noting the top three.

Answer: There are important research needs for each step of program implementation—mapping, social mobilization, mass drug administration, and monitoring and evaluation. Top research questions include: For mapping—Is an integrated mapping protocol really needed? How can we validate mapping tools and protocols as the basis of public health decisions? For mass drug administration—How do we overcome the Loa Loa problem? How do we develop models for sustainable service delivery that are appropriate for, but not necessarily specific to NTDs? For M&E—Can we develop simple, accurate coverage surveys? How do we validate methodologies for stopping MDA and conducting post-MDA surveillance? Social mobilization research issues were not identified.

- Question: Identify the opportunities and challenges to addressing these priorities, including the role of other NTD partners and donors.

Answer: One challenge related to prioritizing operational research is the fact that research needs will evolve as the Initiative evolves. The NTD operational research agenda must be flexible and seize opportunities as they arise. Operational research should capture both quantitative and qualitative data. Capturing qualitative data is a challenge for NTD operational research as social science/scientists are not typically incorporated into the research agenda. This area of NTD research must be fostered as it is of utmost importance to the success of the Initiative. Finally, with regard to the role of other NTD partners and donors, the evaluation of new diagnostic tools is an important activity under the purview of the Initiative. However, the creation of new diagnostic tools is outside of the scope of the Initiative and must receive other partner/donor support.

## Country Selection

The issue of country selection was divided into three subtopics discussed in breakout sections:

### *A. Tiered Approach to Country Selection*

Participants were asked to focus their discussion and recommendations on three questions:

- Question: What are the opportunities and challenges to the tiering approach to country selection proposed in the working paper?

Answer: An important opportunity of the tiered approach is that it is potentially more inclusive than USAID's typical competitive process. For example, countries with low capacity and/or poor communication structure will have the opportunity to request and receive NTD support. In contrast, under a competitive process, such countries are typically unaware of the funding announcement, or compete poorly compared to high capacity countries. There will, however, be challenges to reaching out to low capacity countries. In particular, some countries will require technical support to prepare applications. Those countries with poor communication and health infrastructure may need a good deal of technical support.

- Question: Do we need to prioritize or weight by the factors mentioned in the country selection working paper? Are there other factors that should be considered?

Answer: The Initiative may want to consider limiting the pool of eligible countries. The eligible pool could be limited to the 30 countries with the highest burden or to countries with the highest prevalence, or could prioritize countries by elimination status. In Latin America and Asia, criteria for inclusion should include prevalence of two overlapping disease burdens, whereas in Africa, appropriate criteria should include three overlapping disease burdens. Another factor that the Initiative may want to consider is a selection/funding process that would support regional approaches to NTD control, including opportunities for countries to target residual foci that overlap national borders.

- Question: Are there any other issues we should consider in the approach to country selection?

Answer: USAID should collaborate with WHO to communicate requests for proposals through WHO's in-country and regional networks to ensure all countries are aware of requests.

### *B. New Opportunities for Leveraging Funds*

Participants were asked to focus their discussion and recommendations on five questions:

- Question: What opportunities for leveraging funds have been successful in other health areas that could be applied to the President's Initiative?  
Answer: Pharmaceutical industry NTD drug donation is an excellent example of successful leveraging. Without these donations, treatment would cost far more than its current estimated cost of ~\$1 per person per year. Leveraged funding has also increased as a result of the involvement of top level politicians in countries such as Rwanda, Tanzania, and Burkina Faso.
- Question: How would we assess the feasibility and success of matched funds?  
Answer: Monitoring and evaluation of results is extremely important for assessing feasibility and success. Sound M&E systems need to be in place which can measure results of additional funding.
- Question: What are the disadvantages/challenges for leveraging funding?  
Answer: Donor fatigue is a challenge for leveraging funding. Another challenge is the potential for donors to feel that their contribution is insignificant compared to the Initiative announcement of \$350 million. Finally, a major disadvantage of leveraging funding is the possibility that funding commitments are made but not met, and the negative impact of this funding shortfall on the NTD program as a whole.
- Question: What other leveraging issues should be considered?  
Answer: Find partners outside the health sector, such as water and sanitation. Arrange meetings with top level leaders of the US and potential donor countries to get highest level buy-in. Arrange top level bank meetings, including, for example, executive directors from the Asian Development Bank, Inter-American Bank, and World Bank. Consider approaching different donors – perhaps China or Brazil. Use the ever expanding health insurance schemes to deliver NTD treatments where needed and appropriate.
- Question: How do we ensure annual release of government budgets? Can matching be used to stimulate government financing?  
Answer: Governments must have a budget line item for NTD control and these funds must be released early in the financial year. Furthermore, endemic districts should budget for NTD drugs. With regard to matching, it may be worthwhile to ask local companies to donate and have their donations be linked to government funding. Mozambique serves as a successful example of political commitment to NTD control—a budget line item is provided for treatment activities.

### *C. Sustainability, Elimination, and Exit Strategies*

Participants were asked to focus their discussion and recommendations on three questions:

- Question: What do we need to think about to ensure sustainability of our work on NTDs? Are there other health areas/programs/partners we can learn from?

Answer: Programs should be designed with sustainability, elimination, government commitment, and an exit strategy in mind. A good product that demonstrates value with a well-established cost-benefit will lead to sustainability. Actions at the international level can facilitate sustainability at the country level. The Initiative could learn from the successes of PEPFAR and PMI, particularly with regard to scaling up. The Initiative could also learn from other health interventions that have proven sustainable, including vitamin A distribution, and immunization programs. A good example of sustainability planning is that of APOC—Recognizing that its financial commitment would end within 3-5 years of initial funding, APOC addressed sustainability from the outset by fostering community ownership and NGO support.

- Question: What are the considerations for decreasing or stopping support to countries? What are the issues/options for stopping support once technical targets are met?

Answer: Costing and impact data are needed to assess sustainability of existing NTD control programs. Program costs do not necessarily decrease as programs scale down; there are still fixed costs for monitoring and evaluation, and containment of pockets of disease that need to be considered. Exit strategies also need to be funded.

- Question: Identify any other issues related to sustainability, elimination, and exit strategies that should be considered for the Initiative.

Answer: A government budget line for NTD control will demonstrate government commitment and help attract external support. Countries must take responsibility and integrate interventions into the primary health care system. Local partners should be included – commercial, NGO, and academic. E.g. local phone companies can be enlisted to share health messages. Central procurement should be considered for non-donated drugs; this would establish a market and therefore the demand needed for companies to produce an adequate supply.

### Next Steps

A number of key outcomes and follow-up steps emerged from the meeting:

- Existing donors will continue to work together to combat NTDs
  - USAID will continue to work with pharmaceutical partners to improve demand forecasting, enhance coordination with drug donation programs, provide support to countries for logistics, and jointly tackle severe adverse event reporting issues
  - The NTD community will explore areas of integration (e.g. water and sanitation) and will highlight to external groups the benefits of NTD control to other areas of development

- WHO will host two follow-up task forces, one on monitoring and evaluation and another on drug supply and delivery
- WHO will convene the next Global NTD partners meeting in December 2009
- CDC, in collaboration with USAID, WHO and the Bill and Melinda Gates Foundation, will define an appropriate complementary research agenda that capitalizes on ongoing research and addresses the priorities of the Initiative
- USAID will continue to explore issues pertaining to sustainability, including culling lessons learned from community programs, and potentially bringing together a task force to offer recommendations
- USAID will process ideas shared pertaining to the selection of countries for inclusion in the Initiative. As soon as selection criteria are solidified, USAID will share this information with countries through USAID and WHO communication channels. Countries and other meeting participants may be asked to comment on USAID's eventual strategy for selecting countries.

USAID will continue to work with its partners to plan for implementation of the Initiative. Through proper planning and resource allocation, USAID will ensure that the Initiative achieves its goal of providing treatment to 300 million people within the next five years. The October meeting of stakeholders was a productive step towards attaining this goal.