Integrated Implementation of Programs Targeting Neglected Tropical Diseases through Preventive Chemotherapy: Identifying Best Practices to Roll Out Programs at National Scale

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Abstract. In 2006 the U.S. Agency for International Development (USAID) established the Neglected Tropical Disease (NTD) Control Program to support national governments in developing successful, cost-efficient NTD programs that integrate disease-specific programs into coordinated national initiatives, in accord with the World Health Organization recommendations. A 3-stage "roll-out package" has been developed for effectively integrating and scaling up such programs to full-national scale. Stage-1 lays the groundwork—identifying NTD leadership within the Ministry of Health, conducting a national Situation Analysis, formulating a multiyear Plan of Action, and undertaking a funding gap analysis. Stage-2 focuses on scaling up the integrated NTD program—convening national stakeholder meetings, developing annual work plans, carrying out disease mapping, and establishing monitoring and evaluation activities. Stage-3 aims at ensuring effective management—identifying clear roles and responsibilities for partners, and creating a central coordinating mechanism. Assessment and reassessment of these complex NTD programs that target literally billions of people are essential to establish "best practice" strategies for long-term public health success.

INTRODUCTION

In recent years, the World Health Organization (WHO) has promoted the concept of integrated preventive chemotherapy (PCT) as the principal strategy for control or elimination of a group of seven debilitating infections recognized as neglected tropical diseases (NTDs)-lymphatic filariasis (elephantiasis), onchocerciasis (river blindness), schistosomiasis (snail fever), three soil-transmitted helminthiases (caused by Ascaris, Trichuris, and hookworm), and blinding trachoma.¹ These diseases affect more than 2 billion people in the developing world, with many suffering simultaneously from multiple NTDs. With diagnostic and treatment tools that are effective, easy to use, and available at minimal or no cost, these NTDs are now considered by WHO to be "tool-ready" and are targeted for control or elimination through a number of large-scale global health initiatives supported through WHO's coordination and programmatic guidance.^{1,2}

Underpinning most of these initiatives are enormous donations from private sector pharmaceutical companies^{3–7} of the specific medications that can be used to treat each disease safely, simply, and effectively through large-scale PCT. The treatment regimens vary from administration once or twice per year to once every 2 years, given either to entire populations at-risk for the disease(s) (i.e., mass drug administration [MDA]) or targeted to specific at-risk groups, such as school-age children or specific occupational groups. Although it is unquestioned that these donations† are absolutely necessary for the current global initiatives, it is also important to recognize that the donations alone are not sufficient. There must be two additional, essential spheres of partnership: first, with the ministries of health (MOHs) of the affected countries who, together with other public sectors (e.g., education), take responsibility for responding to the very great public health challenge of reaching and treating all the targeted at-risk populations; and second, with funding and technical assistance that can aid the ministries to carry out these programs in countries with insufficient domestic resources to address these challenges alone.

A principal source of this external funding support in recent years has been the U.S. Agency for International Development (USAID). In 2006, USAID established the NTD Control Program, implemented by RTI International, with the expressed purpose of supporting national governments to develop successful, cost-efficient NTD control programs that integrate or bundle their disease-specific programs into coordinated initiatives and then to link these programs effectively with other elements of their established national health delivery systems. The achievements of the first seven countries participating in this USAID-supported NTD Control Program during its first 3 years have been reviewed in detail.⁸ Table 1 summarizes key quantitative elements from that earlier description with more current, updated information that includes the NTD Control Program's fourth year. Although these results can be recognized as only output measures not yet translated into impact measures-which are of greatest importance to health and economic development in these affected countries-still it is clear that by any standard, the accomplishments of these national NTD control programs after just a few years of operation are both remarkable and commendable.

It should not be surprising, however, that the accomplishments of these national programs did not come easily or without challenges. Indeed, many lessons were learned over time as good practices became better, better practices became best practices, and best practices improved and evolved into evidence-based policy that can be shared across countries. Because the expansion of integrated national NTD control programs worldwide is still in its infancy, and since many more countries still need to begin their programmatic activities, this report is meant to capture the early experiences of countries introducing and/or scaling up integrated NTD activities during the NTD Control Program's first 4 years and to

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[†]Albendazole (GlaxoSmithKline, Brentford, Middlesex, UK); Azithromycin [Zithromax] (Pfizer, New York, NY); Ivermectin [Mectizan] (Merck & Co., Inc. Whitehouse Station, NJ); Mebendazole (Johnson & Johnson, New Brunswick, NJ, USA); Praziquantel (Merck-Serono, Geneva, Switzerland).

NTD control prog	gram output m	etrics: years 1–	4		
Indicator	Year 1	Year 2	Year 3	Year 4	Cumulative 4-year total
Number of countries beginning MDA programs each year with					
USAID support	4	1	2	3	10
Number of persons treated each year with USAID support	16,339,325	27,638,323	55,894,206	70,001,700	169,873,553*
Number of treatments provided each year with USAID support	36,816,157	58,029,384	129,200,566	165,412,570	389,458,677*
Number of districts <i>newly treated</i> each year with USAID support	106	52	169	287	614
Program coverage (persons treated/persons targeted—range					
across all drug packages each year)	69–100%	57-97%	62-100%	64-100%	57-100%
Value of drugs donated each year to NTD Control					
Program countries	\$404 million	\$507 million	\$577 million	\$686 million	\$2.174 billion
Number of workers in training programs supported by USAID					
each year	107,269	158,731	221,412	389,214	876,626*

TABLE 1

NTD control program output metrics: years 1

*Includes people treated (or trained) more than one time during the four years. NTD = neglected tropical disease; MDA = mass drug administration; USAID = U.S. Agency for International Development.

identify practices that are now appreciated as successful strategic approaches (or best practices) for developing and rolling out integrated NTD control programs at full national scale. It also documents how a learning agenda, generation of evidence, and programmatic refinement have been used by WHO and its partners to shape global health policy.

METHODS

The USAID has supported the implementation of integrated programs targeting NTDs in 13 countries through the NTD Control Program. A detailed description of the Program has been presented previously,⁸ but a number of program elements need special emphasis because of their demonstrated importance and applicability in specific settings, their programmatic benefits and efficiency gains, and their influence on the structure and operational approaches of the *national* NTD control programs being supported.

Aims of the NTD Control Program. The stated aims of the NTD Control Program reflect the intent of USAID to support national governments in their roles as the stewards of NTD programs. Specifically, the Program's principal aims from the beginning have been to 1) support and empower national governments to develop integrated NTD control programs embedded, where possible, within existing service delivery platforms and to scale up these programs to full national level; 2) provide technical assistance for planning, budgeting, and reporting; 3) promote cost-efficiency; and 4) ensure national

TABLE 2NTD Control Program: years 1–4

County	Lead NGO
Bangladesh*	RTI International
Burkina Faso	Schistosomiasis Control Initiative
Cameroon	Helen Keller International
Ghana	World Vision
Haiti	IMA-World Health
Mali	Helen Keller International
Nepal*	RTI International
Niger	Schistosomiasis Control Initiative
Sierra Leone	Helen Keller International
Southern Sudan	Malaria Consortium
Tanzania*	IMA-World Health
Togo	Health and Development International
Uganda	RTI International

*MDA activities *supported by NTD Control Program* not yet started by Year 4. NTD = neglected tropical disease; NGO = nongovernmental organization. ownership, continued commitment, and resource mobilization for sustained support for NTD control.

Participating countries. Countries currently participating in the NTD Control Program are identified in Table 2, along with the principal nongovernmental organizations (NGOs) supporting them. The first five countries (Burkina Faso, Ghana, Mali, Niger, and Uganda) were selected because they already had pilot programs in place for integrated control of NTDs that had been sponsored as operational research studies by The Bill and Melinda Gates Foundation and by the U.K.'s Department for International Development through the Liverpool NTD Support Center. Because scaling up to fully national programs was a stated goal of the NTD Control Program, these countries were able to take immediate advantage of additional program resources to support scale-up activities. Additional countries have come into the program progressively, so that by the end of the Program's fourth year, 13 countries were included, 10 of which had already begun implementation of their yearly USAID-supported MDA activities. It is from these 13 countries that the lessons learned and best practices described below were derived.

Operations, standards, and metrics. Countries were supported for only those operations and technical strategies fully in line with recommendations and guidelines provided by WHO.^{2,8} Where global guidance for aspects of implementing integrated programs was lacking, the NTD Control Program developed and tested new tools and approaches in consultation with national programs and WHO. For example, a common monitoring and evaluation (M&E) framework to support integrated implementation was absolutely essential for program success and needed to be developed on a common platform for maximal usefulness. Such a platform was developed collaboratively by the national programs, NGOs, NTD Control Program, and WHO, and it has been used in nationally scaled programs.⁹ The principal metrics assessed are those identified in Table 1.

RESULTS

During the first 4 years of NTD Control Program operations, there were many lessons learned. As a practical outcome, the Program developed and refined, in concert with its partners, a strategy and supporting tools for initiating and sustaining integrated NTD country programs. The strategy reflects consensus on a sequence of important steps and activities that lead to well-designed, government-led, cost-effective, efficient, and integrated national NTD control programs. The sequence has been termed the *roll-out package* and consists of three principal stages:

- 1. laying the groundwork;
- 2. rolling out an integrated program; and
- 3. establishing effective management.

The utility and technical soundness of this package have recently been acknowledged through endorsement of WHO's Strategic and Technical Advisory Group (STAG) as the rollout package for global use.‡ This endorsement facilitates access to proven NTD strategies and tools for countries beyond those that can be supported by USAID, and through spreading the efficiency gains, can stimulate expansion of NTD control efforts globally.

Stage 1: Laying the groundwork. Ensuring commitment by the national government is likely the most important element for both short- and long-term success of a national NTD control program. Indeed, it is an aspect of the roll-out package that needs to be addressed, not just at the earliest stage of program development, but at every opportunity where reinforcement is possible. Its measures are not just the financial or personnel contributions of the government but also the commitment to reorganizing management structures to ensure effective, integrated NTD control programs. A principal indicator of such commitment, assessed by the NTD Control Program, is the designation of a point person within either the MOH or ministry of education (MOE) who will coordinate activities of the individual NTD control programs and lead an integrated approach to their control. Sustained and/or increasing levels of investment by the government is another marker for which measuring tools have been developed (discussed below). Commitment is also demonstrated through documentation of the country's NTD problems, of a strategic national plan to address these problems, and of an appreciation of the cost of carrying out this plan.

The Country Situation Analysis Tool is used to compile and define the country's NTD problems. This analysis provides a detailed, up-to-date, standardized account of the available evidence for the prevalence of NTDs and for specific control activities and any related research ongoing in the country. Such an analysis is an essential first step for planning integrated activities and is particularly valuable in defining a baseline for stakeholders during the early planning for integration defining gaps in available information and activities, advocating for donor support, and identifying potential partners for implementation, technical assistance, and operational research. Ideally, the analysis is prepared by a team of local, diseasespecific experts and academics, thereby engaging a cadre of local technical stakeholders early in the process and encouraging their involvement in program planning at the earliest stages. Although the situation analysis can be time consuming to develop, having accurate and complete information and engaged local expertise results in significant time-savings and efficiencies at later stages in the process of program startup.

A multiyear National Plan of Action (POA or "Master Plan"), recognizing the NTD challenges and potential platforms on which integrated programs can be launched, must be formulated to prioritize and address these diseases. Once the situation analysis is complete, it will be clear that there are some areas where program implementation can begin immediately and others where additional NTD prevalence information (e.g., disease mapping) is necessary. Thus, the initial POA must include the progressive roll out of both these sets of program activities; and, as mapping is completed, the national POA must be updated appropriately. Such a POA should be developed by the government with its stakeholders and key partners in NTD control and with full engagement by WHO, which has created a standardized framework for these plans.¹¹ A national POA that documents a rational and comprehensive approach is essential for coordinated action at the country level and is also the basis for determining the program's funding needs.

A funding gap analysis is needed for identifying costs for the NTD program envisioned in the national POA. A specific tool (described in detail elsewhere¹²) to analyze the costs and needs of integrated NTD control programs was developed by the NTD Control Program to provide standardized detailed quantification of the costs for implementing integrated NTD control activities in line with international guidelines, with the country's national plan, and with existing resources available from the government and other donors. This tool is particularly valuable for ensuring recognition of the contributions that governments make toward their national NTD control by quantifying their inputs of largely in-kind resources, such as staff time, materials, and health system infrastructure. Once the funding gap is identified for NTD interventions, country programs and potential donors can be provided with clear information about what is required to achieve the national program's goals for NTD elimination or control. The Funding Gap Analysis Tool empowers governments to coordinate the various donor inputs in support of a comprehensive plan and budget. It provides an essential base for scale-up plans and resource allocation and serves as a valuable tracking tool for documenting opportunities for cost-efficiencies and government commitment over time.

Stage 2: Scaling up an integrated NTD program. Ideally, a country's comprehensive integrated NTD control program would begin its roll out with all the preliminary groundwork completed. In reality, of course, that simply does not happen, as many groundwork and roll-out activities are carried out simultaneously. Regardless of whether they are carried out simultaneously or sequentially, there are a number of key elements that can be identified for the successful roll out of any national NTD program.

Meetings of national stakeholders. To present and refine both the POA (based on the situation analysis) and the results of the funding gap analysis, a meeting of all stakeholders including the drug donation programs and other potential donors—should be convened by the MOH, and, when appropriate, in concert with the MOE. The WHO support for these meetings is very valuable for endorsing technical decisions. The stakeholders meeting is an important opportunity to provide a transparent presentation of funding requirements, roles and responsibilities, and program scale-up targets to all concerned parties. Government leadership is reaffirmed as discussions of how to address the existing financial and technical

^{‡&}quot;STAG recognizes the *package of programmatic and M&E tools* jointly developed by WHO and NTD partners as current best practice; and recommends that WHO formally adopt this package to roll out preventive chemotherapy interventions...and operationalize M&E tools in a regional context."¹⁰

gaps are viewed in the context of a broader national program. Deliberate assessment of the capacities of all partners to contribute to a POA, along with identification of all possible existing service delivery platforms (e.g., schools, child health days) on which the program could be based, can yield efficiencies for scale up by not requiring costly new infrastructure or networks. Such inclusive consultation can stimulate the willingness of partners to expand their activities, such as adding delivery of an additional drug to a previously singledisease project, to support the national scale up of an integrated approach. Even in settings where partners already have strong working relationships, the stakeholders meetings held regularly enhance these partnerships among the various levels of government ministries and with other implementing partners. Most country programs have institutionalized annual stakeholders meetings both to report back to partners on program results and to review the annual work plan.

Annual work plan development. Ideally, stakeholders reconvene each year to develop a detailed annual work plan and budget. The process of developing the plan reinforces integrated planning grounded in an understanding of the challenges and successes of the previous year, encourages joint discussions about where cost-efficiencies can be made, improves understanding of the requirements and priorities of individual disease programs, and produces a detailed plan and budget to which the entire team can commit. Modifications of the POA or changes in the NTD funding gap that bear on the implementation activities and strategy can also be accommodated during these annual work plan sessions.

Disease mapping. For countries to plan for implementation most effectively and to apply for essential drugs, the endemic NTDs must be mapped accurately.§ In many countries, mapping for one or more diseases is not complete so that national implementation scale up cannot be accurately planned for or budgeted. Determining the extent of disease burden and distribution is a critical initial step for all country programs. The need for disease mapping should be clearly defined, beginning with the situation analysis and then progressively undertaken according to the guidelines from WHO and the drug donation programs.

Monitoring and Evaluation. The NTD Control Program developed a system for simple, standard integrated monitoring of results that can be adapted and implemented in each country setting—tracking disease-specific treatment goals and integration indicators for total population treated, population coverage rates, and combined treatments provided.⁹ With this system, managers and donors have prompt, regular semiannual reports on progress toward goals (by country and disease target) that can be shared with district-level stakeholders, and between country programs, as appropriate. Any programmatic weaknesses, such as low uptake of drugs during MDA campaigns, can be quickly identified and addressed to ensure public health progress. Integrated reporting and monitoring forms have facilitated the ability of individual program managers to understand the requirements of all the endemic NTDs and have encouraged joint participation by diseasespecific program managers in the monitoring process.

Stage 3: Establishing effective management.

Establishing clear roles and responsibilities. The challenges inherent in combining (or even just coordinating) multiple disease-specific programs in a country are all too obvious. Therefore, developing consensus on managerial arrangements is essential-first, within the national government (notably between the MOE and MOH) about how the leadership of a national NTD program will be defined (including the specific roles of each government entity); and second, among the partners with respect to their roles, responsibilities, and intended contributions toward national NTD control efforts. Although an agreed POA and successful stakeholder meetings are important steps in defining these roles, clarification of the flow of funds and the associated responsibilities is also essential. Indeed, the degree of transparency (i.e., understanding) of this flow of funds and responsibilities is often a principal driver of the effectiveness with which the partnership functions. It, therefore, deserves appreciable attention.

Central coordinating mechanism A central-level coordinating mechanism, such as a steering committee that includes disease-specific program managers (i.e., an NTD Task Force), has proven invaluable in providing a critical forum for planning, problem resolution, and advocacy within the country. The significant challenges of *integrating* strong and independent disease-specific programs can be overcome through strong leadership by a higher level government colleague who can mobilize the efforts of a team of previously independent program managers to achieve rapid, cost-effective integration. Central coordinating mechanisms, meeting 2–4 times per year, have been institutionalized in all implementing countries as a means of ensuring representation for all appropriate diseasespecific programs, and for other government stakeholders, especially the MOE.

DISCUSSION

The challenge of *integrating* multiple disease-specific control programs-here interpreted primarily as enabling programs to carry out similar activities in a most efficient and cost-effective manner-is one that has been taken up enthusiastically by WHO and the national programs supported by the USAID NTD Control Program.^{1,8,14-18} Because past experience with such integration was largely anecdotal, it was one of the principal aims of the NTD Control Program to identify empirically the most effective and efficient strategies that could later be used to inform other programs also seeking to integrate their NTD activities. The enormous challenges facing the establishment of successful national scale MDA programs have recently been emphasized, along with the importance of careful monitoring to ensure their effectiveness.¹⁹⁻²¹ Indeed, it can only be through repeated examination of such programs-the efforts made, lapses identified, and remedies attempted—that better and better practices will be identified. Although defining the very best strategies for initiating these integrated programs might still lie in the future, the experiences from more than a dozen countries during the NTD Control Program's first four years have given clear indications both of what works well and of what likely pitfalls might appear in the start-up phase of these national programs. The recent endorsement of the resulting NTD roll-out package by WHO's

[§] As described in WHO guidelines,¹³ program-oriented mapping is not "prevalence mapping," but "action mapping" that provides a geographic depiction of *what needs to be done* for integrated NTD control (i.e., which drug packages to be administered) at each district (or other subunit) throughout the country.

Box 1 Roll-out package elements

Lay the groundwork
Ensuring government commitment
Performing a situation analysis
Creating a POA (Plan of Action)
Analyzing the funding gap
Roll out program
Convening stakeholder meetings
Developing a work plan
Mapping disease distribution
Defining an M&E strategy
Establish management
Agreeing on roles and responsibilities
Organizing a central coordinating mechanism

NTD Scientific and Technical Advisory Group¹⁰ is a strong acknowledgment of the evidence base for this emerging approach and the optimism for its long-term success.

Box 1 summarizes the components of what today is considered the most effective roll-out strategy. These elements and, to a lesser degree, the order in which they are instituted are essential for creating effective and efficient integrated programs targeting the NTDs. There are many instances that could be cited where failure to attend to one or more of these essential elements early in the roll-out process-i.e., having a lack of sufficient government commitment, a poor understanding of disease distribution, an inadequate assessment of funding needs, poorly engaged stakeholders, an imprecise work plan, and the like-have caused programs to falter initially. The details of some of these failures and the remedies applied have been previously recorded,15,18-21 and other accounts will follow from subsequent country reports. The purpose of this work, however, has been to summarize the key lessons learned from these early experiences and to define what appears today to be the most effective roadmap to successful program development. This roll-out strategy provides a strong foundation for the complex partnerships among private- and public-sector organizations that must thrive and be sustained for these programs to succeed. As this roll-out package has evolved in concert with WHO's NTD Control Department, it also reflects its current approach to integrated control of the seven tool-ready NTDs¹ that are targeted through PCT using the technique of large-scale mass or targeted drug administration. Because MDA can be extremely complex and diverse in its organization-both within and across individual countries-it is essential that the roll-out strategy leading to it provides for well-grounded, solid, and fully supportive partnerships to ensure long-term program success.

Such partnering in support of national NTD programs by USAID now falls conceptually within the U.S. Government's recently defined Global Health Initiative (GHI²²) whose principal emphases—on gender equality, country ownership, strengthening health systems, promoting partnerships, fostering coordination and integration, improving M&E, and promoting innovation—are all fully consonant with those of the NTD roll-out strategy. Overall, the roll-out strategy represents a strong focus on host-country government ownership and leadership. Furthermore, the success of the first 4 years of the NTD Control Program clearly reflects the very important GHI goal of innovation for success. Indeed, the next phase of the NTD Control Program—including both expanding to additional countries and quantifying program impact on the broader measures of societal health, education, and economics will not only further strengthen the evidence base for optimizing integrated control of the NTDs but, at the same time, will fully support the more expansive goals and targets of both the GHI and the similar bilateral and multinational initiatives in global health currently being undertaken or anticipated.

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