FIDELIS—Innovative Approaches to Increasing Global Case Detection of Tuberculosis

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Tuberculosis was declared a global public health emergency in 1993. In 2003, only 45% of the world's estimated new smear-positive tuberculosis cases were detected—well below the 70% global case detection target set by the World Health Organization.

The FIDELIS (Fund for Innovative DOTS Expansion Through Local Initiatives to Stop TB) initiative is a new global disease control initiative that has been developed to rapidly assess and implement innovative approaches to increase tuberculosis case detection. To date, 32 projects have been approved—covering approximately 378 million people in 13 countries—24 (75%) of which are in the world's 6 highest-burden countries. A wide range of target populations and interventions have been incorporated into successful FIDELIS projects. The FIDELIS initiative may serve as a model to discover best practices to address other urgent global public health problems. (*Am J Public Health.* 2006;96:14–16. doi:10.2105/AJPH.2004.056762)

BARRIERS TO GLOBAL TUBERCULOSIS CONTROL

Tuberculosis was declared a public health emergency by the World Health Organization (WHO) in 1993.[1] Despite this unprecedented focus and the existence of effective and increasingly available treatments, tuberculosis continues to ravage many people worldwide. Every year, approximately 8 million people become ill with tuberculosis and 2 million die from the disease.[2] Of all tuberculosis cases, more than 90% occur in the developing world, where 75% of cases are in the most economically productive age group (15–54 years).[1]

Although the principles of the WHO-recommended directly observed therapy short course strategy (DOTS) have been widely accepted, most developing countries have been unable to expand DOTS as rapidly as needed.[1] In 2003, the global detection rate of smear-positive cases within DOTS programs was 45%, well below the target of 70%.[3] A failure of countries to reach global case detection targets remains one of the greatest barriers to achieving global tuberculosis control. New and effective approaches to finding and successfully treating additional tuberculosis cases are urgently needed.

PROGRAM DESCRIPTION: THE FIDELIS INITIATIVE

FIDELIS (Fund for Innovative DOTS Expansion Through Local Initiatives to Stop TB) is an US$11 million fund launched in April 2003 to increase case detection of new smear-positive cases of tuberculosis, while maintaining high cure rates within the DOTS strategy. The project's activities are implemented by in-country contractors (e.g., local nongovernmental organizations, governments, academic institutions), which submit proposals for FIDELIS funding.

Initial funding for FIDELIS came from the Canadian International Development Agency, and the project is managed by the International Union Against Tuberculosis and Lung Disease (The Union). The Union, which was originally known as the International Union Against Tuberculosis, was founded in Paris in 1920. Its mission is the prevention and control of tuberculosis and lung disease, as well as related health problems, on a worldwide basis, with particular emphasis on low-income countries. A full-time designated FIDELIS coordinator at The Union is responsible for the initiative. In addition, a global contracts manager is responsible for all contract negotiations, and 1 of 3 FIDELIS technical advisors is assigned to each funded proposal for ongoing communication, monitoring, and reporting.

Since the initiative's inception in April 2003, 4 application rounds have been completed. Each round involves a Web-based call for applications and initial screening to determine whether proposals meet eligibility criteria (e.g., countries in which the program would operate must have a per capita gross national income of less than US$1000 and proposals must request between US$150 000 and US$250 000). Eligible proposals are then peer reviewed by 2 independent experts, who are drawn from the Stop TB Partnership, from WHO-designated

"high-burden countries" (i.e., those countries with the highest estimated numbers of new cases of tuberculosis each year), and from the academic community. The final recommendation of proposals for contract negotiations is made by a proposal review committee. This committee is composed mainly of experts who represent countries with the highest burden of tuberculosis, including current and former National Tuberculosis Program managers.

In evaluating proposals, 2 key principles of the FIDELIS initiative are given particular attention—a focus on people with limited access to health services and the cost-effective, sustainable nature of the chosen interventions. The number of additional weighted treatment successes (AWTS) is the main outcome measure for FIDELIS projects. (All new smear-positive cases detected within FIDELIS projects must be designated according to their access to care; cases designated as "limited access to care" are given greater weight than other cases.) Projects are funded for an initial period of 1 year and must achieve a cost per AWTS of less than US$80. Failure to meet these stringent targets will reduce opportunities for funding beyond the first year of project activities. In contrast, a clear demonstration of successful and cost-effective approaches can result in a rapid and marked increase in funding support to scale up these interventions.

A total of 32 projects covering a population of approximately 378 million people has been recommended for contract negotiations from the first 4 application rounds. The 32 projects include 10 from China, 5 from Pakistan, 3 from Indonesia, 2 from Kenya, 2 from Bangladesh, 2 from Tanzania, 2 from Nigeria, and 1 each from Sudan, Tajikistan, Madagascar, Somalia, Sri Lanka, and Uganda; 24 (75%) of the projects are located in the world's 6 countries with the highest burden of tuberculosis. Approximately US$7.1 million has been committed to these 32 phase I projects (i.e., projects funded for a 1-year period, after which successful projects may apply for a second year of funding [phase II]).

A wide range of innovative approaches have been incorporated into FIDELIS projects to date (Table 1), including the mobilization in rural China of junior high school students to identify people with the symptoms of tuberculosis in their own families and, in sub-Saharan Africa, the creation of peripheral diagnostic centers within urban slums. In one South Asian project, tuberculosis patients must provide a nominal deposit when initiating treatment, which will be refunded if the full course of antituberculosis medication is completed. One of 3 FIDELIS projects funded in Indonesia has trained several hundred community volunteers to identify people with symptoms of tuberculosis, to facilitate transport for diagnosis, and to ensure that diagnosed cases complete their full course of antituberculosis treatment.

DISCUSSION AND EVALUATION

Will all innovative approaches introduced in FIDELIS projects succeed in efficiently detecting and successfully treating additional tuberculosis cases? The answer is almost certainly no. Many if not most innovative approaches to scientific and medical problems initially fail. However, those approaches that are ultimately proven effective are often the elusive solutions to our greatest challenges. Moreover, opportunities to test new approaches within the setting of a public health program are often lacking.

FIDELIS provides a competitive and rigorous process for funding innovative projects (only 32 of 99 proposals submitted in the first 4 application rounds were approved for contract negotiations). In contrast to most overseas development assistance projects, the process of proposal review, contract negotiation, and disbursement of funds within FIDELIS has been extremely timely. In the first 4 application rounds, the time between application deadline and notification of successful applicants ranged from 33 to 44 days. Moreover, once the successful projects were notified, contracts were negotiated in a timely manner (most within 2 months) and funds were disbursed no later than 2 weeks after contracts were signed. Most importantly, the process is fair, transparent, and accessible to those countries most affected by tuberculosis.

NEXT STEPS

In the first group of FIDELIS projects, early case-finding results and interim cost per AWTS are promising. Time will prove which approaches are truly worthy of expansion. An independent assessment group (unconnected with the donor, The Union, FIDELIS, or its implementing partners) will visit several FIDELIS projects to determine the validity of the reported results. The lengthy nature of tuberculosis treatment means a

KEY FINDINGS

- An efficient model of external review and implementation of innovative approaches to increase tuberculosis case detection has been established in a relatively short time.
- Of the 32 projects recommended for contract negotiations, 24 (75%) are in the world's 6 countries with the highest burden of tuberculosis.
- A wide range of target populations and interventions to increase tuberculosis case detection have been incorporated into successful FIDELIS projects.
- The FIDELIS model may be appropriate for addressing other perplexing global public health problems.

TABLE 1—Target Groups and Primary Interventions of Approved FIDELIS Projects (n = 32), Rounds I–IV

Primary Intervention[a]	Main Target Population[b]						
	Urban Poor	Rural Poor	Urban and Rural Poor	Government Occupational Health Services	Police and Military Personnel	Geographically Isolated People	People With Limited Local Services
Strengthened referral system			1			1	
Improved diagnostic capacity			1				
DOTS implementation/reinforcement	1		2	1	2	1	1
Community-based DOTS		1	1			1	2
Active case finding		2	1				
Enhanced community awareness		2					
Enhanced local services	1		1			1	3
Involvement of private HCWs	1	1	2				1

Note. FIDELIS = Fund for Innovative DOTS Expansion Through Local Initiatives to Stop Tuberculosis. DOTS = directly observed therapy short course strategy; HCWs = health care workers. Data shown are the numbers of projects that include the indicated primary intervention and main target population.
[a]Several projects use more than 1 intervention; the table lists the primary intervention as indicated in the work plan.
[b]In many projects, there is also overlap in the target groups—for example, many geographically isolated populations are poor and also have limited local services.

delay of 8 to 10 months before complete treatment outcomes are available. In the meantime, FIDELIS has developed a model to efficiently review, implement, and evaluate innovative approaches to a perplexing public health problem.

The list of global public health problems that might benefit from a FIDELIS-like process is lengthy. Delivery systems for antiretroviral therapy could arguably top that list. Other technically sound interventions where operational delivery remains the key challenge, such as insecticide-treated mosquito nets to prevent malaria, may also benefit from the FIDELIS approach. Finally, the FIDELIS initiative does not obviate the need for long-term bilateral and multinational efforts in global tuberculosis control; the need for such global commitments has never been greater. The FIDELIS model may provide evidence for which approaches are successful, which can then be incorporated into larger, long-term projects, such as activities funded by the Global Fund Against HIV/AIDS, Tuberculosis and Malaria. ■

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Contributors

Both authors originated this field action report. I.D. Rusen prepared the first draft of the article. D. Enarson reviewed and provided critical input to the article.

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References

1. *Treatment of Tuberculosis: Guidelines for National Program.* 3rd ed. Geneva, Switzerland: World Health Organization; 2003.

2. Dye C, Scheele S, Dolin P, Pathania V, Raviglione MC. Global burden of tuberculosis: estimated incidence, prevalence and mortality by country. *JAMA.* 1999;282(7):677–686.

3. *Global Tuberculosis Control—Surveillance, Planning and Financing.* Geneva, Switzerland: World Health Organization; 2005. Report no. WHO/HTM/TB/2005.349.

Resources

For more information, go to the FIDELIS Web site at www.fidelistb.org.